

Improving Liver Allocation: MELD 3.0 FAQ

This document provides background information and answers to frequently asked questions related to the updated model for end stage liver disease (MELD) score, or MELD 3.0, slated for implementation in July 2023.

Additional resources about the changes to liver allocation are available on the OPTN website, including the following FAQ documents:

- General Implementation: more detail on the implementation of the new policies
- Pediatric: more detailed information about PELD Cr, Status 1A, and Status 1B
- Patient-focused: information on the policy changes for patients

If you have additional questions that are not answered here, please contact member.questions@unos.org for assistance.

Background

The primary audience for this document is adult liver transplant programs preparing for implementation of MELD 3.0.

MELD 3.0 improves the accuracy of the MELD calculation by:

- Incorporating additional variables (albumin and sex)
- Updating coefficients for existing variables
- Introducing interaction terms
- Lowering the maximum creatinine value from 4.0 to 3.0 mg/dL.

MELD 3.0 will apply to all adult liver transplant candidates (registered after turning 18) and to adolescent candidates (age 12-17).

In addition to MELD 3.0, there will also be policy changes related to the following aspects of liver allocation:

- Pediatric end-stage liver disease (PELD) score
- Pediatric Status 1A and Status 1B candidates
- National Live Review Board (NLRB) Guidance for pediatric candidates
- Hepatocellular carcinoma (HCC) language

You can read more about the overall project [here](#). You can also learn more specific details about MELD 3.0 in the MELD and PELD scores calculation guide, available [here](#).

New Data Collection

For all MELD candidates (age 12 and older), transplant programs will be required to submit an albumin value when editing a candidate record, as albumin is now included in the MELD 3.0 calculation. Albumin is already required when adding an adult or adolescent liver candidate to the OPTN Waiting List.

In addition, because MELD 3.0 includes additional points for adult female candidates, there are changes to data collection related to the candidate's sex outlined below.

Implementation Overview

To give transplant programs time to submit the required data for their candidates, the implementation of MELD 3.0 will occur in two phases.

Phase 1:

- Planned to be implemented on June 15, 2023
- Will provide transplant programs the opportunity to enter required data for all candidates prior to implementation of MELD 3.0 in Phase 2.

Phase 2:

- Planned to be implemented on July 13, 2023
- New MELD 3.0 calculation will be used for allocation

Frequently Asked Questions

How and why is the MELD score changing?

MELD 3.0 will address the sex-based disparity that has existed in liver allocation since the original MELD score was implemented. MELD 3.0 includes 1.33 points for candidates who are female. In addition, MELD 3.0 better predicts risk of waitlist mortality for all liver candidates by updating the coefficients for each of the variables in the score, adding albumin as a factor, introducing interaction terms, and lowering the maximum creatinine value from 4.0 to 3.0 mg/dL.

What exactly is changing with data collection related to a candidate's sex?

The 1.33 points for adult female candidates included in MELD 3.0 are intended to address a disparity as females have historically had consistently lower transplant rates. In order to ensure the points are provided to the appropriate candidates, there will be a few important changes to data collection related to a candidate's sex.

First, across all organs, the field labeled "Gender" will now be labeled "Birth sex." The new data label for this field does not change the purpose of the field, and you do not need to make any changes to your candidates' information because of this update.

In addition, for adult liver candidates, there will be a new field labeled "Sex for Purposes of Adult MELD Calculation." This field will account for situations where a candidate's sex may be different than their birth sex. Because MELD 3.0 includes 1.33 points for female candidates, the "Sex for Purposes of Adult MELD Calculation" field will allow transplant programs to appropriately categorize their candidates for the purposes of the MELD score.

Why is the OPTN switching from collecting "Gender" to "Birth Sex" and adding the "Sex for Purposes of Adult MELD Calculation" field?

The Centers for Disease Control and Prevention (CDC) defines gender as "the cultural roles, behaviors, activities, and attributes expected of people based upon their sex."¹ The World

¹ See CDC.gov for more information.

Health Organization further explains that gender, “refers to the characteristics of women, men, girls, and boys that are socially constructed. This includes norms, behaviors, and roles, associated with being a woman, man, girl, or boy, as well as relationships with each other.”²

The CDC defines sex as, “an individual’s biological status as male, female, or something else. Sex is assigned at birth and associated with physical attributes, such as anatomy and chromosomes.”³ Therefore, across organs, the OPTN is updating the label for the “Gender” field to be “Birth Sex” to align with current data collection standards. The existing data definition for this field describes birth sex.

In the context of liver allocation, the sex-based disparity that MELD 3.0 will address is driven by creatinine in the MELD calculation. Creatinine, which estimates glomerular filtration rate (GFR), is known to be lower in individuals with low muscle mass. Therefore, creatinine can overestimate renal function in liver transplant candidates with low muscle, thereby underestimating their risk of mortality in the MELD score. Female candidates tend to have lower muscle mass, and as a result, their true risk of waitlist mortality was often not be appropriately captured by the previous MELD calculation. To address this, MELD 3.0 includes 1.33 points for female candidates.

