

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 an equitable manner. They follow a deliberate and transparent process to identify ways to improve the national system, weigh alternative solutions to problems, and gather and respond to public feedback from a variety of perspectives to ensure the proposed solution best serves patients, consistent with the regulatory requirements that apply to organ allocation policies.

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 OPTN committees and the OPTN Board of Directors.

All OPTN 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 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). OPTN 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 predict 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 members of the public who want to share 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 proposed changes.

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. As a general matter, those with the highest MELD or PELD scores get first consideration for liver offers at each level of distribution.

Is there a problem with the existing system?

In some parts of the United States, transplant candidates often become much sicker (their MELD or PELD score gets much higher) before they are likely to be transplanted than patients in other areas. In some areas, many patients are listed at liver transplant programs; in others there are relatively few. There are also geographic differences in how many people donate livers in some areas. Under the current distribution system, this means that some areas will have more organs available for local patients, while others will have less.

The current 11 regions vary widely in geographic size and population. They were never designed to balance the relative number of potential organ donors and transplant candidates in a given area of the country. In some parts of the country, people tend to die more often from causes that make donation possible. Those aren't always the same as the areas where high numbers of patients need liver transplants.

By regulation, OPTN allocation policies must, among other factors, be based on sound medical judgment, seek to achieve the best use of donated organs, and shall not be based on a candidate's place of residence or listing except to the extent required to satisfy other factors. The OPTN and transplant community must always balance these factors as organ allocation policies are created and changed.

Would more organ donors solve this problem?

Organ donation from deceased donors 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 are involved in a number of initiatives to increase both the public awareness of 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 wouldn't solve the problem of geographic imbalances in the availability of organs. 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 other parts of the country there are more patients who need transplants than in other areas.

What has the OPTN recommended previously to address disparity in liver distribution?

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

The OPTN/UNOS Liver and Intestinal Organ Transplantation Committee resolved that variance in MELD scores at transplant is a key measure to improve geographic equity. As a potential solution, the committee investigated establishing new distribution districts that, unlike the current regional system, create a better balance between the number of liver candidates and donors within various areas of the country. The committee published a concept document in June 2014 outlining its deliberations and seeking public input.

The committee hosted public forums in September 2014 and June 2015 to gather input about the redistricting concept and potential consequences, as well as to seek recommendations for other approaches to address geographic disparity in patient access to liver transplantation, as measured by MELD scores at transplant. The committee formed a number of subcommittees to review further the issues identified and make recommendations for the full committee to consider.

In August 2016, the committee distributed for public comment a proposal to modify liver distribution policy based on eight districts. The committee received significant feedback in response to this proposal. A key concern raised by many was the prospect that many livers may be transported over greater distance, often by air transportation. Based on public input, the committee is no longer investigating the eight-district model.

Is a different concept being proposed now?

The Liver and Intestinal Organ Transplantation Committee has developed a new proposal that, based on available statistical modeling, addresses measures of geographic disparity while not significantly increasing travel time or flight travel for livers.

Beginning in July 2017, the committee will seek public comment on a new proposal. The new proposal would not redraw existing donor service area or regional boundaries. It would, however, provide greater allocation priority to candidates listed at hospitals within 150 nautical miles of the donor hospital, regardless of the donor service area or region where these nearby candidates are located. In this way it would provide earlier access to available livers for candidates at a greater medical priority level who are outside, but nearby to, existing regional boundaries.

When could a proposed policy come for a vote, and go into effect if approved?

The Liver and Intestinal Organ Transplantation Committee will issue its current proposal for public comment, currently scheduled to begin July 31 and end October 2, 2017.

Based on public feedback to a proposal and reconsideration by the committee, the earliest a final proposal could be offered for a vote by the OPTN Board would be December 2017. Implementation of an approved policy would come several months later, to allow for computer programming and education of transplant professionals and patients about the new system.

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

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.

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.

Is the simulation model available for other researchers to use for their own analyses?

Yes. The SRTR's LSAM (Liver Simulated Allocation Model) is available upon request for researcher use. National transplant data sets for researcher use are also available. The equations and formulas used in the optimizations have been published. For more detail, contact the SRTR directly (srtr@srtr.org).