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PROviding Better ACcess To ORgans: A Comprehensive Overview of Organ-Access Initiatives from the ASTS PROACTOR Task Force

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Abbreviations:

ACOT, Advisory Committee on Organ Transplantation; AOPO, Association of Organ Procurement Organizations; ASN, American Society of Nephrology; ASTS, American Society of Transplant Surgeons; AST, American Society of Transplantation; DCDD, Donation After Circulatory Determination of Death; DNDD, Donation after Neurologic Determination of Death; DoT, Division of Transplantation; DTCP, Donation and Transplantation Community of Practice; HRSA, Health Resources and Services Administration; MELD, Model for End-Stage Liver Disease; OPO, Organ Procurement Organization; OPTN, Organ Procurement and Transplantation Network; PMP, Per million people; SCCM, Society of Critical Care Medicine; TTS, The Transplantation Society; UNOS, United Network for Organ Sharing

Abstract

The American Society of Transplant Surgeons (ASTS) PROviding better Access To Organs (PROACTOR) Task Force was created to inform ongoing ASTS organ access efforts. Task force members were charged with comprehensively cataloguing current organ access activities and organizing them according to stakeholder type. This White Paper summarizes the task force findings and

makes recommendations for future ASTS organ access initiatives.

Introduction

Organ transplantation is fundamentally limited by the availability of transplantable organs. In the United States 22 people die each day because they do not have access to a life-saving organ.(1) Previous attempts to respond to this public-health crisis have demonstrated that concentrated, multi-stakeholder efforts with strong leadership can increase organ availability. In 2003 the Donation and Transplantation Community of Practice (DTCP) was formed to engage in Breakthrough Collaborative initiatives utilizing the principles of metric identification, joint accountability, and best-practice application to increase deceased donor organ donation.(2, 3) The immediate post-Collaborative period was marked by a striking increase in deceased donors from 6,457 donors in 2003 to 8,017 donors in 2006.(4) Despite this encouraging increase, organ donation growth in the post-Collaborative period stagnated, with deceased donor volumes oscillating around the 8,000 donor/year mark for nearly a decade. The past two years has seen a substantial increase in deceased donor activity with 9,079 donors in 2015 and 9,970 in 2016, due in part to the increase in deaths associated with opioid use.(5) Despite this apparent success, 12,192 people were removed from the waitlist in 2016 due to death or becoming too sick to transplant.(6) **(Figure 1)**

Expanding access to transplantation by increasing deceased donation, living donation, and organ utilization is a central component of the ASTS's vision of "saving and improving lives with transplantation." Accordingly, in 2015 American Society of Transplant Surgeons (ASTS) President Charles Miller, M.D. commissioned the ASTS PROviding better Access To Organs (PROACTOR) Task Force. The charge of this task force is to identify mechanisms through which the ASTS and its membership can effect change to reduce, and eventually resolve, the critical organ shortage.

The initial goal of the task force was to develop a comprehensive understanding of current organ-access initiatives implemented by stakeholders

within the U.S. and internationally. To create this catalogue, stakeholders were categorized according to type and assigned to task force members who performed literature reviews, internet searches, and personal inquiries to identify organ-access initiatives in a wide variety of arenas. These broad catalogues were then reviewed by the task force leadership, with highlights organized and summarized in this White Paper. Additionally, considerations are presented for future application of ASTS efforts and resources towards achieving the society's mandate to eliminate mortality on the wait list due to organ unavailability.

Overview of Initiatives By Stakeholder Group

ASTS

In 2015 the ASTS increased its efforts dedicated to organ access, including the creation of the PROACTOR Task Force and the dedication of the 16th and 17th annual Winter Symposia to the theme of increasing organ availability. These efforts continued in 2016 with ASTS participation in the White House Organ Summit, as well as partnership with the Laura and John Arnold Foundation and the American Society of Transplantation to solicit novel metrics to reduce risk-aversion within transplant centers.(7, 8) Finally, in 2017 the ASTS created the ASTS Donation after Circulatory Determination of Death (DCDD) Task Force to help standardize organ recovery and utilization protocols to improve the use of this growing category of organ donor.

At the committee level, the ASTS has taken a multi-faceted approach to organ availability. In 2009, the Ethics Committee published "Stimulus for Organ Donation: A Survey of the American Society of Transplant Surgeons Membership", delineating member views on acceptable and unacceptable strategies to increase organ donation.(9) The same year, the Ethics and Executive Committees published a response to the Declaration of Istanbul, outlining the Society's strong support for the principles outlined in the Declaration and discussing potential obstacles to implementation in the United States.(10)

The Ethics Committee has also developed ASTS positions on conscious DCDD donation(11) and kidney paired donation.(12)

The ASTS Scientific Studies Committee is currently engaged in developing a research grant to assist ASTS members in conducting single-center or multi-center studies on organ donors, transplant recipients of expanded criteria donors, donation after circulatory determination of death, and living donation. The Scientific Studies Committee also partnered with the Ethics and Standards and Quality Committees to propose draft guidelines that address barriers to deceased donor research and complexities regarding consent from donors, transplant recipients, and providers.