To ensure that the appropriate candidates are provided the 1.33 points, there will be a new data field, “Sex for purposes of adult MELD calculation.” For the majority of transplant candidates, their sex for purposes of adult MELD calculation will be the same as their birth sex. However, there will be some candidates whose sex for purposes of adult MELD calculation is different than their sex at birth. This field is included to ensure that candidates are appropriately categorized for the purposes of the MELD 3.0 score.

Can you please provide more detail on “Sex for Purposes of Adult MELD Calculation?”

“Sex for Purposes of Adult MELD Calculation” is based on the emerging Health IT standard, “Sex for Clinical Use.”⁴ For the purposes of the OPTN, the clinical use of the data is the MELD 3.0 score.

There are two response options for this field: Male and Female.

The response to this data collection is left to the discretion of the transplant program in consultation with the candidate and their clinical team.

Transplant programs should consider providing a response of “Female” if the candidate’s sex recorded at birth is female or if the candidate’s sex recorded at birth is male and, for example, the candidate is currently taking feminizing gender-affirming hormone therapy.

Similarly, transplant programs should consider providing a response of “Male” if the candidate’s sex recorded at birth is male or if the candidate’s sex recorded at birth is female, and, for example, the candidate is currently taking masculinizing gender-affirming hormone therapy.

Will MELD 3.0 use a candidate’s birth sex or sex for purposes of adult MELD calculation?

² See who.int for more information.

³ See CDC.gov for more information.

⁴ See HealthIT.gov for more information.

The MELD 3.0 score will use a candidate's sex for purposes of adult MELD calculation, meaning that candidates whose sex for purposes of adult MELD calculation is female will receive the 1.33 points for female sex in their score.

For candidates added to the OPTN Waiting List after Phase 1 implementation of MELD 3.0, "Sex for Purposes of Adult MELD Calculation" will be a required field when adding the candidate and the calculation will use the response provided to this data field.

However, for candidates already on the OPTN Waiting List, the "Sex for Purposes of Adult MELD Calculation" field will be null at the time of Phase 1 implementation. If a transplant program provides a response to the "Sex for Purposes of Adult MELD Calculation" field, the calculation will use that value in MELD 3.0. If no value is provided, the calculation will default to the response provided for "Birth sex." Transplant programs are encouraged to review their candidates and provide a response to the "Sex for Purposes of Adult MELD Calculation" field as necessary.

What type of documentation do I need to maintain related to "Sex for Purposes of Adult MELD Calculation"?

A candidate's sex for the purposes of adult MELD calculation is ultimately left to the discretion of the transplant program in consultation with the candidate. Members may be asked to provide documentation during routine monitoring, but policy does not specify which documentation is required. Any documentation supporting the candidate's sex for the purposes of adult MELD calculation would be acceptable, especially if the candidate's sex for the purposes of adult MELD calculation differs from their birth sex. Examples of such documentation include taking gender-affirming hormone therapy.

Where can I find more detail on MELD 3.0?

You can find more detail about MELD 3.0 on the OPTN Website. If you are looking for specific information about the calculation, please refer to the calculation guide, available [here](#).

What happens if I do not provide a required lab value for my candidate during Phase 1?

If you do not provide a required laboratory value used in MELD 3.0 before Phase 2 is implemented, the candidate's calculated MELD score will be set to null upon implementation of Phase 2 and their medical urgency status will be set to MELD or PELD 6. Users will see the reason why the MELD score is set to null in the OPTN Computer System.

Will I be able to see which candidates are missing lab values before implementation of Phase 2?

Yes, there will be candidate-level reports in the OPTN Computer System that will include detailed information about your program's candidate. This report will be available approximately one week after Phase 1 is implemented. You can access the report within the OPTN Computer System by navigating to the Data Services portal, then selecting OPTN Data Files on the left hand side of the screen, and then filtering the "Organ" field to "Liver".

The report will include the following information for each candidate (in addition to general demographic information):

- Pediatric at time of listing (Yes/No)
- Birth Sex
- Sex for purposes of adult MELD calculation
- Liver-intestine candidate (Yes/No)
- Missing Lab Data

The report will also include the following information using **both the previous MELD and MELD 3.0**, based on the information that is available for the candidate:

- Calculated score
- Lab recertification due date
- Medical Urgency Status

These reports will help transplant programs see which candidates are missing required lab values, how candidate scores will likely change based on current information, and the new lab recertification dates based on the new scores at the time of implementation. Reports will be updated weekly.

How are adolescent candidates handled under the new score?

In the current liver allocation system, adolescent candidates (age at least 12 and less than 18) are assigned a MELD score. Under this new policy, adolescent candidates will continue to utilize MELD 3.0, but both male and female adolescent candidates will receive the 1.33 points that will be provided to all adult female candidates. This is based on data that shows there is no sex-based disparity in the adolescent population.

Both male and female adolescent candidates registered before turning 18 will maintain the 1.33 points if they remain on the OPTN Waiting List after turning 18.