

CHAPTER 1

Organ Allocation: NOTA, the OPTN, and Policy Development

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The history: why did deceased donor allocation begin?

Successful kidney transplantation began in 1954 between identical twin brothers at Peter Bent Brigham Hospital. In 1958, immunosuppression was successfully used for renal transplants in fraternal twins. Non-twin siblings were transplanted in 1960 and then non-siblings in 1961. The year 1962 saw the first successful transplant using a deceased donor kidney allograft with the introduction of azathioprine. The Uniform Anatomical Gift Act allowed those aged 18 and over to donate their organs upon death in 1968. The year 1972 saw the discovery of cyclosporine, with its introduction to patient use in 1983. With the introduction of cyclosporine, the early success due to improved acute rejection rates in deceased donor transplantation was dramatic, and the modern era of solid organ transplantation began and expanded to other extra-renal organs.

In the early and mid-1960s, as individual transplant centers originated and developed their associated hospital-centered organ procurement organizations (OPOs), there was a very high rate of early severe rejection and graft loss in deceased donor kidney transplants. The early transplant pioneers in this pre-cyclosporine era understood that they could not easily overcome the immunological barriers of greatly mismatched organs. The odds of finding well-matched organs for their small patient lists with their few local donors were scant. They saw success with better genetically or HLA (human leukocyte antigen)-matched living donor organs and attempted to extend this to deceased donor transplantation by joining together with other transplant centers and their local OPOs to better the odds of their patients finding well-matched deceased donor organs. David Hume and Bernard Amos began the effort as SEROPP, the South-Eastern Regional Organ Procurement Program. This effort expanded to eight

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transplant centers in the Southeast and became SEOPF, the Southeastern Organ Procurement Foundation. Soon, other adjacent centers sought membership in SEOPF, and this membership organization began to grow. SEOPF developed the Kidney Center that assisted with deceased donor kidney matching 24 hours a day. Eventually, this was renamed the United Network for Organ Sharing, UNOS. As government regulation became formal through the development of the National Organ Transplant Act (NOTA), UNOS separated from SEOPF as a not-for-profit organization; so it could apply for the Organ Procurement Transplantation Network (OPTN) and Scientific Registry for Transplant Recipients (SRTR) contracts created in NOTA and administered by the Health Resources and Services Administration (HRSA) of the US Department of Health and Human Services (HHS). UNOS remains a membership organization consisting of transplant centers, OPOs, donor families, organ recipients and candidates, prior living donors, and others interested in organ transplantation. The Kidney Center celebrated 30 years of continuous operation in 2012 [1].

Organ allocation

Organ allocation in the United States is governed by a complex, multi-faceted set of policies. These policies are used to program the national allocation system by which candidates are identified and prioritized for organ offers. There are many players in the field of organ transplantation, and the field is highly regulated at multiple levels. At the federal level, NOTA and OPTN Final Rule set the requirements for policy development. These requirements are executed by the OPTN Board of Directors and its 20 committees (Figure 1.1) in the development of policies. Policies are developed collaboratively within the committee and Board structure, with input and comment provided by the transplant community, general public, and HRSA representation. The regulatory requirements,

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|--|----------------------------------|
| • Ad hoc Disease Transmission Advisory | • Operations and Safety |
| • Ad hoc International Relations | • OPO |
| • Ethics | • Pancreas Transplantation |
| • Executive | • Patient Affairs |
| • Finance | • Pediatric Transplantation |
| • Histocompatibility | • Policy Oversight |
| • Kidney Transplantation | • Thoracic Organ Transplantation |
| • Liver and Intestinal Organ Transplantation | • Transplant Administrators |
| • Living Donor | • Transplant Coordinators |
| • Membership and Professional Standards | |
| • Minority Affairs | |

Figure 1.1 OPTN/UNOS Committees.

