

**Pre-Application Technical Assistance Webinar
Transcript**

**Moderator: Mary Ganikos
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1:00 pm CT**

Coordinator: And this is the conferencing operator. The call is now being recorded. If you have any objection, you may disconnect at this time. Please utilize your mute button when not speaking. You may press star six to mute and un-mute your line. And you may begin.

Mary Ganikos: Okay. Welcome everyone. I see that we have a few people on the line and I'm delighted that you've joined us. I'm with the Division of Transplantation, Healthcare Systems Bureau. We have - our titles are pretty vague in the government -- or our affiliations -- and I'm delighted to have this opportunity to talk with you today about a grant program focusing on increasing organ donation.

The purpose of this webinar is to introduce to you the Division of Transplantation and provide an overview of the donations field, the need to increase donation and DoT -- that's the Division of Transportation -- DoT's 2014 grant program to identify and replicate strategies that are successful for increasing organ donation.

A key we're going to slide is overview. I'm assuming that you all are either unfamiliar or minimally familiar with the field of donation as well as DoT's grant programs, so I'm going to provide a broad overview of both to peak your interest and hopefully encourage your investigation into this important life-saving public health issue.

So let's start with an introduction of HRSA and the Division of Transplantation. HRSA is the Health Resources and Services Administration and it's one of 11 agencies within the U.S. Department of Health and Human Services. You may recognize some of the other agencies such as CDC, HIH, or FDA; they are our sister agencies and we are similar to those in terms of our position to HHS - Health and Human Services.

Each agency has a specific mission and HRSA's overall mission is to serve the underserved. HRSA's organizational structure includes four major bureaus and several offices. The Division of Transplantation was in HRSA's Healthcare Systems Bureau. And the grant programs we'll discuss today are staffed by the organ tissue, blood stem cell donation branch, often referred to as the Donation Branch.

DoT has two major programmatic functions and these are - I'm sorry, I thought I was on a different slide. The Division of Transplantation is an entity within HRSA's Healthcare Systems Bureau and we have - yes, two major functions; organ donation and transplantation programs and the national blood stem cell transplantation program.

Mary Ganikos: Today we're going to be addressing the donation - organ donation program. And so DoT's functions in the organ donation program are twofold; first is to provide support and oversight for the transplant system in the U.S. and it's efforts to promote evidence based organ allocation policies and system and

two, to increase organ donation. So the latter -- two -- is largely the responsibility of the donation branch, which we strive to accomplish by implementing a national program of grants, contracts, and special projects and outreach efforts. Some of our outreach efforts include sponsoring radio ads, developing and making available print materials for organizations to use to promote organ donation, developing documentaries for public broadcast, and implementing targeted national campaigns to reach various special populations.

So there are two types of organ donors; deceased and living. Deceased donors can provide several organs and - but people who donate while living generally only provide one. While not at the same time, an individual might be able to donate a kidney and a liver segment, but that rarely happens - a living individual. That just isn't common, but yes, it can happen.

Because they are key to understanding the donation process and are very involved in local donation outreach efforts and many of our grants, I'm including a brief overview of the role of an organ procurement organization commonly referred to as an OPO in the field. OPOs are local level organizations that have two major functions, somewhat like the Division of Transplantation.

Their function at the -- on the clinical side -- is to organize the clinical recovery process when a potential donor actually becomes available in a hospital and to implement community level outreach strategies to increase donor registration in their service areas. There are 58 OPOs in the U.S. and Puerto Rico and each OPO has its own exclusive, geographically defined service area where it implements its mission.

So how does deceased donation happen? Every state, the District of Columbia, Puerto Rico have or have access to an electronic database that serves as a donor registry in which state residents can enroll to legally indicate their wish or authorization to become a donor. Since organ recovery at an individual's time of death cannot take place without legal consent, the registry plays a significant role in the donation process.