The ASTS Living Donation Committee has outlined best practices for long-term care of living donors and developed informational materials to be distributed to living donors. Furthermore, the ASTS participates in the administration of the National Living Donor Assistance Center , currently the most comprehensive mechanism for reducing financial disincentives to living organ donation.(13)

The Government and Scientific Liaison Committee provides ASTS representation on the Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing (UNOS) Board of Directors, which participates in developing organ donation policies for the OPTN. The Legislative Committee has compiled an extensive library of advocacy letters that are available to the public on the ASTS website, many of which support initiatives aimed at increasing organ availability. Furthermore, the Legislative Committee played a key role in the passage of the HIV Organ Policy Equity Act in 2013.(14, 15) Organ donation is a key component of the National Transplant Surgery Fellowship Curriculum, developed by the Curriculum Committee to educate ASTS Abdominal Transplant Fellows. Lastly, the Diversity Issues Committee has developed an Educational Materials for Minorities page housed on the ASTS website.(16) This webpage contains ASTS educational videos in Spanish on living kidney and liver donation. It also includes other websites specifically designed to help the Hispanic/Latino community make informed treatment

decisions about kidney donation and transplantation by providing resources and neutral information.

U.S. and International Transplant Societies

The U.S. transplant societies comprise a large, diverse, impactful group of organizations that have a foundational mission to improve and augment organ transplantation. As expected, the missions and initiatives of these societies overlap with each other and with the mission and initiatives of the ASTS.

The American Society of Transplantation (AST) is the largest transplant organization in North America with over 3,300 members.(17) The AST influences organ access through provider education, patient information, and public policy initiatives. Accordingly, the AST dedicated the 2016 Cutting Edge of Transplantation Meeting to resolving the organ shortage through practice, policy, and politics.(18) Several important living donation initiatives are contained within the AST Live Donor Community of Practice. This specialty-focused group within AST provides multidisciplinary provider education via online communities and webinars, including a series of web-based educational modules called “Maximizing Your Living Donor Program.” AST has also developed a Live Donor Toolkit aimed at increasing awareness and education for living donation.(19)

As the professional organization linking all 58 U.S. organ procurement organizations (OPOs), the Association of Organ Procurement Organizations (AOPO) promotes their vision that “those in need of a transplant receive donated organs or tissues in a timely manner in order to end deaths on the waiting list.”(20) AOPO supports organ access through educational activities for organ procurement professionals, as well as governmental advocacy on behalf of OPOs. AOPO operates a voluntary, peer-review accreditation process designed to help OPOs improve performance.(21) Furthermore, AOPO publishes the “WikiDonor” online donor management handbook to serve as a resource for donor management by OPO staff.(22)

NATCO, the Organization for Transplant Professionals, unites a diverse group of transplant professionals ranging from procurement practitioners, hospital development specialists, and transplant center nurses and allied health staff.(23) NATCO's contributions to organ access are primarily derived from educational support to improve the performance of members involved with deceased donation and donor management. NATCO has recently become more involved with advocacy related to organ access issues, particularly support of the Living Donor Protection Act.(24)

Other national transplant-specific organizations, including the American Foundation for Donation and Transplantation, (25) promote organ donation as part of their core mission. Additionally, local and regional transplantation societies, the largest of which is the Texas Transplantation Society, promote organ donation through state-level advocacy and state legislation initiatives to complement larger, national initiatives.(26)

International transplant societies provide a common link for the often disparate practices of organ transplantation throughout the world. The Transplantation Society (TTS) is the largest international transplant society and has been particularly instrumental in supporting the Declaration of Istanbul and other ethical efforts in transplantation. The TTS sponsors several novel initiatives dedicated to increasing organ access, including the "Transplantation for Schools" program which provides a pragmatic toolkit for teachers to educate students about organ donation in an age-appropriate manner.(27)

U.S. Medical Societies

Medical and surgical societies play an integral role in uniting physicians along specialty lines and providing support for research and clinical practice, along with a political voice. The majority of practicing U.S. physicians belong to one or more societies, with a trend towards increasing membership in specialty societies and decreasing membership in general physician societies.(28) Most societies are either discipline-specific or disease-specific and provide information

for patients and providers regarding transplantation as an option for the relevant end-stage disease. However, most of these societies currently provide only cursory education and policy initiatives with respect to increasing organ availability. A notable exception is the American Society of Nephrology (ASN), a strong advocate for living kidney donation which recently has been a vocal supporter of the Living Donor Protection Act of 2016.(29)

- Nearly all deceased donors are cared for in an intensive-care setting. Accordingly, The Society of Critical Care Medicine (SCCM) and the American College of Chest Physicians are ideal partners for efforts directed at recognition and referral of potential donors, application of donor-management guidelines, and opportunities for future research in deceased-donor interventions. (30, 31) Both societies are active in improving deceased donor management through both educational initiatives as well as a consensus statement regarding ICU care of potential organ donors in partnership with AOPO.(32) Additionally, SCCM partnered with AOPO, UNOS, The American Thoracic Society, and the International Society of Heart and Lung Transplantation to create an official ethical and policy considerations document concerning DCDD donation.(33)

Organ Procurement Organizations (OPOs), United Network for Organ Sharing (UNOS), and Donor Registries

The core purpose of the 58 U.S. OPOs is to facilitate deceased donor organ donation within a designated donor service area. OPOs are driven both intrinsically by their mission and extrinsically by regulatory bodies to increase organ availability. Accordingly, OPOs are essential partners for any initiatives aimed at increasing deceased donor organ availability and utilization.

