Frequently Asked Questions about Liver Allocation and Distribution

General Questions

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 fair and efficient as possible. 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.

We rely 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 our 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.

We also use the extensive data available through the OPTN database, and scientific analyses of data performed by the Scientific Registry of Transplant Recipients (SRTR). 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, we depend 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. Most 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 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.

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 are able to

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.

Federal regulation directs that the national transplant system should 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.

Would more organ donors solve this problem?

Deceased organ donation has increased nationwide by almost 12 percent in the last five years and continues on a record-setting trend thus far in 2016. 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 2015, nearly 6,800 liver transplants were performed nationwide involving deceased donors. This is an increase of 11 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 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. 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.

Are changes pending?

In August 2016, we will publish a proposal for public comment that would change the geographic distribution system for liver transplantation. The committee sponsoring the proposal will consider all opinions and suggestions to ensure that the system that's ultimately adopted is as fair as possible while also reflecting the feasibility of the donation and transplantation process.

The OPTN/UNOS Liver and Intestinal Organ Transplantation Committee developed the proposal as summarized below. The committee most likely will revise the proposal based on the initial set of public feedback and publish it for a second round of public comment in January 2017. The proposal will only be considered for a final vote once all substantive comments have been addressed.

Are there other liver-related issues going out for public comment?

Yes. Another issue affecting differences in MELD scores at transplant is the fact that some patients receive an exception score for medical conditions that the MELD formula was not designed to address. Exception scores that do not meet certain criteria defined in policy are assigned by medical professionals (regional review boards) in each region. The way these scores are assigned in one region may be different from the way they are assigned in another region.

We seek public comment on two proposals to create greater consistency nationwide in how exception scores are assigned. One proposal addresses MELD exception criteria for adult liver candidates to be used by a future national review board. The other proposal clarifies the criteria used to provide automatic exception scores for liver candidates with hepatocellular carcinoma

(HCC), a form of liver cancer. HCC is the most common condition for adults who have a MELD exception.

Questions about the proposed changes to liver distribution

What is the process that has led to this proposal?

(Note: A detailed timeline of liver policy development since 1987 is available here.)

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.

The OPTN/UNOS Liver and Intestinal Organ Transplantation Committee resolved that variation 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 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.

The proposal being issued in August 2016 reflects the consensus recommendations of the various subcommittees as well as the full committee. The committee expects the public comment process will generate additional feedback that will help further refine a final proposal for later consideration by the Board. The process may involve more than one round of public comment.

What is being proposed?

The policy proposal recommends establishing eight liver distribution districts nationwide. As compared to the current 11 regions, these districts would reflect a better balance of organ availability with the number of liver candidates. Candidates in the most urgent medical condition (those with a MELD/PELD score of 29 or higher) would be considered for compatible livers within their district before local matching for less sick candidates. The ultimate goal is to increase consistency across the country in candidates' medical score at the time of transplantation.

Candidates listed at hospitals both inside the district and within 150 miles of the donor's location would receive three additional allocation points. This would lower the chance that a liver would travel to more distant candidates when a local patient has a similar level of medical urgency.

The proposal would not change the current MELD or PELD allocation formulas used to determine the level of medical urgency of liver candidates. It would only address the size of the area where the sickest candidates would first be considered for livers donated in various parts of the country.

Why are new districts being proposed? Were other alternatives studied?

Frequently Asked Questions about OPTN Liver Policy

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. The eight-district model provides a more consistent alignment of the number of donors available to the number of transplant candidates in various parts of the country.

In its concept paper published in 2014, the Liver and Intestinal Organ Transplantation Committee asked for feedback on four-district or eight-district alternatives. It also asked for additional recommendations of distribution concepts to study.

The transplant community recommended that the committee further study the "concentric circle" model. Similar to the current distribution system for heart and lung transplantation, this approach would first match urgent candidates at hospitals within a certain radius of the donor location (for example, 250 miles).

The committee reviewed simulation modeling data of the concentric circle concept and determined that while it would be an improvement over the current distribution system, it didn't appear to increase fairness as well as a district-based approach. In addition, the committee generally agreed that an eight-district system would be more broadly acceptable than the four-district option in terms of managing transplant-related costs, transportation and logistical issues.

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 were 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.

For this proposal, the Liver and Intestinal Organ Transplantation Committee reviewed a number of data requests and analyses, including simulation modeling, to compare the differential effects of a number of proposed policy alternatives. The committee also considered data presented by a number of members of the transplant community participating in two public forums in 2014 and 2015.

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.

How will this impact individual hospitals? Will they do fewer or more transplants? Could some close?

Frequently Asked Questions about OPTN Liver Policy

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 modeling of the current proposal shows that it would effectively reduce much of the local variation in the MELD scores of transplant recipients. The models can't predict impacts on individual programs or donation service areas.

It would be premature to assume that any specific hospital might do fewer or more transplants, or even close, based only on a proposed policy. When allocation policies change, transplant programs and organ procurement organizations sometimes change their behavior as well. Transplant programs may change their criteria regarding the patients they accept for their waiting list and the organ offers they accept. These changes can't be predicted and are not part of the simulation modeling.