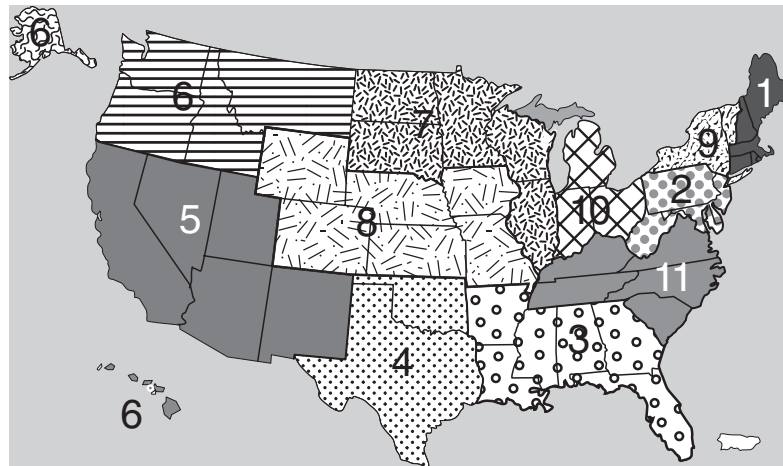


Figure 1.2 The UNOS regions.

applicable ethical frameworks, and policy development process are described in greater detail later in the chapter.

Organ allocation for kidney, pancreas, and liver grafts has traditionally followed the concept of “local, then regional, then national” allocation. The local unit of allocation generally involves the center(s) served by an individual OPO. The country has traditionally been divided into 11 regions as seen in Figure 1.2. The regions are based mainly from historic sharing arrangements. Heart and lung allocation has transitioned to a concentric circle model centered on the location of the donor hospital. The zones include the transplant hospitals that are 500, 1000, 1500, and 2500 nautical miles from the donor hospital. The remaining chapter discusses the regulatory and ethical frameworks that guide the development of organ allocation policies.

Regulations governing organ transplantation

National Organ Transplant Act (NOTA)

The NOTA was passed in 1984 when the Congress recognized the need for a transplantation network. NOTA is the regulation that established the OPTN and the SRTR. NOTA called for the OPTN and SRTR contracts to be operated by a private, non-profit organization(s) under federal contract.

The OPTN is a unique public-private partnership that links all of the professionals involved in the donation and transplantation system. The primary goals of the OPTN are to

- increase the effectiveness and efficiency of organ sharing and equity in the national system of organ allocation;
- increase the supply of donated organs available for transplantation.

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The UNOS, based in Richmond, Virginia, administers the OPTN contract. The SRTR contract is administered by the Chronic Disease Research Group of the Minneapolis Medical Research Foundation. The HRSA of the US Department of HHS is the issuing agency for both contracts.

The OPTN acts through its Board of Directors. The current UNOS Board also presently serves as the OPTN Board of Directors, with the addition of HRSA representatives to complete the OPTN Board. Board members, chosen through an open, comprehensive nomination process, bring a wealth of commitment and technical knowledge to guide the OPTN in establishing and maintaining policies and procedures for the field of transplantation [2].

Organ Procurement and Transplantation Network (OPTN) Final Rule

Effective March 16, 2000, the Department of HHS implemented a Final Rule establishing a regulatory framework for the structure and operations of the OPTN. Under the terms of the Final Rule, policies intended to be binding upon OPTN members are developed through the OPTN Committees and Board of Directors and then submitted to the Secretary of HHS for final approval.

Among other items, the OPTN Final Rule addresses the organization of the OPTN, membership, policies, listing requirements, organ procurement, identification of recipients, allocation of organs, designated transplant program requirements, and reporting requirements.

With regard to allocation of organs, the Final Rule has requirements for policy development. Allocation policies shall

- “be based on sound medical judgment;
- preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient . . . ;
- be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;
- be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;
- be reviewed periodically and revised as appropriate;
- include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program’s application of the policies to patients listed or proposed to be listed at the program;
- not be based on the candidate’s place of residence or place of listing, except to the extent required [by points 1–5 above]” [3].

Responsibilities of OPTN

The OPTN helps ensure the success and efficiency of the US organ transplant system. OPTN responsibilities include

- facilitating the organ matching and placement process through the use of the computer system and a fully staffed Organ Center operating 24 hours a day;
- developing consensus-based policies and procedures for organ recovery, distribution (allocation), and transportation;
- collecting and managing scientific data about organ donation and transplantation;
- providing data to the government, the public, students, researchers, and the Scientific Registry of Transplant Recipients, for use in the ongoing quest for improvement in the field of solid organ allocation and transplantation;
- developing and maintaining a secure Web-based computer system, which maintains the nation's organ transplant waiting list and recipient/donor organ characteristics (UNETSM and DonorNetSM);
- providing professional and public education about donation and transplantation, the activities of the OPTN, and the critical need for donation [4].

