

Modification to the Pediatric Heart Allocation Policy

[Heather is speaking] Hello and welcome to today's webinar, "Modifications to the Pediatric Heart Allocation Policy."

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This webinar is being recorded.

Our speakers today are

Dr. Bill Mahle Pediatric Cardiologist, Division Director, Professor of Pediatrics at Sibley Heart Center, Emory School of Medicine and Chair of UNOS Pediatric Committee;

Dr. Ryan Davies Cardiothoracic Surgeon, Nemours Cardiac Center at the A.I duPont Hospital for Children and Member of UNOS Thoracic Committee.

We also welcome Kandi Neilson. She is a Site Surveyor in the Member Quality Department at UNOS.

By the end of today's webinar, you will be able to:

Define the new pediatric heart Status 1A and Status 1B criteria

Use resources to assist you in complying with the policy changes and

List the three additional upcoming modifications to the pediatric heart allocation policy

Dr. Mahle, I have you up first to talk to us today about the upcoming policy changes.

Welcome, Dr. Mahle.

[Bill is speaking] Thank you. I am happy to be here. Today we are going to talk about upcoming changes to the pediatric heart allocation policies. The OPTN/UNOS Board of Directors approved four modifications to pediatric heart allocation policy:

1. Pediatric heart status 1A and 1B criteria are redefined
2. To qualify for ABO-incompatible heart offers, the isohemagglutinin titers are increased to 1:16 or less for candidates who are one year of age or older but registered before their second

birthday

3. Allocation priority of urgent potential heart recipients registered before their first birthday and potential transplant recipients eligible to receive ABO-incompatible heart offers were changed
4. The option to register heart candidates as in utero was eliminated.

Please note this webinar will focus on **redefining Status 1A and 1B** which will be implemented on March 22. The other changes are currently scheduled to be implemented Q4 2016. Although we're focusing on the first change, we will briefly review the other three at the end of the presentation.

Let's take a look at the new 1A requirements. To register a transplant candidate as pediatric status 1A, the candidate's transplant program must submit a Heart Status 1A Justification Form to the OPTN Contractor.

The candidate's transplant program may assign the candidate pediatric status 1A if the candidate is less than 18 years old at the time of registration, and meets at least one of the following new criteria:

1. Requires continuous mechanical ventilation and is admitted to the hospital where the candidate is registered.
2. Requires assistance of an intra-aortic balloon pump and is admitted to the hospital where the candidate is registered.
3. Has ductal dependent pulmonary or systemic circulation, with ductal patency maintained by stent or prostaglandin infusion, and is admitted to the transplant hospital where the candidate is registered.
4. Has a hemodynamically significant congenital heart disease diagnosis, requires infusion of multiple intravenous inotropes or a high dose of a single intravenous inotrope, and is admitted to the transplant hospital where the candidate is registered.
5. Requires assistance of a mechanical circulatory support device.

Now what has changed?

1. For mechanical ventilation, we clarified that the mechanical ventilation needs to be continuous; and the candidate is required to be admitted to the hospital where they are registered. This means that candidates supported by CPAP or BiPAP wouldn't qualify under this criterion because those are not continuous ventilatory support systems.
2. The main change for the intra-aortic balloon pump candidates is that we now require them to be admitted to the hospital where they are registered.
3. In the new policy, criterion 3 permits candidates who are admitted to the hospital with ductal dependent pulmonary or systemic circulation, with ductal patency maintained by stent or prostaglandin infusion, to be registered as status 1A. Note there is no age requirement associated with this criterion.

4. Criterion 4 permits candidates who are admitted to the hospital with a hemodynamically significant congenital heart disease diagnosis who are treated with multiple intravenous inotropes or a single high dose inotrope to be registered as status 1A. UNOS will maintain the list of qualifying congenital heart diseases and qualifying inotropes and dosages.
5. The language surrounding criterion 5 has been clarified slightly. Current policy says the candidate requires assistance of a mechanical assist device and the new policy clarifies this means assistance of a mechanical **circulatory** support device.

We'll talk about status 1A exceptions later in this presentation.

Let's talk about 2 hypothetical patients. In the **first** scenario, a 10 month old heart patient who is admitted to the transplant hospital is being added to Waitlist. In order to determine their medical urgency status, we look at their medical record. There, we find the patient is being treated with a single high dose intravenous inotrope and has congenital heart disease diagnoses of ventricular septal defect and aortic stenosis.

