

Questions and Answers For Patients and Families About MELD and PELD

The United Network for Organ Sharing (UNOS), a non-profit charitable organization, operates the Organ Procurement and Transplantation Network (OPTN) under federal contract. On an ongoing basis, the OPTN/UNOS continuously evaluates new advances and research and adapts these into new organ transplant policies to best serve patients waiting for transplants.

As part of this process, the OPTN/UNOS developed a system for prioritizing patients waiting for liver transplants based on statistical formulas that are very accurate for predicting who is most likely to die soon from liver disease. The MELD (Model for End Stage Liver Disease) is used for adult patients and the PELD (Pediatric End Stage Liver Disease Model) is used for pediatric patients.

This document will explain the reasons for adopting this system and how it will affect patients on the waiting list.

What is MELD? How will it be used?

The Model for End-Stage Liver Disease (MELD) is a numerical scale, ranging from 6 (less ill) to 40 (gravely ill), that is used for adult liver transplant candidates. It gives each individual a 'score' (number) based on how urgently he or she needs a liver transplant within the next three months. The number is calculated by a formula using three routine lab test results:

- bilirubin, which measures how effectively the liver excretes bile;
- INR (prothrombin time), which measures the liver's ability to make blood clotting factors; and
- creatinine, which measures kidney function. (Impaired kidney function is often associated with severe liver disease.)

The MELD score replaced the previous Status 2A, 2B and 3 categories. The status 1 category (patients who have acute liver failure and a life expectancy of less than 7 days without a transplant) remains in place as the highest priority for receiving an organ and is not affected by the MELD system.

A patient's score may go up or down over time depending on the status of his or her liver disease. Many patients will have their MELD score assessed a number of times while they are on the waiting list. This will help ensure that donated livers go to the patients in greatest need at that moment.

What is PELD? How does it differ from MELD?

Candidates under the age of 18 are placed in categories according to the Pediatric End-stage Liver Disease (PELD) scoring system. PELD replaced the previous Status 2B and 3 for pediatric patients; Status 1 remains in place and is not affected by PELD.

PELD is similar to MELD but uses some different criteria to recognize the specific growth and development needs of children. PELD scores may also range higher or lower than the range of MELD scores. The measures used are as follows:

- bilirubin, which measures how effectively the liver excretes bile;
- INR (prothrombin time), which measures the liver's ability to make blood clotting factors;
- albumin, which measures the liver's ability to maintain nutrition;
- growth failure; and
- whether the child is less than one year old.

What Led To the MELD/PELD System?

In recent years, patients needing liver transplants had been grouped into four medical urgency categories. The categories were based on a scoring system that included some laboratory test results (such as bilirubin, INR and albumin) and some symptoms of liver disease (such as ascites and encephalopathy).

One concern with using symptoms in scoring is that different doctors might interpret the severity of those symptoms in different ways. In addition, this scoring system could not easily identify which patients had more severe liver disease and were in greater need of a transplant.

Research showed that the MELD formula very accurately predicts most liver patients' short-term risk of death without a transplant. The accuracy of the formula did not improve when other factors were added, such as the cause of liver failure or observed symptoms, such as ascites, encephalopathy, or other complications of liver diseases. The MELD and PELD formulas are simple, objective and verifiable, and yield consistent results whenever the score is calculated.

OPTN/UNOS committees developed the liver policy based on MELD and PELD. The policy proposal was twice published for public comment. It was approved by the OPTN/UNOS Board of Directors in November 2001 and went into effect in February 2002. The OPTN/UNOS Patient Affairs Committee and patient/family representatives on the OPTN/UNOS Board of Directors offered key support for the revised system.

How is waiting time counted in the system?

Under the previous system, waiting time was often used to break ties among patients of the same medical status. Various studies, including one done by the Institute of Medicine, reported that waiting time is a poor indicator of how urgently a patient needs a liver transplant. This is because some patients are listed for a transplant very early in their disease, while others are listed only when they become much sicker.

Under the MELD/PELD system with a wider range of scores, waiting time does not have to be used as often to break ties. Waiting time will only determine who comes first when there are two or more patients with the same blood type and the same MELD or PELD score.

If a patient's MELD or PELD score increases over time, only the waiting time at the higher level will count. (For example, someone who has waited 40 days with a score of 12, and 5 days with a score of 15, would only get credit for 5 days of waiting time at the score of 15.) However, if the patient's MELD or PELD score decreases again, he or she would keep the waiting time gained at the higher score. (Using the earlier example, if the patient's score goes from 12 to 15 and back to 12, he or she would have 45 days of waiting time at the score of 12.) Patients initially listed as a Status 1 would also keep their waiting time if their condition improves and they later receive a MELD/PELD score.

Patients with higher MELD/PELD scores will always be considered before those with lower scores, even if some patients with lower scores have waited longer. (For example, a patient waiting for one day with a score of 30 will come ahead of a patient with a score of 29, even if the patient with a 29 has waited longer. This is because the patient with a score of 30 has a higher chance of dying on the list.)

What if I had been on the waiting list when the system changed?

For the first year of the MELD and PELD system, a transition plan was in place for liver candidates awaiting a transplant at the time of the change to maintain their priority gained under the previous policy. This priority phased out according to how urgent those patients were at the time of the policy change. After the transition period ended, those candidates still awaiting a transplant were prioritized only by their MELD or PELD score. If you were listed for transplant at the time the policy became effective (February 27, 2002), your transplant team would best be able to address any questions about the transition and/or your current medical status.

All patients newly listed for a liver transplant since February 2002 receive priority only by their MELD or PELD score, based on their current lab results.

Do MELD and PELD account for all conditions?

MELD/PELD scores reflect the medical need of most liver transplant candidates. However, there may be special exceptions for patients with medical conditions not covered by MELD and PELD. If your transplant team believes your score does not reflect your need for a transplant, they can seek a higher MELD/PELD score than the one determined by lab tests alone.

Is this system likely to change?

As transplant professionals apply and learn from the system, some changes will likely be required to better meet patients' needs. In fact, this system is designed to be flexible and allow

improvements. In transplantation, as in all scientific fields, new studies are taking place all the time to learn how to save more lives and help people live longer and better.

What if I have more questions?

If you have any further questions or concerns, you should contact your transplant team for further information. Additional details about the OPTN, UNOS, allocation policy and patient informational resources are available on the following websites:

<http://www.optn.org>

<http://www.unos.org>

<http://www.transplantliving.org>