Most registries have some -- and these are donor registries -- most registries have some affiliation with the motor vehicle agencies in their state and people can sign up at the DMV and most states have an online registration capability of - well. Of people who do join a registry, most -- about 98 to 99% -- do so at the DMV. Registries contain only names of people who have given their consent to be a donor, not people who do not wish to donate. It's a registry of committed organ donors.

When a death occurs in a hospital, the hospital notifies the OPO. The OPO professional coordinates a physical evaluation to determine if the deceased is medically able to be a donor and checks the state's organ donor registry to see if the deceased is on there. If the individual is listed in the registry and has been determined medically eligible, organ recovery can take place with no further ado or authorization from anyone else. If the deceased is not listed in the registry, donation professionals must seek consent from next of kin.

So how are organs allocated or directed to people on the waiting list? The organ procurement and transplant network -- which we refer to as the OPTN - - is a national computer system that maintains a list of all people in the U.S. waiting for an organ transplant. It is administered under contract to the Department of Health and Human Services. The OPTN contains specific factors about each wait-listed patient that are important in matching donors to

recipients. Some of these factors include blood and tissue type, body size, severity of illness, time on waiting list and geography.

When a donor becomes available, the same type of information about the donor is entered into the computer system and the computer prints out a prioritized list of the best matched patients for each organ. The transplant team notifies it's patients of the availability of the organ and prepares them for surgery. The OPO professional at the donor's hospital arranges for the removal and transportation of each organ to the intended recipient's hospital.

And you may wonder why I mention that geography is an important issue in transplanting organs and that is because some organs can travel farther than others. Some organs can stay outside of the body longer than others. But geography does become an issue in organ allocation.

So why focus on organ donation and transplantation? Organ transplantation is truly an amazing surgical specialty. It is the only option available to save the lives of people with end-stage organ disease. It literally is the last chance those people have to continue living. Just one donor can save up to eight lives and enhance more than 50 others through the donation of corneas and other tissues. But eight lives through organs and they can enhance many others through organ - through eyes and tissues.

So the good news is from 1988 to 2012, 535 - 535,578 lives were saved by 263,368 organ donors. In 2012, more than 28,000 lives were saved by more than 14,000 donors and currently there are more than 100 million registered donors in the U.S. So that's pretty neat. That's the good news.

So we say 100 million registered donors, so why the problem? And you may be wondering why there's a shortage of deceased donors today. So let's

explore this issue. The first thing to understand is that each death can occur in one of two ways - that death -- any death -- can occur in one of two ways. The heart and circulatory system stops functioning first or the brain stops functioning first. Each situation results in the cessation of the other.

Specifically, when the brain ceases to function, the heart and circulatory system also will cease to function and vice versa. Our organs depend on a continuous supply of oxygen to maintain their integrity. When the heart and circulatory system cease to function, the oxygen supply to the organs is discontinued and the organs begin to decay. In the case of brain death, however, artificial supports -- ventilators -- can keep the heart pumping blood and oxygen throughout the body to keep the organs viable for transplantation.

Consequently, the vast majority of donors come from brain deaths. Because of the need for ventilation, only deaths that occur in hospitals have the potential to result in organ donations. And of the 2.4 million deaths that occur each year, less than one million occur in hospitals. It's estimated that only 9,500 to 10,000 of those deaths are from brain deaths. That number is even further reduced by subtracting out those who are not medically eligible, such as those with HIV, active cancer, or active infections. And a lack of family consent in the case where there is no donor registry designation also can preclude donation.

So you can see that although there are 100 million registered, not everybody can become an organ donor. More people can become eye and tissue donors, but not - but the number that can result from organ donation is really whittled by a lot of these issues that we just went over.

So the sad news is that at the end of 2012, the waiting list for organs was large -- more than 117,000 -- and the - and all of those are waiting for an organ --

not for tissues and eyes -- but all for a life-saving organ. And because the 14,000 donors weren't enough to meet the need, 7,000 of the wait-listed people died waiting in 2012.

From 1988 to August 2013, more than 122,000 deaths have occurred among people wait-listed for an organ transplant. And the waiting list grows daily, usually by about 100 people per week. It really increases very, very quickly. By August 2nd, 2013 it had already grown to 119,035. And so while the annual number of donors also grows, it grows at a much slower pace.

