CATEGORY 5
ADVANCING ORGAN DONATION

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Award Category:
Advancing Organ Donation
Title:
Launching a National Living Donor Registry

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Problem/Situation:
The Need for Living Donors is Great:
- 91,817 Americans are awaiting a lifesaving kidney transplant
- 23,401 kidney transplants were performed in 2019 yet only 6,867 were from living donors
- More lives would be saved through living donation; however, there is no uniform national call to action for living donation.
- The majority of the public expresses support of living donation; however, the number of living donor transplants has remained flat.
- Estimates reveal for every 35 living donors, there may be another 26 willing to donate.
- There are a great number of barriers to finding and identifying potential living donors for those waiting for a lifesaving kidney transplant, including access to information, methods to express interest and access to screening.
- Transplant Centers are not equipped with personnel and resources to efficiently conduct an abundance of outreach for increasing non-directed living donor interest nor providing education and conducting preliminary screening in a manner.

The success and Reach of the existing National Registry offers a unique opportunity
- Launched in 2015, the National Registry has added more than 7 million registered organ, eye and tissue donors from all states.
- We recognized the opportunity to expand consumer generosity by offering an opportunity for living donation to the ~4,000 persons a day after completing registration as deceased donation through the National Registry.
- Although there is anecdotal evidence that ‘high profile’ living kidney donor transplants raise awareness, these national news, or viral social media stories lack a ‘call to action,’ for those viewing the stories who may feel compelled to act.

Innovative Solutions are needed for this Health Crisis
The National Living Donor Registry will launch in 2021. This will be the first national-reaching living donor registry in the United States allowing persons expressing interest in donation the option learn about living donation, to express their interest in becoming a living donor and complete initial steps in the living donor screening process. The registry will foster the addition of a call to action for national media stories or events, a proven strategy for deceased donation and bone marrow registrations. The registry creates an opportunity for families, organizations or donor champions to conduct ‘drives’ similar to those utilized in bone marrow without overburdening living donor staff at individual transplant centers.

Methods/Practices/Interventions:
A workgroup of experts from the donation and transplantation community was convened which served to:
- Establish appropriate and effective questions and criteria for living donor screening
- Design parameters for transplant center participation
- Ensure collaboration and sharing of expertise from all key players in the living donation arena
- Obtain critical feedback from key stakeholders representing regulators, nonprofits and professional societies
Research was conducted in three key realms providing critical feedback to shape the design of testing, screening and educational messages
- Focus groups - A nationwide sample of 500 qualifying adults: (Age 21-60, 50% non-Hispanic Caucasian, 25-30% African American, 25-20% Hispanic or Asian, Not opposed to organ and tissue donation) and a nationwide sample of 50 previous living donors were surveyed on the user friendliness (usability) of web pages for the living donor registry website to gain insights on what aspects, if any, need design improvements. The results showed the web pages performed well in communicating the intended information with minor suggestions for improvement that have been addressed.
- Clinical testing of the use of saliva to screen for ABO and HLA- 40 saliva samples compared the ABO and HLA saliva results to HLA and ABO serum results from the same participants at two different labs confirmed accuracy of saliva testing. 100% of comparisons came back as matches.
- Performance of Registry and Logistics - Simulated personal health information results were created and uploaded into the registry portal for access by participating transplant programs. In our next phase, pilot transplant program staff will access the portal using a rigid but efficient authentication process. This simulation will further test authentication procedures, data sharing techniques, ease of use accessing the registry portal, etc.
Through partnerships with other donation and transplantation community leading organizations we have developed and will execute and manage this new National Living Donor Registry in a collaborative fashion. The living donor registry will begin with four pilot transplant centers who will be provided 50-100 saliva collection kits each to distribute to prospective living donors

- Prospects will go through the process of registering through the National Living Donor Registry and submitting saliva samples using the at-home collection kit.
- A link to a user experience survey will be included in the confirmation email to the living donor prospect to get real time feedback for adjustments and improvements before launching to nationwide.

Findings/Solutions/Conclusions:

- The National Living Donor Registry will be built on the existing National Registry for deceased donor registrations and will include an easy and accessible way to test a potential living donor.
- Living Donor Prospects will be asked to complete a health screen questionnaire and to select their preferred transplant center from a list based on their geographic preferences.
- If the answers meet a predetermined threshold, then the individual would be asked if they would like to receive a “test kit” in the mail. A saliva kit would be mailed to the prospect.
- Once completed, the kit is returned via mail to a lab for testing - at no cost to the prospect. Lab testing would determine blood type and HLA typing.
- The test results and health information would then be uploaded to a secure database (backend of the registry) where the data is attached to the potential donor’s registration record.
- The transplant center selected by the potential donor will be notified via email and dashboard notifications that they have a new living donor prospect waiting.
- Transplant center staff will assess the potential donor’s information through a secure portal using authentication by the national organization responsible for the data system housing the nation’s waiting list.
- We expect to see even greater successes than those evident from the Israeli model, in which a community organization has expanded living donor kidney transplantation by facilitating altruistic living unrelated donor transplantation.