Would this proposed policy increase the number of transplants?

This policy proposal is primarily intended to address known geographic differences in how sick patients must become before they have access to liver transplants. In and of itself, it would not be expected to increase the number of liver transplants.

As noted above, any new policy or change to existing policy may lead to other behavioral changes by donation and transplant professionals. This, in turn, may affect the number of transplants in ways the modeling can't predict.

Liver transplants have continued to increase over a five-year period, which also has spanned implementation in 2013 of a policy (Share 35) that shares livers more broadly for urgent liver candidates.

Could this proposed policy increase the distance organs travel? Could organs take longer to place?

Many livers would still likely be used for candidates relatively close to the donor. The median distance of travel, based on simulation modeling, may increase, but the median amount of time the organ must be preserved (ischemic time) is not expected to increase greatly. If donation and transplant professionals need to establish new working relationships for considering some organ offers, there could be some instances where organs take longer to place. This will be one of the outcomes studied if the policy is implemented.

Will this policy increase cost?

Transport costs are likely to increase in instances where organs must travel farther. This may be offset by reduced pre-transplant costs of supporting very sick transplant patients, if more of them can be transplanted at lower levels of medical urgency with reduced need for critical care before and at the time of transplant.

When will this proposed policy go into effect if it is approved?

There is no firm timetable for a final vote. Public comment is an important, early step in the policy-making process. The initial proposal may well be revised based on public comment, and the revised version would again be circulated for additional feedback.

The earliest a final proposal would be expected to come for a formal vote is June 2017. Implementation of a final policy would come at least several months later, to allow for computer programming and education of transplant professionals and patients about the new system.

Frequently Asked Questions about OPTN Liver Policy

Technical Questions

What analytic approaches have been used to address this problem?

The committee directed the design of a redistricting concept using mathematical optimization. Optimization analysis is applied in many fields to identify the best possible approach or alternative which meets a set of design constraints. In addition to healthcare, engineering and physical sciences, optimization is commonly used in economics.

In this circumstance, optimization was used to define several redistricting options that would improve candidate access to donor livers based on where candidates are listed and where there are donors in the United States.

After redistricting and concentric circle options were developed, simulation modeling was used to examine the effects of allocation on various outcomes of interest, including geographic variation in median MELD at transplant. Simulation modeling has been used to analyze many OPTN policy proposals for nearly 20 years. It is a standard statistical approach in many fields for design and improvement of complex systems, from engineering to communications to healthcare.

Many of these analyses have been published in peer-reviewed journals and presented at leading conferences. For example, the modeling used to project the effect of the Share 35 policy was found, in a post-implementation analysis, to have correctly predicted the direction of change of most outcome metrics of interest.

Why is the variance of median MELD at transplant considered the measure of fairness for this proposed policy?

The committee concluded that in a fair liver allocation system, patients in one part of the country shouldn't need to become significantly sicker than those in other areas before they have access to a transplant. The MELD score assesses the severity of liver disease. For this reason, the committee decided that the most appropriate measure of fairness was to have median MELD scores at time of transplant be similar across the country.

The committee has studied other metrics including rates of death on the waiting list, total deaths due to liver disease, and transplant rates by the local donor service area or region. Evidence suggests that all of these metrics are highly correlated, meaning that improvements in one metric will likely be reflected in the others. The committee ultimately considered these metrics, while important, to be secondary to disease severity at transplant.

Why are eight districts proposed, instead of four or six?

The sponsoring committee investigated several options for the number of mathematically optimized areas of distribution, including four, six and eight districts. Simulation modeling concluded that all district scenarios reduced geographic disparity in access to transplantation, as compared to the current 11 distribution regions.

Feedback received from donation and transplant professionals during two public forums indicated that the four-district concept would pose significant logistical challenges. Six- and eight- district models performed similarly in many key measures based on simulation modeling. Ultimately the Committee recommended the eight-district model as an improvement over the current system while also being similar to the logistics of the existing regional system.

Frequently Asked Questions about OPTN Liver Policy

Why isn't the analysis based on data from this year?

The committee wished to study the impact of proposed policies on three- to five-year post-transplant survival, since many effects of transplant policy are more apparent in the longer term. Five year survival data requires five years to accumulate; trying to extrapolate the five-year impact of more recent data may lead to inaccurate predictions that would compound over time.

In addition, it's important to use the same data set to compare the results of various policy alternatives. If one scenario is modeled based on data using a different time frame than others, it may not yield directly comparable results.

The simulation modeling analyses are based on actual patient data for transplant candidates listed on the liver waiting lists as of December 31, 2006, and candidates added to those waiting lists and organs donated between January 1, 2007, and December 31, 2011.

Previous OPTN policy development initiatives, including Share 35 for liver and the kidney allocation system (KAS), have successfully used historical data in simulation analysis to predict important impacts of those initiatives.

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.