And that has been and continues to be the single biggest challenge in organ transplantation today. The surgical, medical, and pharmaceutical expertise is in place and transplants are done daily with great success rates. Mostly we just need more donors. And the first step on the road to getting more donors is to ask people and encourage people to sign up in their state donor registry.

Here you can see the magnitude of the problem in graph form. And the need -- the waiting list -- is indicated in green - clearly is not only greater but -- as I said -- continues to grow at a pace that greatly outpaces the supply of the number of donors, which you see in the red line. The blue line -- which is the number of transplants -- is greater than the number of donors, again, because deceased donors can provide more than one organ.

So this gives you the breakdown of the waiting list by organ. Clearly kidney is the organ most often needed and -- fortunately for kidney patients -- they can be sustained for a time on dialysis. However, that is not a permanent solution and nor is it a pleasant solution. But it does keep a person alive for a time. But you are tethered to going to the dialysis center several times a week. And it just is not - doesn't have the quality of life that a transplanted organ would give to somebody.

So there are two unique challenges - and probably more than that. But let's look at two unique challenges in the world of donation and transplantation today. And one is minorities. As you can see from this chart, the need for transplantation is disproportionately high among minority populations. This is especially true for kidneys and as a result of the very high rate of diabetes and hypertension in our general population and especially in minorities.

Let's look at the black population as an example. Blacks are about 13% of the general population, 29% of people waiting for any organ, 34% of people waiting for kidneys, 20% of people who receive any organ in 2012, and 25% of kidney recipients in 2012, and 17% of deceased donors and 16% of kidney donors in 2012. So their need greatly exceeds the - their donation rate. And again, to donate - all of the ethnicities donate in proportion to their population, but the issue is not that - the issue is needs are greater transplant needs are greater. So similar trends, although less pronounced are evident in the other minority populations.

So while it's important to increase the number of donors in the general population, it's also important to increase donation among minority populations. But it should be known that organs are not matched according to race or ethnicity. That does not figure in to the matching issues that we discussed a little bit ago. And people of different ethnicities can indeed match one another. However, since compatible blood types are essential for transplantation and certain blood types are more common in specific ethnic groups, people of any ethnicity will have a better chance of finding a matching donor if there are more donors of their same background.

Perhaps not surprisingly, the 50 plus population is another group that has an elevated need for transplantation. As you can see in 2012, people 50 plus were

64% of the overall waiting list and 60% of recipients. In that same year they were 35% of donors. According to a 2005 national survey conducted for HRSA by the Gallup organization, 21% of people 50 and older believe they're too old to be organ donors. And with 99 million people in this country 50 and older, that means about 21 million believe they're too old to register.

Yet, there have been organ donors and organ recipients into their 90s. One of the things that we have seen from the state donor registries is a drop-off of registration by people over 50. And so HRSA -- together with the Administration on Aging and the National Institute on Aging and NIH is sponsoring a national campaign to inform older adults that they are not too old to sign up to be donors and to encourage them to enroll in their state donor registry.

Although many 50 plus believe they're organs are be too old to be donors, we really need to correct that myth and let them know that that is absolutely not the case. The main issue is the viability of your organs at time of death.

Now we'll switch gears to our grant programs and give you a little orientation to these. And then perhaps you can understand the urgent need for more donors and why we are supporting grants to increase donation.

The first grant program -- social behavior interventions to increase solid organ donation -- is a research based program to identify strategies that are successful in increasing donor registration and family consent for deceased donations. And this program fund project for up to three years in donation.

And the overall aim of the second program -- public education efforts to increase solid organ donation -- is to promote the widespread use of strategies

already shown to be effective in other areas and in other populations. And this program funds projects up to two years in duration.

Both programs also support projects to increase a commitment of parents and legal guardians to donate a minor child's organs in the event of the child's death. And that focus is new for 2014. This is the first year that we're sponsoring that.