Under federal law, all US transplant centers and OPOs must be members of the OPTN to receive any funds through Medicare. Other members of the OPTN include independent histocompatibility laboratories involved in organ transplantation; relevant medical, scientific, and professional organizations; relevant voluntary health and patient advocacy organizations; and members of the general public with a particular interest in donation and/or transplantation.

Responsibilities of the Scientific Registry of Transplant Recipients

The Scientific Registry of Transplant Recipients is a national database of statistics related to solid organ transplantation—kidney, liver, pancreas, intestine, heart, and lung. The SRTR contract was administered by UNOS until 2000, then the Arbor Research Collaborative for Health with the University of Michigan until 2010, and currently by Chronic Disease Research Group of the Minneapolis Medical Research Foundation.

The registry covers the full range of transplant activity, from organ donation and waiting list candidates to transplant recipients and survival statistics. Its purpose is to

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- support the development of sound policy;
- encourage research on issues of importance to the transplant community;
- facilitate responsible analysis of transplant programs and OPOs.

Data in the registry are collected by the OPTN from transplant hospitals and OPOs across the country. The SRTR supplements this information by using the Social Security Master Death Data Base and Medicare database for potential re-initiation of renal replacement therapy via dialysis [5]. SRTR data will be discussed further in Chapter 9.

Ethical frameworks used in organ allocation policy development

In 1994, the OPTN/UNOS Board of Directors approved a set of guidelines for creating equitable organ allocation policies. The statement describes how organ allocation policies should balance the principles of utility (i.e., the net medical benefit to all transplant patients as a group) and justice (i.e., equity and distribution of the benefits and burdens among all transplant patients) [6].

The OPTN policy for equitable organ allocation *strikes a balance* among the following principles. The policy must

- 1 enhance the overall availability of transplantable organs;
- 2 allocate organs based on medical criteria, striving to give equal consideration to medical utility (i.e., *net* medical benefit to all transplant patients as a group) and justice (i.e., equity in distribution of the benefits and burdens among all transplant patients);
- 3 provide transplant candidates reasonable opportunities to be considered for organ offers within comparable time periods, taking into consideration similarities and dissimilarities in medical circumstances as well as technical and logistical factors in organ distribution;
- 4 respect autonomy of persons.

The goal of the OPTN organ allocation system is to achieve, *in balance with one another*, the following objectives:

- 1 Maximize the availability of transplantable organs by
 - a promoting consent for donation;
 - b enhancing procurement efficiency;
 - c minimizing organ discards;
 - d promoting efficiency in organ distribution and allocation.
- 2 Maximize patient and graft survival.
- 3 Minimize disparities in consistently measured waiting times until an offer of an organ for transplantation is made among patients with similar or comparable medical/demographic characteristics. (At the

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present time, there are no waiting list criteria; therefore, commencement of waiting time varies among patients.)

- 4 Minimize deaths while waiting for a transplant.
- 5 Maximize opportunity for patients with biological or medical disadvantages to receive a transplant.
- 6 Minimize effects related to geography.
- 7 Allow convenient access to transplantation.
- 8 Minimize overall transplantation related costs.
- 9 Provide for flexibility in policy making.
- 10 Provide for accountability and public trust.

Policy development process

OPTN/UNOS strives to develop policies that are based on the best available evidence and are consensus driven. The field of organ transplantation depends on the input and collaboration of many people and organizations. It is vital to ensure that all interested parties are given a voice and an opportunity to provide input into the policy development process. The following describes how the process incorporates this input along with evidence analyses in policy development, which can be seen in Figure 1.3.