[Heather is speaking]

Which criteria allow this patient to be status 1A?

- A. Admission to hospital
- B. Single high dose IV inotrope
- C. Congenital heart disease diagnosis
- D. All of the above

[Stop for 10 seconds to allow poll to be answered]

Dr. Mahle, it looks like most people chose:

The right answer/wrong answer. What is the right answer?

[Bill is speaking] The most appropriate response would be all of the above. Hospital admission, single high dose inotrope, and congenital heart disease all qualify this patient for Status 1A citing criterion 4: congenital heart disease diagnosis. When entering this data, we would find a checkbox to report ventricular septal defect(s), but aortic stenosis is not listed. This can be reported under "other" and then entered into the open field.

Note that at least one IV inotropic support dosage value must be entered in order to add the candidate.

The hemodynamic measurements are no longer collected here.

Let's take a look at another case.

In the **second** scenario, a 2 year old patient with congenital heart disease is admitted to the transplant hospital registering him. The child has a stent that had been placed by transcatheter technique in order to maintain ductal patency.

[Heather is speaking]

Which criteria allow this patient to be status 1A?

- A. 2 year old with Congenital Heart Disease
- B. Admitted to the hospital with stent placement

[Stop for 10 seconds to allow poll to be answered]

It looks like most people chose (3/4). Which status criterion is correct?

[Bill is speaking] B. Admitted to the hospital with stent placement. This patient meets Status 1A according to criteria 3: Has ductal dependent pulmonary or systemic circulation, with ductal patency maintained by stent or prostaglandin infusion and admitted to the hospital.

I will now have Dr. Davies present the new Status 1B Requirements.

[Ryan is speaking] Thank you for the opportunity to present to you this afternoon.

So what are the 1B requirements? First to remind you, in order to assign a candidate pediatric heart status 1B, the candidate's transplant program must submit a Heart Status 1B Justification Form to the OPTN Contractor. **Please remember a candidate is not assigned pediatric status 1B until this form is submitted.**

I will now list the new 1B requirements; then I will describe the differences between the old policy and the new policy.

1. Requires infusion of one or more inotropic agents but does not qualify for pediatric status 1A. The OPTN Contractor maintains a list of the OPTN-approved status 1B inotropic agents and doses.
2. Is less than one year old at the time of the candidate's initial registration and has a diagnosis of hypertrophic or restrictive cardiomyopathy.

Now what has changed?

Criterion 1 remains fairly similar to the previous policy. It clarifies that candidates who are treated with inotropes but do not meet the dosage requirements to qualify for status 1A, or who aren't admitted to the hospital, will qualify for 1B instead. *Additionally, candidates who don't have a congenital diagnosis but are maintained on inotropes will qualify for status 1B rather than status 1A.* Like Status 1A, UNOS will maintain a list of the OPTN-approved inotropic agents and doses specific to status 1B candidates.

Criterion 2 has changed significantly. It used to permit any candidates less than 6 months old to qualify for 1B. Now, the criterion focuses more on the candidate's diagnosis. To qualify, a candidate must have a diagnosis of restrictive or hypertrophic cardiomyopathy, and be less than 1 year old at the time of their initial registration.

Criteria 3 and 4 from the previous policy have been removed. Candidates can no longer qualify for status 1B by meeting certain height or weight requirements.

We'll talk about status 1B exceptions later in the presentation.

A candidate may retain pediatric status 1B for an unlimited period, *it does not expire*, and this status does not require any recertification. However, if the candidate's medical condition

changes and the criteria used to justify that candidate's status are no longer accurate, then the transplant program is responsible for updating the candidate's registration in Waitlist.

For example, if the candidate still needs a heart transplant but is no longer being treated with inotropes, and the candidate doesn't meet any of the other criteria for status 1A and 1B, then the program must update the candidate's registration and list the candidate as status 2.

What happens when a candidate's pediatric status 1A expires?

Like before, the candidate will be assigned pediatric status 1B. The policy states that within **24 hours** of the status change, the transplant program must report to the OPTN Contractor the criterion that qualifies the candidate to be registered as status 1B. The *transplant program*, must classify the candidate as pediatric status 2 or inactive status if the candidate's medical condition does not qualify for pediatric status 1B.

Let's talk about a **third** hypothetical patient. A 3 year old heart patient with dilated cardiomyopathy was registered in Waitlist as Status 2 prior to the March 22nd implementation date. Two weeks after the policy change the child's health worsens. The child is admitted to the hospital and is placed on high dose inotropes.