OPOs are the most visible and well-resourced entities promoting awareness and understanding of deceased donation at the local level. OPOs sponsor public events, minority outreach programs, and community and business

partnerships aimed towards increasing deceased donation. Most of these efforts currently involve drives to join state donor registries. State donor registries are authorized via state legislative code and are, in most cases, operated independently of the OPOs themselves or the state government. Currently, each state has its own donor registry without a cohesive, national service; however Donate Life America provides a common online portal for individuals to register themselves in their appropriate state.(34)

Innovations in deceased donation require close collaboration between OPOs, donor hospitals, and transplant center groups. Donor intervention trials designed to improve donor organ quality exemplify this cooperative relationship. For example, the 2015 investigation of the effect of therapeutic donor hypothermia on kidney graft function was facilitated by partnership between academic centers in California and Oregon with two large OPOs in California.(35) Donor intervention trials present unique ethical and logistical challenges which are currently being examined by The National Academy of Medicine (formerly Institute of Medicine) via a multi-stakeholder Committee on Issues in Organ Donor Intervention Research which includes strong representation from OPOs.(36)

Novel approaches that challenge the traditional donation model also arise from multi-stakeholder collaboration led by OPOs. In St. Louis, Missouri the partnership between Mid-America Transplant Services and the local transplant centers manifested in the creation of a free-standing donation facility where over 90% of donors in the donation-service area are transferred. This departure from the traditional deceased donation model has been shown to result in higher donor organ yield and lower cost.(37) Other OPOs have begun using similar donation facilities including Gift of Life Michigan,(38) Center for Organ Recovery and Education in Pittsburgh,(39) and Donor Alliance in Denver.(40)

Although OPOs have traditionally focused on deceased donation, several OPOs have engaged in activities related to living donation. In 2004 the transplant centers and OPOs comprising UNOS Region 1 reported their experience with a

two-tiered kidney exchange program.(41) This program facilitated exchanges between incompatible live donor pairs within the region, and also allowed incompatible donors to donate to the waitlist in exchange for high priority for their intended candidate to receive a deceased donor kidney. In 2005 the Washington Regional Transplant Community OPO published a description of their OPO-administered non-directed living kidney donor program. This program increased the OPO-procured kidney organ pool by 5%.(42) More recently, the four California OPOs working together under the Donate Life California organization launched Living Donation California in 2013.(43) This state-authorized information and referral service provides education about living donation, and helps refer non-directed living donors to local transplant centers.

As the contract administrator of the OPTN, UNOS is an essential component of the U.S. deceased donation system. UNOS provides the infrastructure required for deceased donation and organ allocation, and provides education and awareness about organ donation on a national scale. UNOS also administers HRSA/OPTN-directed initiatives including task forces geared towards increasing deceased donation and organ utilization. OPTN Task 6, the Deceased Donor Potential Study, was commissioned in 2010 with the goal of identifying the true larger potential for deceased organ donation in the U.S. This study estimated the true donor potential in the U.S. to be between 35,000 and 40,000 donors per year, a striking number which finds most unrealized potential in deaths of individuals aged 50-75 years.(44) More recently, OPTN Task 18, also known as the Collaborative Innovation and Improvement Network (COIIN) project, was established with the goal of using alternative monitoring of transplant programs to reduce risk-avoidance behaviors with respect to kidney graft utilization.

Non-Profit Organizations

A large number of non-profit organizations dedicated to increasing deceased donation by creating awareness are present on the local, regional, and

national levels. Several large, event-based organizations such as Transplant Games of America(45) generate sufficient media attention to positively impact organ donation awareness. Other large, national organizations such as The American Transplant Foundation also have the resources and scope to impact donation registrations.(46) Select smaller organizations may also have a large impact on awareness via large-scale media, including Donate Life Hollywood which aims to eliminate donation misconceptions such as the “stolen-kidney” storyline from television and film.(47)

The majority of organ-donation awareness organizations are small organizations that operate at the local or regional level, often in memory of a deceased organ donor. Although these organizations share similar missions and goals, there is limited coordination between these groups that would serve to synergize their effect towards increasing organ donation. Considerable resources are donated to and invested in these organizations for both operational and mission-directed purposes, yet the overall impact of these organizations with respect to increasing organ availability through awareness is difficult to measure.