So lets' look at the social and behavioral research program. And the goal here is to implement and test the effectiveness of novel strategies to increase -- as I said -- individual consent -- sometimes called authorization -- for deceased donation. Family consent or authorization for donation of a deceased loved one's organs at the time of death and commitment, again, of parents and legal guardians to authorize organ donation for a minor child in the event of the child's death.

The performance measures - there are spelled out for both - for this grant program. And there are three performance measures that really parallel the actual goals and the - of the grant program. And so one performance measure -- meaning each project -- must address one of these three performance measures. So increase the number or rate of individuals who designate their consent to become donors in their state registry, increases in the rate of family consent for deceased relative or friend of these individual, and increases in knowledge among parents and guardians about transportation and donation among minors and increases in willingness of these guardians and parents to donate their children's organs should they die.

And, if older minors are included in the target population -- that's probably those in their teens -- the performance measure also must include their knowledge of the need for donation and transplantation among minors and

willingness to be a deceased donor and sharing that decision with family.

That's a long winded performance measure, but I think -- especially because this is the first year we're offering this option -- we wanted to make sure it was well explained - or we hope it's well explained.

And here you'll see some additional requirements of this grant program and others are contained in the FOA; the funding opportunity announcement. This grant program supports applied or intervention research efforts. Applications must propose the implementation of a specific strategy or campaign that addresses one of the three performance measures and a sound and rigorous research methodology to evaluate the effectiveness of the intervention. These projects must involve experimental or quasi experimental design and descriptive research is not acceptable.

Projects may implement and evaluate an intervention or there may be something that's ongoing that you find novel and creative and all you need are funds to do the evaluation component of it. So you can apply for only evaluation funds. The interventions and methodology are required to be based on and guided by one or more published theories of health behavior change that are relative to the project or various aspects of the project.

And what I mean by various aspects is some projects follow a different health behavior change theory for different parts of a campaign or an application that they see fit.

So the types of studies you can do in this grant program are pilot studies, which tests an intervention that has not before been tested for its effectiveness in the donation field. It could have been effective in some other field and you want to implement it here or it's a new idea that you have developed yourself. A replication study - and that tests the strategy already shown to be effective

on a particular population or setting and you would be trying it for its potential effectiveness with a different population or setting.

And an extension project; and this type of project builds on results of a pilot project by adjusting or adding some new dimension to the original intervention and attempts to strengthen the intervention.

Whereas the social and behavioral research program is designed to identify successful outreach interventions, the purpose of the public education grant program is to enable the replication and roll-out of successful strategies and models in other areas of the country. Projects can focus on increasing public commitment to donation as expressed through the donor registry enrollment or increasing parents and guardian's knowledge of and commitment to their child's donation should death occur. So it has those two foci.

And this - the public education has two categories; replication of a project that's already been shown to be effective and development of a project that replicates a model that has been shown to be successful in changing health behavior in that the outreach strategy contains both community based motivational interventions and reinforcing media and outreach - media outreach strategies. So you can propose to do either one of this type of strategy - project.

And the evaluation is a different component. These are -- again -- not research projects but a well-developed evaluation strategy including process. And outcome measures is required to determining the effectiveness of the project and then process evaluation is to be measured as a timely achievement of the different milestones of the project and the resolution of problems. And outcome evaluation would focus on donor registry enrollment or

parent/guardian commitment to their child's donation, depending, of course, on the focus of your project.

So DoT recognizes that many factors can infringe on and influence and individual decision about donation. And these grant programs support what we refer to applicant initiated focus. And applicants have the discretion to propose any intervention setting or target group that they can justify as addressing an unmet need and having potential to meet their project goals and objectives. Excuse me.

This and the subsequent two slides will give you an idea of the variety of settings, target groups, and populations used in previous projects funded by these two grant programs. So just to give you an idea of the diversity of types of things that people have been funded to investigate. And that doesn't mean that these populations or issues can't be revisited; it just means that these are examples.

