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Directors' Report – Biannual Update on UNOS December 2014

OPTN/UNOS Board of Directors Meeting Highlights

The OPTN/UNOS Board of Directors met November 12-13 in St. Louis. The Board took action on a number of items, with key topics described below. An executive summary listing all Board actions is available on the OPTN website:

<http://optn.transplant.hrsa.gov/converge/members/executiveSummary.asp>.

Board Actions:

Member probations

In separate actions, the Board approved a designation of probation for two members: Nebraska Organ Recovery System and Erie County Medical Center. The circumstances leading to the actions are not related. Each institution will be subject to additional review and monitoring while continuing a quality review and improvement process.

Living donor evaluation and consent

The Board approved a set of policy requirements for medical/psychosocial evaluation and informed consent procedures for living donation of kidney, liver, lung, intestine and pancreas. Similar policies have been in effect since February 2013 for living donor kidney transplantation. The newly approved policies address commonalities for living donation of kidney, liver, lung, intestine and pancreas, while specifying additional criteria most appropriate to each organ type.

Potential donor disease transmission risk

The Board approved policy revisions to help minimize the risk of transmitting blood-borne infectious disease through transplantation. The policies conform to guidance issued in June 2013 by the Public Health Service to reduce the transmission risk of diseases including HIV and hepatitis. The new and updated requirements apply to both deceased and living donors and address a variety of topics including:

- laboratory testing of potential donors and recipients, including new requirements related to nucleic acid testing (NAT)
- collection, storage, tracking and reporting of donor and recipient specimens
- informed consent of potential recipients
- donor risk assessment and screening

In addition, the Board endorsed a guidance document to help screen potential donors for seasonal and geographically endemic infectious diseases.

VCA membership requirements; guidance on donor authorization

The Board accepted a clarification to membership requirements for vascularized composite allograft (VCA) transplant programs, directing them to specify to the OPTN the type(s) of VCA transplantation they intend to perform.

The Board also endorsed a guidance document to help OPOs develop protocols for authorization to donate VCA.

Liver allocation

The Board adopted amendments to liver allocation policy to cap the assignment of a liver exception score at 34 for candidates with hepatocellular carcinoma (HCC), and to delay HCC exception score assignment.

Histocompatibility requirements

The Board approved expanded HLA typing requirements for transplant candidates and deceased donors to provide greater consistency across all organ types.

The Board also approved inclusion of histocompatibility testing requirements within the OPTN kidney paired donation pilot program.

Membership process for geographically isolated transplant programs

The Board endorsed an addition to the OPTN bylaws to address potential approval of a transplant program if the prospective program cannot satisfy current key personnel requirements due to geographic isolation.

Nominations for upcoming election

The Board ratified a slate of nominees for election to open positions for the 2015-2016 Board term. Voting materials, including an election ballot and brief biographical sketches of nominees, will be sent to voting representatives of OPTN/UNOS member institutions in early 2015.

Other Highlights:

UNOS staff updates

David Klassen, M.D., recently joined UNOS as Chief Medical Officer. He has served previously on the OPTN/UNOS Board of Directors and multiple committees and was medical director of the kidney and pancreas transplantation programs at the University of Maryland Hospital.

Mike Pressendo was recently named UNOS' Director of Communications. He has held leadership positions with a number of agencies and organizations and was most recently vice president of communications for Federal Reserve Information Technology.

Brian Sullivan recently joined UNOS as Director of Technology Operations. He held senior-level positions at AOL and was most recently vice president of systems operations at NeuStar, Inc.

UNOS has established a Department of Member Quality, combining the previously separate departments of Evaluation & Quality and Membership. The department will be headed by a director (currently vacant; UNOS is recruiting for this position) and will have two assistant directors. Jacqueline O'Keefe will oversee operational activities (compliance and safety

investigation, member applications, quality monitoring and MPSC operations) and Matt Belton will supervise monitoring activities (site survey, allocation analysis and performance analysis).

Strategic Planning

UNOS is working on a revised set of strategic plans for the OPTN and for UNOS' corporate efforts, with the goal of finalizing new plans in mid-2015. As part of this process, UNOS sought feedback on strategic priorities at fall Regional meetings as well as at the November Board meeting. Additional information will be forthcoming.

Liver distribution concepts

Following the September 16 public forum, the Liver and Intestinal Organ Transplantation Committee formed three ad hoc subcommittees to address key areas of additional study:

- Refining metrics of access disparity and ways to optimize distribution
- Identifying financial implications of alternative sharing methods
- Addressing transportation/logistical issues associated with potential broader sharing

Each of the ad hoc subcommittees includes current committee members as well as non-committee members with expertise in these topics. An additional subcommittee of the current committee is addressing the topic of increasing liver donation and utilization. The groups are meeting by conference call through April 2015 to develop consensus-based recommendations.

An additional public forum is planned to share the subcommittees' recommendations and again gather professional and public input to guide policy development. A specific forum date has not been established but is anticipated for May 2015; registration details will be forthcoming as soon as they are available.

Kidney and pancreas allocation systems implemented; lung allocation revisions pending

On October 30, revisions were implemented to pancreas and kidney-pancreas transplantation. They are intended to optimize access for pancreas candidates without adversely affecting kidney-only candidates, and to reduce the complexity of offers involving kidneys.

On December 4, significant revisions were implemented to OPTN kidney allocation policy. They are intended to enhance the effectiveness of kidney transplantation and improve access for biologically disadvantaged candidates.

Modifications to lung allocation policy will be implemented in February 2015. They include new data variables to calculate the lung allocation score (LAS), new LAS defaults for missing or expired data, and additional diagnoses within the existing diagnosis groupings.

UNOS has made available a variety of training sessions and informational resources to help members manage the transition to the new systems, as well as educate transplant patients and their families about them.

TransNet (Electronic tracking and transportation)

The project originally known as electronic and transportation (ETT) is now known as TransNet, a service of the OPTN. The project is currently in a second round of field testing involving eight OPOs.

In 2015, the service will be made available for OPOs on a voluntary basis. UNOS will host a series of “train the trainer” sessions beginning in March for OPOs interested in participating. Additional information, including training registration, is forthcoming soon.

Living kidney donation consensus conference summary

Eleven transplant-related societies, organizations and companies, including UNOS, participated in a living kidney donation consensus conference in June. A number of best practices were discussed regarding education of transplant candidates and potential living donors, transplant program efficiency, public policy issues and research priorities. An executive summary of the conference is available on Transplant Pro: <http://transplantpro.org/wp-content/uploads/Executive-Summary-Live-kidney-donor-consensus-conference-2014-docx-2.pdf>

How to Stay Current

UNOS’s website and monthly communication via [Transplant Pro](#) maintains up to date information on policy activities, including policy notices and public comment; compliance and safety information; OPTN guidelines, OPTN committee newsletters and more. Anyone who doesn’t currently receive the monthly e-newsletter may [subscribe here](#).