Implications/Relevance:

POTENTIAL TO SAVE MORE LIVES

- To date, there are 1.5 million new registrants in the National Registry each year. If 1 percent of those expressed interest in learning about being a living donor and ultimately were evaluated and cleared as living donors the potential for an additional 15,000 potential living donors in the US per year could be realized.
- If only half of those potential donors ultimately donated a kidney to one person, 7,500 more lives would be saved.
- If each of these 7,500 donors started a kidney paired donation (KPD) chain (on average, KPD chains result in 3 transplants) this would mean 22,500 more lives saved. Please note that the number of living-kidney donor transplants in the United States totaled 6,867 in 2019.

Learning Objectives for this presentation

- Review rationale for a uniform national platform to promote altruistic living kidney donation
- Provide overview of the new National Living Donor Registry
- Outline the success of promoting living kidney donation when a standard call to action is available.

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Citations:

https://optn.transplant.hrsa.gov/data/ accessed December 2, 2020

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Advancing Organ Donation
Title:
Multimedia Education to Facilitate Communication About Living Kidney Donation: A Proof of Concept

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Problem/Situation: To increase living-donor kidney transplantation (LDKT), educational interventions are needed that support candidate communication. This pre-post study tested the feasibility and acceptability of an educational communication intervention about LDKT named KidneyTIME, which leverages animated video education and content sharing using ubiquitous technologies.

Methods/Practices/Interventions: Adult kidney candidates undergoing transplant evaluation/re-evaluation and their caregivers at a single transplant center viewed different sets of KidneyTIME animations prior to transplant evaluation, with online access to all animations over 6 weeks. Change in LDKT knowledge, communication self-efficacy, and concerns was assessed before and immediately after exposure and 3 weeks later. Also assessed were post-exposure animation acceptability, 3-week self-reported online use and LDKT discussions, and 6-week program feedback.

Findings/Solutions/Conclusions: A total of 82 candidates and 79 caregivers participated. Viewers of KidneyTIME demonstrated increases in LDKT knowledge (r=0.65; +71%) and communication self-efficacy (r=0.53; +48%) and reductions in concerns (r=−0.19; −21%). At 3 weeks, knowledge effect size remained positive relative to pretest (r=0.46; +49%). The intervention was received positively, with 99% of participants agreeing that the animations were interesting or engaging, and 100% saying they would recommend the program to a friend (Figure 1).

Implications/Relevance: KidneyTime improved predictors to increase LDKT and was rated as highly acceptable.

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Figures/Charts/Tables:

![Chart](image.png)
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Turn a Negative into a Positive: List Patients for HCV+ Organs

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Problem/Situation: The transplant community remains in urgent need to expand the organ donor pool for life-saving transplantation. The availability of direct-acting antiviral therapy has changed the way transplant centers consider using Hepatitis C-viremic (HCV) donors in HCV-negative patients. The utilization of HCV-viremic donors in kidney transplant candidates not infected with the virus represents an opportunity for the expansion of this organ donor pool. Transplant candidates must be proactively screened for appropriateness, undergo rigorous review, and receive education on the risks and benefits of accepting such organs. The utilization of HCV-viremic donors is increasing; however, long-term outcome data is currently insufficient. Thus, the American Society of Transplantation urges the use of HCV-viremic donors for HCV-negative recipients in the context of enhanced patient education and informed consent through research protocols. Herein, we summarize an improvement effort in our organizational strategy for the utilization of HCV-viremic organs for HCV-negative recipients.

Methods/Practices/Interventions: This single-center performance improvement initiative summarizes an iterative process to facilitate transplanting candidates with end-stage kidney disease with a kidney from an HCV-viremic organ donor. In Era-1, patients were passively identified by the clinical team and referred to hepatology for education. In Era-2, patients on the active list were proactively contacted regarding the potential of receiving offers for HCV-positive organs. Those interested were educated by the transplant coordinators using standardized training material. As standard practice, new patients who have completed their evaluation undergo transplant education during an activation teaching class. During Era-2, information about the risks and benefits of HCV-positive organ donors was included in this curriculum. Figure 1 outlines the systematic flow of Era-2 patient throughput.

Findings/Solutions/Conclusions: In Era-1, 2.1% (n=9) of waitlisted patients were activated to receive a kidney from an HCV-positive organ donor, while 18% were activated in Era-2 (Figure 2). During Era-2, 332 patients were contacted by telephone to assess their interest in receiving HCV-donor focused education. Of those, 54 patients participated and 50% were clinically eligible and agreed to receive HCV-positive organs. Additionally, 117 patients received education from the activation teaching class with HCV content and 47% agreed to receive these organ offers. Era-2 yielded 82 (18%) patients on the active waitlist eligible to receive HCV-viremic positive donors. The transplant community is exploring opportunities to expand the organ donor pool with efforts to increase the utilization of HCV-viremic organs. We achieved a 18% increase in patients activated for HCV-viremic organs within a 6-month implementation period with our performance improvement effort. Although transplanted patient data is currently unavailable, we remain optimistic that volumes will increase based on current listing activities.