So funding for the Social and Behavioral Interventions for 2014. The total - excuse me. The total amount of funds available to support the first year of new projects is \$1,250,000. And with this amount, we anticipate funding four to five new projects. So I know you can do the math. So we anticipate a grant awards will range from \$250,000 to \$300,000 per year. There is no ceiling, but we - and we recognize that budgets will vary with the complexity of the project and with the indirect cost rate. If - even though there is no ceiling, if you propose something that exceeds the \$350,000, it is useful if you explain why it needed to do that.

There's no requirement for cost-sharing, but -- of course -- in kind contributions are always useful. And the project period -- again -- may be for up to three years and we anticipate a start date of 9/1/14.

And for public education, you'll see that the first year total is - amount of money we have available for the first year of all projects is \$1 million. And we anticipate funding four to five projects at \$200,000 to \$300,000 per year. Same thing about cost sharing and in-kind. Up to two years. And again, a start date of September 1.

We try very diligently to make our schedules such that people are notified in the early summer so you have the summer to put your plans in place and, you know, get moving, but that the start date would be September. Sometimes that works and sometimes it doesn't.

So you need to give thought to who the review panel would be for the specific kind of proposal you're submitting. The review panel composition reflects the requirements of each grant program. And because the social and behavioral research program is a research program, about two thirds of the panel members are social and behavioral researchers and one third comes from the organ donation community, generally people with a public relations, public outreach background.

And similarly, of the three reviewers assigned to prepare a written critique of an application, two are researchers and one is a donation professional. Although only three members prepare a written critique of an application, all panel members receive an electronic copy of all the applications and participate in discussions voting and scoring of each application.

And the flip-flop is the case for the public education effort. Two of the three reviewers on each application will be donation professionals -- generally public outreach, public relations kind of people -- and - from the donation

community - from the OPOs. And one will be an evaluator researcher. But again, the whole committee participates in reading, discussion, and voting.

So where to start? An FOA -- funding opportunity announcement -- provides instruction and further detail about any funding opportunity, including what the program wants to accomplish, who can apply, the requirements of the application and review criteria, etcetera. I strongly recommend that this document become your best friend. It contains an enormous amount of information and can certainly be read more than once.

And it's important to pay particular attention to words and phrases such as must and should and shall, are required to, cannot, etcetera. And make sure that your application addresses the review criteria in their entirety. Every item noted in a criterion is important. And eligibility for our programs are any institution which is public or private not for profit and federally designated organ procurement organizations.

And for an in-depth overview of a funding opportunity announcement it's kindly recommended that you review the following webinar that has been put together by HRSA and really walks you through the - what a funding opportunity announcement is and does and the different components of it.

So a few suggestions here. This grant program - these grant programs involve the fields of research and evaluation and organ donations. And therefore, an effective project team would also involve those two specialties. It may also be prudent to include a representative of the target population on your team. Assess your own skills and knowledge and identify appropriate partners with complimentary expertise. Get together from day one and continue throughout the project.

Don't be a lone ranger. Most of the projects -- if not all -- that we have funded that make it through the research committee in flying colors that enables us to fund them have been submitted by a consortium or a team effort. Some potential collaborators - there are several types of organizations in the transplant community that can provide assistance on a grant project. If you are a researcher you may be looking for donation partners. If you are a service provider or a donation person, you may be looking for a researcher.

So the type you might be looking for will depend on your background and expertise. And the type of organization you might select would depend on the nature of the project. Donate Life America is a national association that engages in public outreach at the national level and has affiliates at the local level. Organ procurement organizations also are valuable resources of collaboration and -- as I mentioned -- many have participated in our grant projects. Local National Kidney Foundation affiliates also conduct outreach activities to increase donor registration.

And transplant centers located in hospitals that perform transplants and interact with donors and recipients also would be - might be useful partners, especially if you're focusing on increasing consent within the hospital at time of death.

If you need to find a partner with expertise in research methods, universities are a good place to look. And because this grant program focuses on health behavior change, you would want a researcher with expertise in social and behavioral research. You might find that type of experience in schools of public health, marketing, communication, health education, psychology, counseling, and others.