A few national organizations have the scope and resources to effect change by influencing policy or promoting disruptive approaches to increasing deceased donation. One such organization, ORGANize, has created a social media-based platform for donor registration utilizing the concept of “social declaration” which has been implemented in six states.(48) This 21st century method of registering first-person intent seeks to become a modern alternative to the association between organ donor registration and motor vehicle licensure.. More controversially, the LifeSharers organization promoted a “closed system” of organ donation to other designated LifeSharer members, but ceased operations in March 2016.(49)

Recognizing the disparity between minority transplant candidate listings and minority deceased donation, several organizations have sought to bridge this gap through community education initiatives. These efforts are spearheaded by large national organizations, including the Association for Multicultural Affairs in

Transplantation(50)and the National Minority Organ and Tissue Transplant Education Program(51) as well as smaller local organizations and OPOs. Furthermore, as the Hispanic population increases dramatically in some parts of the U.S., the explicit support of organ donation by Pope Francis as outlined in the Catechism of the Catholic Church is increasingly important.(52)

Philanthropic organizations have demonstrated interest in the ongoing organ shortage and seek to improve access to organ transplantation via funding of novel projects. The Laura and John Arnold Foundation is a notable supporter of organ-access initiatives, including co-sponsorship of the ASTS/AST project to improve transplant center metrics with the goal of reducing risk-averse behavior by transplant centers.(8) Furthermore, the Arnold Foundation announced \$4.2 million in funding for deceased donor intervention trials to improve organ utilization as part of the 2016 White House Organ Summit.(53)

Non-profit organizations support living donation through several different mechanisms. The National Kidney Registry and the Alliance for Paired Donation facilitate living kidney donation and transplantation through paired exchange.(54, 55) The National Kidney Registry is notable for an “Advanced Donation Program” which provides “vouchers” that allow the living donation event to be uncoupled in time from the recipient’s transplantation.(56, 57) Several other organizations attempt to increase living donation through education, donor support, and awareness. Notable examples in this category include Explore Transplant,(58) which provides educational programs to help potential donors make informed decisions, The John Brockington Foundation which sponsors a “Connect to Transplant” coaching program for former living donors to serve as donor champions,(59) the Kidney Exchange Connection,(60) which provides peer support from prior living donors, and *Renewal* which facilitates directed and altruistic living kidney donation.(61) Additionally, Transplant First Academy is dedicated specifically to helping kidney patients avoid dialysis through a preemptive living donor transplant through educational materials and events.(62) Finally, several organizations seek to increase living donation via advocacy and

policy change. This category is highlighted by Waitlist Zero, which is active in national living donation legislative efforts and leads the Coalition to Promote Living Kidney Donation with the intention of sponsoring a future Living Donation Breakthrough Collaborative.(63)

Transplant Center Initiatives

Individual transplant centers can impact organ access in two primary ways. The first impact is through more effective utilization of organs that might otherwise go unused.(64, 65) Specific centers successfully utilize deceased donor organs such as pediatric en-bloc kidneys,(66) kidneys from donors with severe acute kidney injury,(67) and DCDD liver(68, 69) and lung(70) allografts at rates that far exceed many other programs. Centers have developed advanced surgical techniques to improve utilization of dual lower-quality adult kidneys(71) and to create two adult transplants from a single liver allograft.(72) Furthermore, centers differ markedly in their utilization of living donor organs including living donor liver allografts and incompatible living donor kidney transplants.(73, 74)

The second mechanism individual transplant centers can use to impact organ availability relates to novel initiatives directed towards increasing living donation volume. The Johns Hopkins Live Donor Champion program increases living kidney donation by training a friend or family member to advocate on behalf of a transplant candidate.(75) The Beth Israel Deaconess “House Calls” program may reduce racial disparities in access to living donor kidney transplantation.(76, 77) The Northwestern Hispanic Transplant Program incorporates a number of initiatives, including the development of the bilingual website informato.org which provides culturally-competent education about living donation.(78-80)

Industry

Organ preservation is the biomedical industry’s primary contribution to organ availability. Historically, the development of organ preservation solutions enabled the prolongation of organ storage times, resulting in the ability to match

donor organs with distant recipients.(81) Further innovations include the production of cold pulsatile-perfusion devices for deceased-donor kidneys, albeit with unclear effects on utilization.(82) Current industry advances include expanded application of extra-renal ex-vivo perfusion devices, including hypothermic- and normothermic-perfusion devices for liver allografts. Hypothermic machine-perfusion of “orphan” liver allografts has been shown to improve patient survival and decrease biliary complications.(83) Similarly, normothermic-perfusion devices have been shown to decrease ischemia-reperfusion injury in porcine models of liver transplantation, and encouraging early results from the use of this technology in human liver transplantation may represent another avenue for the improvement of utilization of donor livers.(84-87)

Partnerships with information technology firms may provide novel pathways for increasing both deceased and living donation. A 2012 collaboration between Johns Hopkins University and Facebook generated 13,054 new organ donor registrations in a single day, demonstrating the massive potential of social media as a driver of societal change.(88) This collaboration was brought into the live donation space in 2014 with development of a smartphone app designed to help candidates identify possible living donors.(89) Technology-driven donor registration was boosted in late 2016 when Apple, in conjunction with Donate Life America, provided simple, integrated donor-registration technology with the release of the iPhone OS10 software.(90) Other, transplant-specific technology platforms may have the potential to increase living donation by reducing barriers to donor application. These products include BREEZE Transplant, a web-based patient-intake and decision-support portal which has been shown in a large center to increase living donation volume by 15%.(91)