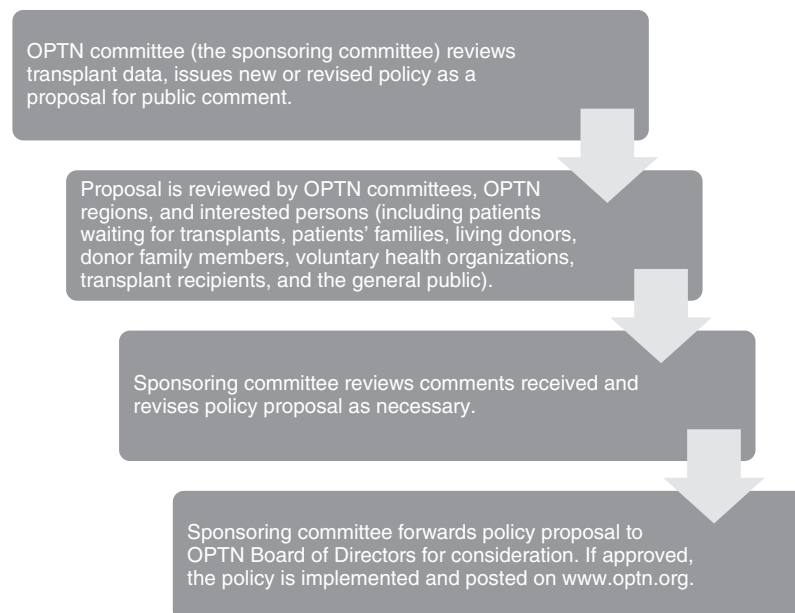


Figure 1.3 OPTN Policy development process.

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The OPTN Board of Directors sets objectives for the network through a strategic plan. OPTN Committees work to meet these objectives by identifying problems within the transplant system that could be addressed through OPTN policy. Changes in policy may have different effects on individuals within the OPTN, depending on the role that each plays. Therefore, committees assess policy approaches from multiple perspectives (e.g., transplant candidate, transplant physician/surgeon, transplant coordinator, etc.). Committees also assess policy as it relates to patient safety, outcomes (e.g., patient and graft survival), and overall equity and efficiency of the allocation system. Based on the overall assessment of the full complement of policy approaches, the committee may select one approach to distribute for public comment as a policy proposal.

During the public comment period (which generally lasts between 45 and 90 days), members of OPTN/UNOS Committees, regions, and the general public are able to provide feedback on the policy proposal. Regional councilors directly advise the Board of Directors on regional discussions and votes pertaining to policy issues.

Following the public comment period, the sponsoring committee is responsible for reviewing and responding to comments provided during the review period. The committee may conduct additional analyses of the evidence before determining whether or not to submit the policy proposal to the OPTN/UNOS Board of Directors. Final proposals generally include communication and education plans, evaluation and monitoring plans, and descriptions of any automated solutions that may be necessary to the computer algorithm that matches donors and potential recipients called UNetsm. The purpose of these plans is to clearly describe the resources and efforts necessary to successfully implement the policy proposal.

Once submitted, the OPTN/UNOS Board of Directors considers the policy proposal in its entirety. After discussion, the Board decides whether the policy proposal should be implemented, returned to committee for further analysis, or not implemented. On rare occasions, the Board may propose amendments to the proposal to address new or unresolved concerns. If the policy is approved for implementation, the sponsoring committee takes steps to notify the membership through an OPTN Policy Notice and may provide additional education opportunities if the proposal has a wide-reaching impact or requires major procedural changes at member institutions.

All substantial policy proposals affecting membership in OPTN/UNOS or organ allocation are distributed for public comment prior to adoption to the Board of Directors. Exceptions may be made in cases where the proposal addresses an immediate patient safety need.

Current organ allocation policies

Deceased donor kidney allocation

The current system has been in place for over 25 years, with relatively minor changes by various Kidney Committees. As immunosuppression has matured, the points used to allocate kidneys have changed dramatically. Initially, “matching” played the major role in allocation with each of the six HLAs used for allocation purposes given two points for each match between the candidate and recipient. The HLA antigens historically include A, B and DR, with each person having two alleles of each, so sometimes written as HLA – A1, A2, B1, B2, DR1 and DR2. A total of 12 points was therefore possible for a “6 antigen match” or “zero-mismatch” between the donor and recipient candidate. Time was given one point for a year of waiting (time placed on the list), and if a candidate was highly sensitized with a panel reactive antibody (PRA) level 80 percent or higher, they received another 4 points. These highly sensitized patients were very difficult to transplant until very recently with advanced solid-phase testing for specific alloantibodies. As immunosuppression improved, HLA-B points were removed when it was shown that HLA-B matching was of very marginal benefit in regard to preventing rejection and was disproportionately unfair due to the difference in HLA-B antigens in African Americans versus non-African Americans. Later, HLA-A points were removed, leaving the current policy of one point for each HLA-DR locus match. Today, patients receive a maximum of two points for HLA-DR matching. Patients still receive 4 points if their calculated PRA (CPRA) is $\geq 80\%$, but the CPRA value is now established by a calculator found on the OPTN website based on donor population genetics, and is a true estimate of the chance of a candidate finding a donor who does not have unacceptable antigens based on sophisticated alloantibody determination in the candidates. *Time is the major determinate of points over the last several years in most areas of the country.* Waiting time is still measured from the time the candidate is placed on the waiting list at a transplant center, which can be anytime after starting dialysis, or with a calculated GFR of 20 mg/dL or less.