And a few additional thoughts to consider. Again, don't underestimate the power of collaboration. Pick your partner carefully and use them well and often. Remember, people are more committed to something in which they have an investment. Don't think you have to reinvent wheels; borrow and adapt. Be flexible; there are always bumps in the road as reality plays havoc with the best made plans.

Here are some resources to get you started. Others are listed in the FOA. And if you are new to the donation field, I highly recommend you familiarize yourself with the four resources listed here. The first two bullets provide links to organdonor.gov where you can find brief descriptions of all the grants DoT has already funded and a bibliography of all of the articles and chapters published by our grantees. And it is a healthy bibliography, we're proud to say.

The third bullet references a book that was edited by two DoT grantees and addresses research on organ donation outreach and promotion. Most of the chapters focus on DoT funded studies and are written by the grantees who conducted them. The first chapter provides a background of the field of organ donation, its players, organizations, conquests, and evolution. And if you are new to the field, that might be a useful source of reading.

And the fourth bullet is a very current Web site of data on organ donation and transplantation. It is very user friendly, enables you to make comparisons of your choice, and develop your own graphs and charts. And obviously that, too, is an organ - a government Web site.

So there are going to be two technical assistance calls for each of these grant programs that DoT will sponsor. And these calls will go into considerably more depth with respect to the FOA and requirements of the grant program.

Whereas here we split it about 50/50 with an overview of the field and the grant programs, we'll go into much more depth on the funding - the 2014 funding opportunity announcement.

So my goal and purpose today was to give you a thumbnail sketch of the organ donation and grant opportunity and I hope that that is what I accomplished. The technical assistance for the public education effort are going to be held -- also by conference call -- two different times and again, you would go through the FOA in more detail.

We also will have a live broadcast and a rebroadcast of a grantee showcase that we have prepared where you will be able to hear from - unfortunately we just learned about a couple hours ago that this will be three different grant projects because one woman's husband is very, very ill and - from an accident so will not be able to participate with us. But these will be a webcast on the live broadcast; obviously will be able to answer questions. On a rebroadcast obviously you will not be able to ask questions.

Here is our contact information. Please feel free to contact Rita Maldonado or me at any time if we can be of assistance. (Unintelligible) is the official point person for these grant programs and is part of our donation branch. So thank you for participating in this webinar; I really hope I have piqued your interest in this issue and please know that when we say contact us for further information that we're quite serious.

We're - we really want to help people get involved in this field and help you put together the best application possible. If you need to identify people in your communities that can help you like people from an OPO or a DLA or, you know, an NKS that can work - possibly work with you on your

application, you know, we would like to provide whatever kind of assistance we can. So please don't hesitate to call.

Operator, can we field any questions right now?

Coordinator: And all lines are open and interactive. If you do have a question, please un-mute your phone and state your name.

Woman: Hello, I'm wanting to make sure that we're going to be able to get a hard copy of your slides. There was a lot of information in there for those of us that are new to this. So will they be e-mailed out to those of us who participated in the call or posted somewhere? What -?

Mary Ganikos: They will be posted on HRSA's Web site. And what I will do is get the exact e-mail address and I'm assuming that we will be able to send that out to you all. Is that correct, Operator? Hello?

Coordinator: You can send out the slides.

Mary Ganikos: Yes, okay. Thank you.

Woman: Great, thank you.

Mary Ganikos: Uh-huh. Any other questions? Well, thank you again for joining us. And I know that it is - it can be overwhelming to think about getting involved in a new field and - but I must tell you that in 1999 everybody that submitted a grant to this program -- because that's when we first started the research program -- it was a new field to all of them and new people have joined over the years. And so it's an interesting - very, very interesting field and very rewarding projects have been conducted. And we encourage you to -- like I

said -- get in touch with us however we can be of assistance. So thank you again and we hope to be hearing from you.

Coordinator: Thank you for participating in the conference today. You may now disconnect.

Group: Thank you.

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