

Frequently Asked Questions Regarding Liver Allocation and Distribution

How are national transplant policies developed?

The committees and Board of Directors of the Organ Procurement and Transplantation Network (OPTN) continually seek ways to match donated organs with candidates in ways that are as equitable as possible and are consistent with the requirements of the OPTN Final Rule. They follow a very deliberate and transparent process to identify ways to improve the national system, weigh alternative solutions to problems, and gather and respond to public feedback to ensure the proposed solution reflects a consensus among many perspectives.

The OPTN relies first on the expertise of people involved in all aspects of the donation process – medical professionals, transplant recipients and their family members, donor family members and living donors – who serve as representatives on the committees and our Board of Directors.

All committee and Board members are volunteers, compensated only for expenses in travel/lodging for meetings. They bring their collective experience and perspectives to address the difficult and complex aspects of ensuring a fair and efficient national transplant system. All Board and committee members adhere to a conflict of interest requirement to ensure that their recommendations or actions serve the public trust.

The OPTN also uses the extensive data available through the OPTN database, and scientific analyses of data performed by the Scientific Registry of Transplant Recipients (SRTR) to inform policy decision-making. The committees that study and sponsor proposals establish performance measures and assess how policies are meeting those measures. They use current and historical data from various sources, applying analytic methods from fields including statistics, epidemiology and operations research. Simulation modeling is often used to see how various policy alternatives may perform as compared to the current system. Analytic research that has been used in OPTN policy development has been published in a number of peer reviewed professional journals.

Finally, the OPTN depends on the input of anyone who wants to share their views through public comment. All proposed substantive changes to policy are published to allow any interested person or organization to ask questions, suggest changes, or voice their support or opposition. Many proposals are revised in some way based on public comment. When necessary, a proposal can go through multiple rounds of public comment if the initial feedback results in major changes.

How are data used to support proposal development?

The OPTN collects comprehensive data on the functioning of the national transplant system, which is used to inform policy development and ensure that policies are based on data and evidence where available. As committees develop policy proposals, they use descriptive and inferential data from this database to inform their decision-making. The Scientific Registry of Transplant Recipients (SRTR) performs inferential data analysis for consideration by OPTN committees. The committees also review historical and current OPTN data provided by UNOS regarding donation and transplantation.

In addition to examining statistical data, committees consider clinical information and expertise, patient and public feedback, and ethical frameworks as important inputs to inform policy development.

The SRTR simulation models used to inform this proposal are designed to estimate whether and how much a potential change will likely affect key measures at a national level (for example, whether differences in MELD scores at transplant will go up or down). The models can't predict impacts on individual programs or donation service areas.

How do we share livers now?

Donated livers are matched with transplant candidates through a local/regional/national sequence of organ distribution. At each level, a medical urgency formula (MELD for candidates 12 years old and older, PELD for those age 11 and younger) assesses candidates' short-term risk of dying without a transplant. Those with the highest MELD or PELD scores get first consideration for liver offers at each level of distribution.

What needs to be improved?

In some parts of the United States, transplant candidates often become much sicker (their MELD or PELD score increases) before they are likely to be transplanted than patients in other areas. In some areas, many patients are listed at liver transplant programs while there are relatively few patients listed in other areas.

Federal regulation directs the national transplant system to distribute organs over as broad a geographic area as feasible and ensure that, to the greatest extent possible, where a patient lives or chooses to list for a transplant should not be a factor in organ allocation.

The OPTN/UNOS Board of Directors resolved in November 2012 that existing geographic disparity in organ distribution is "unacceptably high." It directed the organ-specific committees to define measures of fairness and develop policy to decrease geographic variation.

Would more organ donors solve this problem?

Deceased organ donation has increased nationwide by more than 22 percent in the last five years and continues on a record-setting trend. The OPTN and other national organizations such as Donate Life America are involved in a number of initiatives to increase both the public commitment to organ donation and the utilization of available organs.

As deceased donation has increased, so has the number of liver transplants. In 2016, nearly 7,500 liver transplants were performed nationwide involving deceased donors. This is an increase of nearly 25 percent in the last five years.

Despite this progress, even if everyone who could donate a liver did so, it would not solve the problem of geographic imbalances. In some parts of the country there are more donors than in others, due to overall population size and regional differences in the causes of death that make donation possible. In some parts of the country there are more patients who need transplants than in other areas. Very sick

transplant candidates should have the same access to lifesaving care, regardless of where they live or where they choose to go for a transplant.

What has the OPTN done recently to address geographic disparity in liver distribution?

In December 2017, the OPTN/UNOS Board of Directors approved a proposal recommended by the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee to decrease geographic variation in MELD scores at transplant. Key features of the new policy include providing additional MELD/PELD priority to liver candidates close to the donor location, whether or not they are listed within the same donor service area as the donor, and providing enhanced access to candidates with a MELD or PELD score of 32 or higher. [Link to policy notice.]

Simulation modeling of the likely effects of the revised system suggests it will decrease pre-transplant deaths among liver candidates and increase transplant access for candidates younger than age 18. The modeling does not suggest the system will greatly affect transplant access based on candidates' insurance type (public or private). Similarly, the modeling does not suggest the system will greatly affect transplant access if candidates live in urban settings as opposed to suburban/rural areas.

The Liver and Intestinal Organ Transplantation Committee will continue to study the effects of the system. Through the OPTN policy-making process, it will seek to address any unintended effects.

When will the approved policy go into effect?

No specific date has been established, but the policy is likely to go into effect toward the end of 2018. It will require extensive computer programming and testing, as well as educating of transplant professionals and patients about the new system.

Will people still donate if their organs aren't being used as locally as before?

In a national survey of organ donation attitudes published by The U.S. Department of Health and Human Services, about 82 percent of respondents indicated that they would like their organs to go to more medically urgent patients regardless of where they live in the United States.

What else is being done to address geographic equity in liver transplantation?

Some liver candidates have medical conditions that are not fully addressed by the MELD or PELD formula. These candidates are awarded an exception score, which is meant to better estimate their need for a transplant. Some exception scores also varied in different parts of the country, since they were assessed by individual review boards in each of the 11 OPTN regions.

In December 2017, the OPTN implemented an update to automatic approval criteria for candidates who receive an exception score because they have hepatocellular carcinoma, a form of cancer that is often successfully treated through transplantation. The new policy establishes broader and more consistent criteria nationwide for how candidates with HCC receive exception scores and how those scores may increase over time.

In 2018, the OPTN will implement a National Liver Review Board to replace the 11 regional review boards. This is also expected to further reduce geographic differences in exception score assignments through a common review process and establishment of criteria to apply consistently nationwide.