In 2009, the mandatory sharing rules for zero-mismatch (0-mm) allocation changed to decrease the organs sent long distances to unsensitized patients in order to decrease the very complicated “payback” system across the country, as well as to improve graft function overall since the payback system was resulting in an overall net loss of allograft function. This change decreased the net sharing of kidneys for 0-mm allocation by almost 50% within the first year and has allowed OPOs to pay back their kidney debts and also engage in simultaneous kidney–pancreas (SKP) transplantation (an option that was not available to transplant programs served by OPOs with excessive debt levels).

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“Pediatric Share 35” allocation went into practice in September, 2005. This policy gives pediatric candidates, defined as those placed on the waiting list prior to their eighteenth birthday, high priority for kidneys from local donors under the age of 35 years. These pediatric recipients follow those candidates for multiorgan transplant (pancreas–kidney, liver–kidney or heart–kidney most commonly), and some of the very highly sensitized adults. Overall around the country, most centers have had their time to transplantation for their pediatric candidates decrease dramatically. This has resulted in some areas seeing significant decreases in living donor pediatric transplantation [7].

The summary of the deceased donor allocation system can be found on the OPTN website at http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_7.pdf.

Any changes in policies will be displayed for public comment in this area, and up-to-date policy language will always appear on this site. In June 2013, the OPTN/UNOS Board of Directors approved a proposal to completely overhaul the national kidney allocation system. Implementation of the new system is anticipated to occur by the end of 2014. The new system is hoped to provide better access to kidney transplantation for all groups of candidates while seeking to improve outcomes for kidney transplant recipients, increase the years recipients may have a functioning transplant and increase utilization of available kidneys.

In summary, deceased donor kidney allocation goes through the following categories below with points allocated within the categories as discussed earlier (Time, PRA, HLA-DR matching). For a detailed list, see http://optn.transplant.hrsa.gov/SharedContentDocuments/Kidney_Appendix_A.pdf.

For simplicity, “payback” sharing is not shown in the short summary.

For the Donors ≤ 35 (all SCD):

0-mm allocation (ABO identical, then compatible only for O to B, Pediatric then Adults, Local then Regional then National)

Prior Living Donor in local OPO

CPRA > 80; Local

Pediatric Local

Adult Local

Regional; CPRA > 80, then <80

National; CPRA > 80, then <80

For Standard Criteria Donors >35:

0-mm allocation (ABO identical, then compatible only for O to B, Pediatric then Adults, Local then Regional then National)

Prior Living Donor in local OPO

All Local

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Regional

National

For Donation after Cardiac Death (DCD) Donors ≤35 years old:

0-mm local

Prior Living Donor in local OPO

Local highest scoring high CPRA

Local Pediatrics

All Local

Regional; CPRA >80, then <80

National; CPRA >80, then <80

For Extended Criteria Donors:

0-mm Local, Regional, National

Local only by waiting time points

Regional only by waiting time points

National only by waiting time points

The Kidney Committee's review of allocation options and likely new policy changes that are about to be released for public comment in the fall of 2012 are summarized at <http://optn.transplant.hrsa.gov/kars.asp>.

As of September 2012, the most likely changes being discussed for revision to Kidney Allocation policies are as follows:

- 1 Waiting time starting from the time of onset of chronic dialysis or listing at a transplant center with a GFR \leq 20 mL/min.
- 2 Quality of kidney allograft estimated by a continuous kidney donor profile index (KDPI) [8] and no longer divided into standard criteria donor (SCD) and extended criteria donor (ECD).
- 3 ECD category likely to be replaced by KDPI > 85% (estimated shortest survival 15% of donor organs).
- 4 CPRA points on a sliding scale based on actual number of allografts offered to candidates on the list due to their CPRA. This will increase the number of points greatly after CPRA over 95.
- 5 Wider geographical sharing outside of the local allocation unit for the most highly sensitized patients (CPRA \geq 99%), and higher priority for local candidates with CRPA of 98%.
- 6 Longest 20% estimated survivable organs allotted first to candidates with the estimated longest 20% post-transplant survival.
- 7 No payback of shared kidney allografts.