[Heather is speaking] This is a poll question, so tell us what you think:

Is the child eligible for Status 1B or 2 since the initial listing was before policy change?

- A. Status 1B
- B. Status 2

[Stop for 10 seconds to allow poll to be answered]

It looks like most people chose A/B. Dr. Davies, what is the correct selection?

[Ryan is speaking] The appropriate updated status would be 1B according to the new criteria language because even though the candidate is admitted to the hospital and is treated with high dose inotropes, the candidate does not have a congenital heart disease diagnosis.

Since the child's diagnosis is dilated cardiomyopathy, they would qualify for Status 1B criterion 1: "requires infusion of one or more inotropic agents but does not qualify for status 1A".

If the physician feels that the candidate is as urgent as a status 1A candidate, they could apply for a 1A exception, same as before policy change.

Let's talk about a **fourth** case. On March 23rd, the day after implementation, a 3 year old candidate is registered on the waiting list and has a diagnosis of restrictive cardiomyopathy. So far the candidate is not being treated with inotropes.

[Heather is speaking] This is our last poll question. What is the appropriate status for this candidate? Is it:

- A. Status 1B
- B. Status 2

[Stop for 10 seconds to allow poll to be answered]

In this case most folks chose A/B. What is the best answer?

[Ryan is speaking] Status 2 Even though they have a diagnosis of restrictive cardiomyopathy, they are older than 1 at the time of registration and are not being treated with inotropes, so they qualify for status 2.

I will now go through some Status exceptions and exception extensions:

In regards to Pediatric Status 1A request exceptions, the life expectancy criteria of 14 days has been removed and replaced. Now the policy states that to qualify for a 1A exception, the candidate must be admitted to the hospital where he or she is registered, and the transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status.

The initial review will involve the Regional Review Board retrospectively reviewing requests for Status 1A-exceptions. If approved, status 1A exceptions are valid for 14 days.

The extension process for 1A exceptions is different than current policy.

Under the current policy, extension requests require the transplant program to have a conference with the Regional Review Board. That requirement is being eliminated. Instead, the Regional Review Board will review and decide extension requests retrospectively, and if approved each extension is also valid for 14 days. If no extension is submitted, the heart transplant candidate will be assigned pediatric status 1B.

The pediatric status 1B exception requests process remains the same. The duration will remain indefinite and an extension is not required as long as the candidate's medical condition remains the same.

Upon implementation on March 22, 2016, members will need to use the new pediatric heart Status 1A and 1B definitions to register new pediatric heart candidates.

For candidates who are currently registered as status 1A, you'll be notified in your critical data report in UNetSM that their status 1A justifications are up for recertification, as is done currently. At that point, you'll need to recertify the candidate under the *new* status 1A criteria, and if they don't qualify for status 1A under the new criteria then you should register them as status 1B or status 2, whichever is appropriate.

For candidates currently registered as 1B, their 1B justification don't expire. However, they might not meet the criteria for status 1B anymore because of the changes. You should review all your 1B patients and UNOS encourages you to submit updated justification forms under the new policy,

I want to introduce Kandi Neilson, a Site Surveyor based in the Member Quality Department at UNOS. She will discuss the compliance monitoring.

[Kandi is speaking] The survey process already in place for reviewing status justification forms will not change. Site surveyors will verify candidate status listings as submitted in UNetSM with actual candidate medical record documentation. Site surveyors will also review and verify information entered in the narrative field on the justification form, including information submitted for exception requests.

For Example: If a program reports on the status 1A justification form that their candidate has a congenital heart disease and requires inotropes, then site surveyors will look in the candidate's medical record for daily evidence of the high dose inotrope and hospital admission status. Surveyors will also verify that the congenital heart disease diagnosis listed on the justification form matches the medical record documentation.

If a program reports continuous mechanical ventilation, the site surveyors will look for daily evidence of the ventilator status via medical record documentation. The site surveyors will also verify hospital admission status.

For some criteria, site surveyors may only need to verify a single event instead of daily events. For example, if the candidate has a Berlin Heart and it is reported on the justification form that they require the assistance of a mechanical circulatory support device, the surveyors would look for the implant date of the device in the medical record and would make sure there is not an explant date in the record.