Private insurance companies are key industry stakeholders in transplantation, and their relevance to organ access primarily relates to their ability to facilitate living donation. For example, in 2016 UnitedHealthcare announced coverage for travel expenses related to living kidney donation.(92)

International Initiatives

Deceased donors per million people (PMP) is an imperfect statistic,(93) but is currently the most widely used method of comparing donation rates around the world. In 2015 the United States ranked sixth in the world with 28.5 deceased donors PMP, behind Portugal, Belgium, Iceland, Croatia, and Spain.(94) **(Figure 2)** With a donation rate of 39.7 donors PMP in 2015, the Spanish organ donation system is often viewed as the world's gold-standard. Much discussion of the Spanish system centers on the "opt-out" system of presumed consent. However, several countries have adopted similar programs with variable results, including Brazil and France which both experienced decreased deceased donation following implementation of a presumed-consent system.(95) Close examination of the Spanish organ donation system reveals that their success results from effective utilization of older donors, with over 50% of donors over 60 years of age and 30% over age 70, as well as development of a highly prioritized donation culture and practice imbedded within the healthcare system.(96) In 1989 Spain introduced the National Transplant Organization (ONT), with implementation of Transplant Donor Coordinators (TDCs) in each hospital. TDCs are specially-trained intensive care physicians or nurses charged with identifying potential donors and seeking authorization. The TDCs are monitored by a coordinated national Quality Assurance Program, which provides peer-review oversight of each institution and expedited performance improvement initiatives.(97) Many of the key features of the Spanish model, including hospital-based donation coordinators and a quality assurance program, were implemented in Croatia with dramatic results, including a 2015 donation rate of 39 donors PMP.(94) This demonstrates the reproducibility of these important, but sometimes overlooked, Spanish model concepts.(98)

Israel has taken a different approach to increasing deceased donor authorization rates through incentivization. In 2008 the Israeli Parliament adopted a new law which gave priority to transplant candidates who had themselves

registered to be an organ donor for at least three years prior to being listed as a candidate. Similar priority was given to transplant candidates with a first-degree relative who was a deceased organ donor, as well as to any previous live organ donor who subsequently required a transplant.(99) Analysis of the Israeli deceased donation climate demonstrates that this program is associated with increased authorization rates for organ donation.(100) Similar laws exist in Singapore(101) and Chile,(102) although these systems differ from Israel's initiative by including presumed-consent practices.

In countries where access to deceased donors is limited, the resulting desperation has led to accelerated innovation to provide organs for transplantation. In Japan and South Korea, transplant centers responded to this demand with large-scale innovation in living donor liver transplantation.(103, 104) The significant advances made in the course of developing these large-scale living donor liver transplant programs has inspired similar innovation in North American centers.(105) In South Africa, where transplant surgeons were faced with a large number of HIV-positive patients with end-stage renal disease and limited resources to care for them, innovation took the form of HIV+ donor to HIV+ recipient kidney transplantation.(106) The success of this program inspired investigation into the use of HIV+ organs in the U.S.(107) Countries with inadequate access to standard donation after neurologic determination of death (DNDD) donors have demonstrated innovation in the utilization of organs from DCDD donors. In the UK, utilization of DCDD liver allografts from older donors has changed perceptions of the potential contributions of the DCDD donor pool to liver transplantation.(108) Furthermore, France, Spain, and the Netherlands have demonstrated successful utilization of organs from uncontrolled (Maastricht Category II and V) donors, adding a previously unutilized group of potential donors to the pool.(109-111) This work has led to the development of protocols in select U.S. centers to explore improved utilization of these categories of organ donors.(112, 113) Finally, the Eurotransplant consortium began a Senior Program in 1999 to allow for better utilization of older donor kidneys in older

recipients with excellent results, suggesting that often-discarded older kidneys may provide utility for well-selected older recipients.(114)

Coalition and Government

Several important national coalitions have been formed with the purpose of increasing organ access. The US government plays an important role in facilitating several of these coalitions via the Division of Transplantation (DoT) within the Health Resources and Services Administration (HRSA).(115) The Advisory Committee on Organ Transplantation (ACOT), for example, was established by the HHS Secretary to enhance organ donation and assure the public that the transplantation system is grounded in best available medical science and is fair and equitable. Currently, ACOT has 5 active working groups which are actively examining declining rates of organ donation and geographic barriers in organ distribution.(116) The DoT also sponsored the DTCP which conducted the Breakthrough Collaborative partially responsible for the large increase in deceased organ donors from 2003-2006.(2, 3) The DTCP evolved into the independent organization The Organ Donation and Transplantation Alliance, commonly known as The Alliance, which continues to work towards increasing organ availability in a multi-stakeholder fashion.(117) Recent efforts from The Alliance include The Organ Donation Toolbox which was developed to provide donor hospitals and OPOs easy access to best practices resources.(118) Furthermore, in October 2016 the Alliance sponsored a multi-stakeholder National Critical Issues Forum to promote high-level, disruptive conversation aimed at changing the status quo in organ donation.(119)