Kidney-pancreas allocation

Just a few years ago, there was no mandated manner to allocate SKP organs. Local OPOs were given the authority to decide how they would allocate these organs: whether SKP candidates would have their own wait-list or if SPK candidates would only be eligible for kidney allocation if their

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wait time was competitive with the local kidney waitlist candidates. It was well accepted that candidates on the SPK waiting list, generally type I diabetics, die at a much higher rate than patients on the kidney-alone waiting list. This led the majority of OPOs around the country to give SPK candidates their separate waiting list. The new SKP allocation policy recently went into effect and made this majority practice the national policy. It is available at http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_10.pdf.

“Each candidate registered on the KP waiting list must be diagnosed with diabetes or have pancreatic exocrine insufficiency with renal insufficiency or require the pancreas for technical reasons as part of a multiple organ transplant.” For a patient to accrue waiting time on the KP waiting list, they must qualify to start gathering waiting time for a solitary kidney (policy 3.5.11.1) and fulfill one of the following: (1) on insulin with C-peptide ≤ 2 ng/mL, (2) on insulin with C-peptide >2 ng/mL and BMI less than or equal to the maximum allowable BMI (starting at 28). The BMI will be monitored and adjusted downward if more than 15% of KP candidates on the local kidney list meet the latter criteria for KP listing.

Local offers to pancreas and KP list will precede isolated kidney allocation. P/KP allocation is based off of donor age and BMI as these predict the likelihood of whole-organ versus islet utilization.

- A** For donors ≤ 50 years of age and BMI ≤ 30 :
- a** Local 0-mm CPRA ≥ 80 P or KP
 - b** Local CPRA ≥ 80 P or KP
 - c** Regional 0-mm CPRA ≥ 80 P or KP
 - d** National 0-mm CPRA ≥ 80 P or KP
 - e** Local P and KP
 - f** Regional P or KP (if local OPO offers K) CPRA ≥ 80 , then <80
 - g** National P or KP (if local OPO offers K) CPRA ≥ 80 , then <80
 - h** Local pancreatic islets
 - i** Regional pancreatic islets
 - j** National pancreatic islets
- B** For donors >50 years of age or BMI > 30 :
- a** Local 0-mm CPRA ≥ 80 P or KP
 - b** Local CPRA ≥ 80 P or KP
 - c** Regional 0-mm CPRA ≥ 80 P or KP
 - d** National 0-mm CPRA ≥ 80 P or KP
 - e** Local P and KP
 - f** Local pancreatic islets
 - g** Regional pancreatic islets
 - h** National pancreatic islets
 - i** Regional P or KP (if local OPO offers K) CPRA ≥ 80 , then <80
 - j** National P or KP (if local OPO offers K) CPRA ≥ 80 , then <80

Liver allocation

The model for end-stage liver disease (MELD) score has been used for liver allocation for over 10 years now. The MELD score is calculated from a candidate's total bilirubin, serum creatinine, and international normalized ratio (INR). The MELD score for liver allocation ranges from a low of 6 points (very little probability of dying from liver failure) to a set maximum of 40 points, a very ill patient who is unlikely to survive more than a week without a liver transplant. A calculator is available on the OPTN website to show you how the laboratory value changes affect the score. This MELD score was initially calculated to estimate the survival of end-stage liver disease patients who were being considered for placement of a transjugular intrahepatic portosystemic shunt (TIPS) for severe portal hypertension. It was later shown to predict mortality for those awaiting liver transplantation. The MELD score does tend to favor those with viral hepatitis compared to those with cholestatic diseases. Several modifications to the MELD score have been proposed, with the most common being an increase in MELD points for candidates with low serum sodium (hyponatremia) as these patients tend to be more ill than patients with more normal sodium levels. Some regional review boards will give more points for difficult-to-correct hyponatremic patients, though this is not currently national policy. The other major criticism of the MELD score is that it gives a large weight of points to the serum creatinine value; thus it favors patients with kidney dysfunction. This has led to many liver recipients receiving combined liver–kidney transplants. Patients who are on dialysis receive a MELD score of 20 and are therefore competitive for a liver graft in some areas of the country. Additional details for the liver allocation policy may be found at http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_8.pdf.