The information entered in the narrative field on the justification form is verified for all applications. The site surveyors will verify the information entered matches the medical record documentation. Depending on what information is documented in the narrative, the surveyors will utilize lab results, CT scans, MRIs, as well as other test results, and progress notes to verify the narrative. As mentioned earlier, the survey process for reviewing status justification forms will not change.

Dr. Mahle, I am going to turn it back over to you to discuss other policy changes

[Bill is speaking] This webinar focuses on redefining Status 1A and 1B. As a reminder, this change will be implemented March 22, 2016.

As mentioned earlier, there are three other changes being made to Pediatric Heart Allocation policy. These changes will be implemented Q4 2016. At this time, I want to briefly touch on each of these.

In the new policy, for candidates who are willing to receive intended ABO incompatible heart offers, the only change is for candidates who are older than 1 year at the time of the match. They must be registered before they turn 2 years old, and must be registered as Status 1A or Status 1B, and their isohemagglutinin titer can be as high as 1:16 or less, as compared to 1:4 in current policy.

As a reminder, this change will be implemented at the end of 2016.

In the new policy, allocation priority of urgent potential heart recipients registered before their first birthday and potential transplant recipients eligible to receive intended ABO-incompatible heart offers will also change at the end of 2016.

In the new policy, all candidates who are less than one year old at the time of the match and are blood type compatible with the donor or are eligible to receive an intended ABO incompatible offer will appear in the "primary" blood type classification. This means these candidates appear on the match before candidates who are secondary blood type matches with the donor.

Additionally, in the new policy, candidates who are at least one year old, but are eligible to receive intended ABO incompatible offers will be classified as a secondary blood type match, so they will receive offers much earlier in the allocation order.

Finally, in late 2016 we are going to eliminate the ability for transplant programs to register a candidate while the candidate is in utero.

Very few candidates have been registered at this status since its original implementation in 2000, and often these candidates need to be more carefully evaluated prior to undergoing heart transplant surgery. Policy mandates that an *in utero* heart candidate's waiting time resets upon being born, so there is no additional advantage provided to a heart candidate if they are registered prior to birth except in the extremely rare instance where delivery is specifically performed because a suitable donor has become available.

As we get closer to implementation, UNOS will reach out directly to programs with candidates registered in utero

I will now turn the Q & A discussion over to the moderator.

[Heather is speaking] Thank you Dr. Mahle and to all of our speakers today. We will now move to the Question and Answer session of the webinar. I want to introduce you to our panel for the Q & A session:

They are today's speakers:

Dr. Bill Mahle, Dr. Ryan Davies and Kandi Neilson.

As well as:

Leah Edwards, Principal Research Scientist in the Research Department at UNOS;

Leah Slife, an Evaluation and Quality Analyst for Member Quality at UNOS; and

Liz Robbins Callahan, a Policy manager at UNOS.

We are ready to take questions from participants.

Go ahead and begin submitting your questions now.

Type your questions into the Question Panel and click Send.

The panelists may not be able to address all questions during this Q&A session, however they will address as many as possible. I am going to turn the Q&A session over to Liz Robbins Callahan.

[Liz is speaking] will start with registration questions and then move on to read questions as they come in and panelists will answer –

[at 2 minutes before the hour, the moderator will stop the Q&A and start closing statements]

[Heather—two minute warning] We have enough time for only one more question.

[Liz takes question]

[Heather is speaking] Thank you, Liz, and thank you to all the participants who asked questions.

On March 16th, a recording of this webinar and a link to a systems training video for UNetsm users will be available on the OPTN and Transplant Pro websites. The training video will be posted in the Waitlist online help documentation.

March 22, 2016, the day of the Status 1A and 1B policy changes, both the Policies and the Evaluation Plan will be updated on the OPTN website.

The other modifications to the policy, **Intended ABO Incompatible Heart Offers, Prioritization** changes, and the **Elimination of In Utero Candidate Registration** will be implemented Fourth Quarter 2016.

We hope that you find this information helpful as you implement new processes related to the new Pediatric Heart Allocation Policy changes.

A toolbox will be available on the OPTN and Transplant Pro websites, and will contain the following:

- A copy of the new policy
- A list of the CHD diagnoses and qualifying inotropes
- A recording of this Webinar
- A PDF copy of the slides and the script
- And the link to the systems training video
- Frequently asked questions document

The UNOS Regional Administrators are your first contact for direct questions about policy requirements. Please contact the Administrator for your region with any policy related questions.

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