Several large coalitions have been formed outside the U.S. government to unite stakeholders in an attempt to increase access to organs for transplantation. The National Coalition to Promote Living Kidney Donation combines the efforts of 15 non-profit groups and OPOs to foster public policies that support living kidney donors and living kidney donation, specifically through active lobbying of HRSA to publicly support efforts to increase live organ donation.(120) Additionally, various US transplant-related societies and non-profit organizations have

combined to form the Transplant Roundtable coalition. This coalition serves as a communications vehicle to prevent overlap in society sponsored donation activities, and to provide direction for society sponsored lobbyists that actively work to enhance US organ donation policies.(121)

Summary

In this White Paper the PROACTOR task force details numerous initiatives promoted by a wide variety of different stakeholders, each with the goal of increasing organ availability. When viewed optimistically, the sheer volume and diversity of organ access initiatives and the effort, attention, and resources directed towards this critical issue is encouraging. If one takes a pessimistic view, however, the fact that that these tremendous investments of time, energy, and assets have had only incremental impact on organ availability is discouraging.

As advocates for organ failure patients, it is our obligation to remain unwaveringly optimistic and to continue to work towards the ultimate goal of eliminating mortality on the waitlist due to organ unavailability. Presented with an overwhelming number of potential avenues towards this goal and an equally large number of partners to pursue it with, it is imperative that we align the efforts of our members, our society, and our partners towards the highest-yield paths to increased organ access. Considering the wide scope of current initiatives outlined in this summary, as well as the heterogeneity of the environments in which they have been implemented, identifying the programs that truly “move the needle” can be difficult. Nevertheless, there are several common themes found within the current deceased and living donation and transplantation landscape that can inform the shaping of a more favorable future.

Increasing Deceased Donation and Organ Utilization

The Centers for Disease Control and Prevention reported 8,237 deaths PMP in the U.S. in 2014.(122) Reconciling this figure with the U.S. rate of 28.5 organ donors PMP in 2016 is sobering. Improving this metric will require a concerted multi-faceted approach to improving organ donation and utilization.

Increasing Donor Authorization

Much of the national conversation about increasing organ donation revolves around the concept that encouraging more people to say “yes” to organ donation is the key to saving lives on the waitlist. The promotion of donor authorization is the primary public-facing message of the pro-organ donation movement. This is a reasonable public-education approach given that saying “yes” to donation is a much more accessible concept to a layperson than increasing potential donor recognition, for example. Indeed, a substantial amount of effort and funding is directed towards improving authorization rates through the Donate Life America and state registries, minority outreach programs, large non-profit efforts such as ORGANize, countless smaller non-profits operating with slim budgets, and technology industry partnerships. Unfortunately, despite these intensive efforts and expenditures, the UNOS-reported eligible death authorization rate in 2016 was 75.0%, essentially unchanged from the rate of 75.4% in 2011.(123)

Our national focus on increasing authorization rates is the lens through which observations of successful international donation systems are sometimes misleadingly viewed. For example, many descriptions of Spain’s success in donation focuses on the fact that they have a presumed consent system in place, ignoring the fact that many other nations with presumed consent models experienced decreased donation rates post-implementation.(124) This incomplete understanding of Spain’s success has recently led to controversial government actions such as the proposed “opt-out” bill currently in the Texas legislature.(125)

The stagnation of authorization rates despite conventional and increasingly unconventional means clearly indicates that applying even more focus to authorization is not the solution to our organ shortage crisis. Instead, a more comprehensive understanding of organ availability suggests that high rates of donor authorization are necessary, but not nearly sufficient, to substantially reduce waitlist mortality. Returning to the UNOS-reported 75.0% authorization rate in 2016, one can extrapolate that even an extraordinary authorization rate of 90% of the same pool of referred eligible deaths in 2016 would result in 1,994 more donors – a substantial increase for certain, but not nearly enough to dramatically change the course for patients on large waitlists such as the kidney waitlist.

In order to create impactful change on the waitlist the current focus on the authorization-rate numerator (number of authorized donors) needs to be supplemented by a much more intense focus on increasing the denominator (eligible death referrals). This work requires a two-sided approach involving both 1) increased recognition of currently defined eligible deaths, and 2) a utilization-driven change in the definition of eligible deaths.

Increasing Donor Recognition

Prompt identification and referral of potential donors within hospitals is a critical step in the deceased organ donation process. In Spain and Croatia, improving potential donor recognition via embedded in-hospital donation personnel has been essential to their world-leading productivity.(97, 98) The importance of this concept has long been recognized in the U.S., and in-house OPO coordinator models were lauded as a best-practice over a decade ago as part of the Breakthrough Collaborative.(2, 3) Despite the success of this model, it has been inconsistently applied across the 58 U.S. OPOs, and may be, in part, responsible for their variable productivity. This important OPO practice should be

supported by transplant providers as a mechanism to improve deceased donor recognition.