Implications/Relevance: HCV-viremic donors are an important part of the deceased donor pool that can now benefit a larger number of patients with end-organ failure awaiting a life-saving transplant. Early data including short-term follow up are encouraging, and these organs may represent an important resource in the armamentarium to combat wait-list mortality. As the use of HCV-viremic organs for HCV-negative recipients accelerates, the transplant community must ensure that candidates are identified appropriately and provided education about the risks and benefits of such organ transplants.

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Figures/Charts/Tables:

Figure 1: Systematic flow of patient throughput for Era-2

Note:
TC = Transplant Coordinator
1 Transplant program educates all patients as part of the standardized education process.

TC recommends patient for HCV NAT+ organ
TC calculates APRI and FIB4 (if either/both is abnormal, Fibroscan)
Patient assessed for sustained viral response post completion of therapy
Patient begins 8-12 week treatment regimen
Patient cured of HCV or treated with different regimen

- If Fibroscan is abnormal, referral to Hepatology
- Trained clinician educates patient on HCV+ to transplants

Patient clinically cleared for HCV NAT+ organ?
Patient consents to HCV NAT+ organ?
Clinician documents statement of interest

No - Patient remains on waitlist; consider other options
Yes - Once clinical clearance and consent are complete, TC changes patient status in UNET

Patient is offered HCV+ organ?

No - Patient continues as a standard transplant
Yes - Clinician notes HCV+ organ on surgical consent and obtains patient signature

Figure 2: Flow diagram of outcomes from each Era

Era-1 (Jan 2019-Aug 2019)
No. of ACTIVE status 1 patients: 428

No. of patients who attended HCV class (liver): 11 (3%)
Total no. of patients activated to receive HCV-positive donors: 9 (2%)

Era-2 (Sep 2019-Mar 2020)
No. of ACTIVE status 1 patients: 449

No. of patients who attended HCV class (kidney): 54 (12%)
No. of patients who received education from general teaching class: 117 (26%)
No. of patients activated to receive HCV-positive donors: 55 (12%)
Total no. of patients activated to receive HCV-positive donors: 82 (18%)
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Advancing Organ Donation
Title: Association of Donor Rhabdomyolysis with Kidney Transplant Outcomes

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Problem/Situation: Donor rhabdomyolysis may constrain kidney utilization because of the potential for unfavorable graft outcomes, especially in the setting of extreme donor creatine phosphokinase (CPK) levels; however, there is a paucity of outcomes data to inform organ acceptance decision-making.

Methods/Practices/Interventions: We conducted a single-center retrospective cohort study of adult isolated kidney transplant (KTX) recipients of deceased-donor kidneys with reported donor CPK levels between 2014 to 2019. Minimum follow-up was 6 months. Rhabdomyolysis was defined as peak CPK ≥1000 (5x normal). CPK was further dichotomized into extreme categories at the 75th, 90th, and 95th percentiles. The primary outcome was overall graft survival; distributions were compared with log-rank test. Secondary outcomes were delayed graft function (DGF) and follow-up serum creatinine (SCr) ≥2 mg/dl at 3-, 6-, and 12-months; differences were compared with Chi Square tests.

Findings/Solutions/Conclusions: There were 91 recipients of kidneys from donors with CPK ≥1000 and 134 with CPK <1000. There were no between-group differences in terms of donor, recipient and transplant characteristics, except the CPK ≥1000 group was predominated by donors with terminal SCr ≥2 mg/dl (48% vs 17%, p <0.001) and requirement for acute dialysis (12% vs 2%, p=0.004), respectively. Outcomes of CPK ≥1000 versus CPK <1000 were similar in terms of all-cause graft failure (p=0.599), DGF (53% vs 49%, p=0.607), and SCr ≥2 mg/dl at 3- (15 vs 15%, p=0.951), 6- (20% vs 14%, p=0.294) and 12- (14% vs 11%, p=0.493) months, respectively. Similarly, fractionating CPK groups into more extreme ranges of <3000, 3000-7000, 7001-10,000, and >10,000 (range 10,000 to 35,920) demonstrated no statistical differences in all-cause graft survival (p=0.542) [Figure 1].

Implications/Relevance: Short-term outcomes of kidney transplants from donors with rhabdomyolysis did not differ by CPK level up to >10,000; however, further research with larger sample size at extreme CPK levels and markers of kidney injury is needed.

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References: none

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Figures/Charts/Tables:


Survival

Logrank p=0.5422

-3000
3000-7000
7001-10000
>10000

Years Post-Transplantation

CPK <3000 3000-7000 7001-10000 >10000