

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 has developed a new system for prioritizing patients waiting for liver transplants. This system is based on statistical formulas that are accurate for predicting which individuals are most likely to die soon from liver disease. The MELD (Model for End Stage Liver Disease) is used if adult patients and the PELD (Pediatric End Stage Liver Disease Model) are 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 will be 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).

There is a status 1 category for patients who have acute liver failure and a life expectancy of less than 7 days without a transplant will remain in place. That is 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 will be placed in categories according to the Pediatric End-Stage Liver Disease (PELD) scoring system. PELD will replace Status 2B and 3 for pediatric patients; Status 1 will remain in place and will not be affected by PELD.

PELD is similar to MELD, however, 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 New System?

For the last few years, patients in need of liver transplants have been grouped into four medical urgency categories. These categories were based on a scoring system that included some laboratory tests 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, and other complications of liver diseases. The MELD and PELD formulas are simple, objective, verifiable, and yield consistent results whenever the score is calculated.

OPTN/UNOS Committees developed the new 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. The

OPTN/UNOS Patient Affairs Committee and patient/family representatives on the OPTN/UNOS Board of Directors offered key support for the new system.

How will waiting time be 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 new plan, with a greater range of MELD/PELD scores, waiting time will 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). Patients initially listed, as Status 1 would also retain their waiting time if their condition improves and they later receive MELD/PELD score. 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 a 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 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 been waiting longer because the patient with a score of 30 has a higher chance of dying on the list).

What if I am on the waiting list when the system changes?

A transition plan will allow you to maintain the priority gained under the previous system. If you are an adult Status 2A patient, you will be given priority ahead of a new adult patient listed under the MELD system for the first 30 days, after the new system is in effect. If you do not receive a transplant within 30 days, your MELD score will be calculated at that time, and you will receive 30 days of waiting time, at that score.

If you are a Status 2B or 3 patient, your MELD or PELD score will be calculated at the time the new system goes into effect. If your score stays the same or decreases within the first year, you will keep the waiting time gained under the

previous system. If your MELD or PELD score increases within one year, only the waiting time in the higher status will apply (see previous section “How will waiting time be counted in the system?”). Patients, who are listed after the new system is put in place, will receive a 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 exceptions for patients with special medical conditions not covered by MELD and PELD. If your transplant team believes that your score does not reflect your need for a transplant, they can seek a higher MELD/PELD score than the one determined by the lab tests alone.

Is this system likely to change?

As transplant professionals apply and learn from the new system, some changes will likely be required to better meet patient’s 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 other questions or concerns, you should contact your transplant team for further information. Additional details about the OPTN/UNOS allocation policy and patient resources are available at the following websites:

<http://www.optn.org>

<http://www.unos.org>

<http://www.patients.unos.org>