Although OPOs bear some responsibility for potential donor recognition, hospital care teams who make the referrals also bear responsibility. Accordingly, transplant providers should partner with critical care teams at the local level to emphasize the importance of potential donor referral. Furthermore, the ASTS and other transplant organizations should work at the society level with groups such as SCCM to help develop systems to identify and close the gaps through which potential organ donors fall.

Increasing Organ Utilization

The Deceased Donor Potential Study suggests that the true donor potential in the U.S. is 3 to 4 times the current number of recovered donors. Many of these donors come from categories of donors currently defined as “non-standard” including DCDD donors and older DNDD donors, and are absent from current metrics regarding eligible deaths.⁽⁴⁴⁾ The realization of the potential of the donor pool lies beyond the scope of simply referring and obtaining authorization from increasing numbers potential donors as currently defined. In fact, the key to unlocking this potential rests in our hands as transplant providers through our collective ability and willingness to utilize these “non-standard” organs for our patients. Indeed, the primary driver of organ donation volume in the future is dependent on our transformative expansion of organ utilization.

Improved organ utilization starts with optimized management of the deceased donors and improved assessment of potential organ function. On a broad level, the ASTS and other organizations must partner with SCCM, AOPO, and other stakeholders to improve the standards of donor management to increase the quantity and quality of organs recovered. Imperative to improving donor management is the resolution of barriers surrounding donor intervention trials, and full engagement with the National Academy of Medicine Committee on

Issues in Organ Donor Intervention Research will serve as a critical step in this direction.

Organ utilization, and consequently the definition of what constitutes an acceptable deceased donor, varies greatly between transplant centers. If the potential donor pool is to be maximized, knowledge and skills that facilitate the utilization of donor organs can no longer remain widely discrepant. At the society level, the ASTS can serve as a vehicle for disseminating training to reduce these gaps. For example, society-sponsored training courses or fellowships in the areas of pediatric en-bloc kidney transplantation and split-liver transplantation may improve the broader acceptance of these techniques. Furthermore, continuing to educate providers about the successful use of marginal organs such as older liver grafts and severe acute kidney injury renal grafts may help to reduce the prevalent risk aversion that so often prevents the acceptance of these transplantable organs.

DCDD donors are a rapidly-growing component of the donor pool, comprising 17% of organ donors recovered in 2016.⁽⁴⁾ Despite the fact that 1 in 6 donors currently come from this category, the utilization gap for extra-renal organs from DCDD donors is striking. In order to truly create disruptive change in future deceased donor volume as suggested by the Deceased Donor Potential Study, better understanding and use of organs from DCDD donors is imperative.⁽⁴⁴⁾ The ASTS is currently beginning focused efforts to improve DCDD organ utilization with the establishment of the DCDD Task Force in 2017. This task force, in collaboration with AOPO, seeks to standardize recovery parameters and recovery surgeon training to encourage improved DCDD organ utilization. Furthermore, applying lessons learned from the international experience of older DCDD liver and uncontrolled DCDD kidney utilization may help further maximize the potential of DCDD donation in the U.S.

Industry's contribution to organ utilization lies within the realm of emerging organ preservation and modification techniques. Early demonstrations of success with warm-liver perfusion and other devices in other countries point towards a

future in which the definition of a transplantable organ is changed. The U.S. transplant community and its regulators should embrace the potential of these devices for changing waitlist mortality. Furthermore, transplant centers, OPOs, and regulators on the local, society, and governmental levels need to be cooperative to accommodate the proliferation of these potentially-transformative devices with respect to organ allocation and re-allocation, definition of ischemia times, and other practical matters to help this technology thrive in the U.S. environment.

Implicit in transplant provider and center reluctance towards expanded organ utilization is concern regarding post-transplant outcomes published in current center-specific reports. These reports, with their associated implications for regulatory and financial disincentives, are primary drivers of the risk-aversion that stifles innovation in organ utilization. Current efforts, such as the COIIN project, are welcome steps in the right direction to allow for the exploration of ways to expand organ utilization. Future efforts, including the ASTS/AST/Arnold Foundation projects, may result in the development of transplant center metrics that will improve utilization by reducing risk aversion and rewarding, rather than penalizing, centers for expanding the reach of transplantation.

Finally, organ allocation systems have long been the topic of much debate in the transplant community, but the role of these systems in improving organ utilization is under-discussed. Balancing the Final Rule principles of fair organ distribution and “achieving the best use of donated organs” is difficult, especially because even small changes related to allocation methods or organ descriptions may have unintended consequences that can lead to diminished organ utilization.(126, 127) In fact, the early results of the 2014 Kidney Allocation System, designed in part to improve organ utilization, resulted in a slight early decrease in kidney use.(128) Additional mechanisms such as expedited organ allocation designed to improve utilization have been demonstrated internationally,(129, 130) as well as preferential allocation of older kidneys to older recipients to promote utilization such as the Eurotransplant Senior

Program.(114) Perhaps pilot studies of these programs in the U.S. will demonstrate similar favorable results to drive improved organ acceptance and use.