In addition to the discussed “calculated MELD score” from laboratory values, there are exception points available for certain medical conditions; the most common by far is the presence of stage 2 hepatocellular carcinoma (HCC). The Milan criteria are used to describe the category of early HCC that qualifies automatically for a MELD score of 22 points: one lesion between 2 and 5 cm, or two to three lesions with the largest 3 cm or less, and the others at least 1 cm. More stringent radiological criteria have recently been made policy and are available on the OPTN website. In addition, conditions such as hepatopulmonary syndrome, portopulmonary syndrome, and certain metabolic diseases can qualify for exception points that will increase if the patient is not transplanted within 90 days as long as the candidate continues to qualify for the exception.

Only patients with acute fulminant liver failure or a failed newly transplanted liver graft can qualify for Status 1 listing, and they must requalify every 7 days. Status 1 candidates are in the first category of liver allocation,

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and this group is shared regionally with a local Status 1 candidate prioritized ahead of a regional candidate. The next category of regional sharing was just approved in 2012 and is the group of patients with a MELD score ≥ 35 . It is also prioritized as local before regional, but with each point of the MELD score from 40 down to 35 (e.g., a regional candidate with a MELD score of 39 is prioritized ahead of a local candidate with a MELD score of 38). The next category is local candidates with MELD 29–34, then national liver–intestine candidate, then local MELD scores 15 to 28, then regional 15–34, and National (Status 1 then MELD scores >15). Local, regional, and national candidates with MELD scores <15 are the last three categories for allocation. Candidates with MELD scores at or above 25 must recertify every 14 days and every month for those with MELD scores 18 to 24.

Pediatric candidates are divided above and below 11 years of age and pediatric donors are likewise allocated first to age-equivalent recipients. The pediatric end-stage liver disease (PELD) measure has been more difficult to correlate with pediatric outcome, especially at the lower values.

Recent discussions at the Liver and Intestinal Organ Transplantation Committee have included a look at a change to MELD that would not only attempt to predict pre-transplant mortality, but also consider the likelihood of patient survival after transplant.

Heart allocation

The Heart Allocation System (HAS) utilizes a circular zone concept for allocation units. These five zones are concentric circles of 500 miles from the donor hospital. The degree of illness is determined by a status code. Status 1A candidates are in the hospital with an artificial circulatory assist device just placed, or one with complications. The candidate could also be on mechanical ventilation or on continuous high-dose vasopressors with continuous left ventricular monitoring. After 14 days, most patients in Status 1A who are not unstable will drop to Status 1B (mechanical devices, low-dose pressors). Status 2 contains all other active candidates [9].

Lung allocation

The Lung Allocation Score (LAS) is very dynamic and incorporates measure of urgency for transplant (risk of death without transplant) as well as post-transplant expected survival: http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_9.pdf. There are 12 factors used to predict risk of death, and 7 used to predict post-transplant survival. The Raw Allocation Score is calculated from Transplant Benefit Score minus Waitlist Urgency Score. This number ranges from -730 to $+365$ days and is then normalized on a 0 to 100 scale to give an LAS. Higher scores are

higher priority for allocation. The cause of lung disease is a major predictor of both pre-transplant urgency and post-transplant survival.

Staying in compliance

The Membership and Professional Standards Committee (MPSC) oversees the outcomes of the individual transplant center organ-specific programs, as well as the overall administrative and clinical adherence to OPTN policies. Organ-specific outcome reports, termed the Program Specific Reports (PSR), are published publicly on the OPTN and SRTR websites every 6 months. They include a look at five consecutive groups of 6-month patient cohorts. Thus, they span a two-and-a-half-year period of time with follow-up calculations for 1- and 3-year patient and graft survival and the actual survival is risk adjusted in order to compare a center's outcomes to the national "expected outcomes." The risk-adjusted modeling is complicated and explained in detail on the SRTR website [10]. The PSR tool was begun as an internal quality evaluation tool by the MPSC, but is now used by other external groups. Changes to the PSR metric is being nationally discussed at the time of this publication [11]. A PSR Consensus Conference was attended in May 2012 by many of the transplant community to detail the needs of the public for reporting outcomes, as well as discussions of better methodology to risk adjust and allowances for study protocols and treatment of particularly high-risk recipients who may be denied transplantation without PSR modifications.

The OPTN/UNOS just completed a major rewrite of the Policy Language to help the transplant membership and public more easily understand the multitude of policy amendments over decades. This rewrite clarified the language without making substantiate changes in any of the policies. It is available online [12].

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