None of these mechanisms in isolation can result in drastic correction of the deceased donor organ shortage, but together they can have a synergistic effect. For example, suppose that a liver from an elderly DCDD donor, recovered by a well-trained surgeon and placed on a warm-perfusion device, is allocated to a low-MELD recipient based on a utilization-prioritizing system in a less risk-averse regulatory environment. The liver is then transplanted successfully into the appropriately consented recipient who might otherwise not have access to a transplantable organ. This experience is reported by the transplant team, encouraging other centers to expand their use of DCDD liver grafts. At the donor hospital, use of this organ encourages the critical care team and embedded OPO staff to better recognize and refer similar potential donors in the future, and the donor family becomes advocates to help improve authorization rates in their community. This is the cycle of success that, as transplant providers, we are responsible for initiating.

Increasing Living Donation

The past ten years has been marked by significant strides in living donor organ transplantation. Experience with ABO-incompatible and crossmatch-positive living donor kidney transplantation, as well as the widespread acceptance of paired kidney-donation, has reduced or removed immunologic barriers for many potential donor/recipient pairs. Social media and related technologies support the maintenance of intrapersonal relationships and creation of new ones, and give voice and a wide audience to those who might be seeking a living donor. The National Living Donor Assistance Center has become established to facilitate disincentive-reduction, and major payors starting with United Healthcare have begun to followed suit with their own programs. Living

donor liver transplantation has modestly expanded over the past 6 years and lessons learned from the international experience are being applied in the U.S. Despite these important advances, the 5,979 total living U.S. organ donors in 2016 represents a striking decrease from the peak of 7,004 in 2004.(4) This is a disturbing trend which is difficult to reconcile, and may be due in part to changing characteristics of the recipient population, deceased donor organ distribution, financial concerns, or other poorly-understood factors.(131)

Considering the new tools at our disposal, transplant providers, centers, societies, and regulatory bodies must work in partnership to thoughtfully expand living donation to better serve the needs of the organ-failure population. At the transplant provider and center level, implementation of new strategies that have been shown to be effective such as the Live Donor Champion Program(75) and House-Calls program(76) should be further expanded. At the society level, surgical education regarding best practices such as the ASTS Laparoscopic Donor Nephrectomy Workshop should be continued. Novel initiatives, such as utilizing deceased donor kidneys to initiate living donor chains, should be explored.(132) Additionally, the ASTS should facilitate surgical education in living donor liver transplantation through programs at high-volume centers in North America and overseas.

Removing disincentives to living donation has been a collaborative project of the ASTS with other stakeholders, and these efforts should continue to help re-shape the landscape of living donation in the US. 2016 was an important year in this regard, with passage of the Living Donor Protection Act. This momentum should carry the society towards further breakthroughs in the coming years thorough participation in a Living Donor Breakthrough Collaborative suggested by The National Coalition to Promote Living Kidney Donation. This proposed initiative would complement the recent HRSA/SRTR development of The Living Donor Collective Scientific Registry to better understand living donor risks, outcomes, and other issues relevant to living donation expansion.(133)

In summary, the future of our society, our profession, and most importantly our patients is dependent on the availability of organs for transplantation. The vision of the ASTS is to save and improve lives through transplantation, and to realize this vision, we must all play a role in reducing the organ shortage. We call on every transplant provider, the ASTS, and all stakeholders in our field to rededicate themselves towards this vision through individual and collective efforts so that one day soon the promise of transplantation can be fully achieved.

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Figure Legends

Figure 1. Timeline demonstrating U.S. deceased donor and living donor volumes, waitlist deaths and removals for “too sick to transplant”, and start-of-year waitlist for all organs.

Figure 2. 2015 deceased donor per million population rates in U.S. and selected countries.

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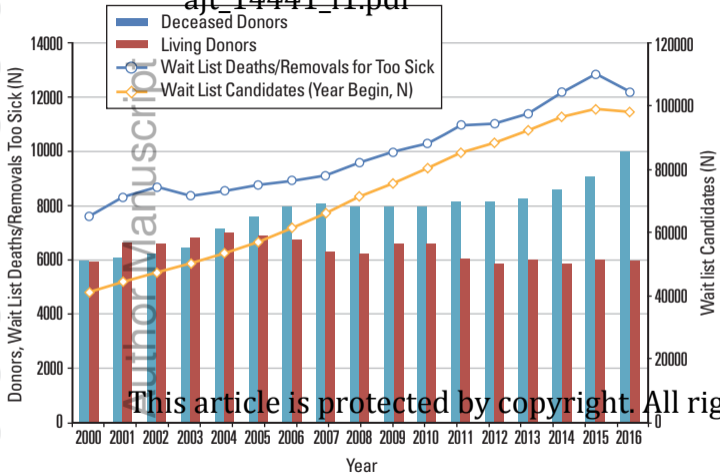
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Deceased Donors per Million People, 2015

