

Amend Adult Heart Status 2 Mechanical Device Requirements

OPTN Heart Transplantation Committee

Purpose of Proposal

- Address the substantial increase in intra-aortic balloon pump (IABP) use within status 2
- Properly align medical urgency of candidates within status 2
- Prevent future status 2 congestion by use of a different device
- Increase access for other status 2 candidates and improve waitlist outcomes

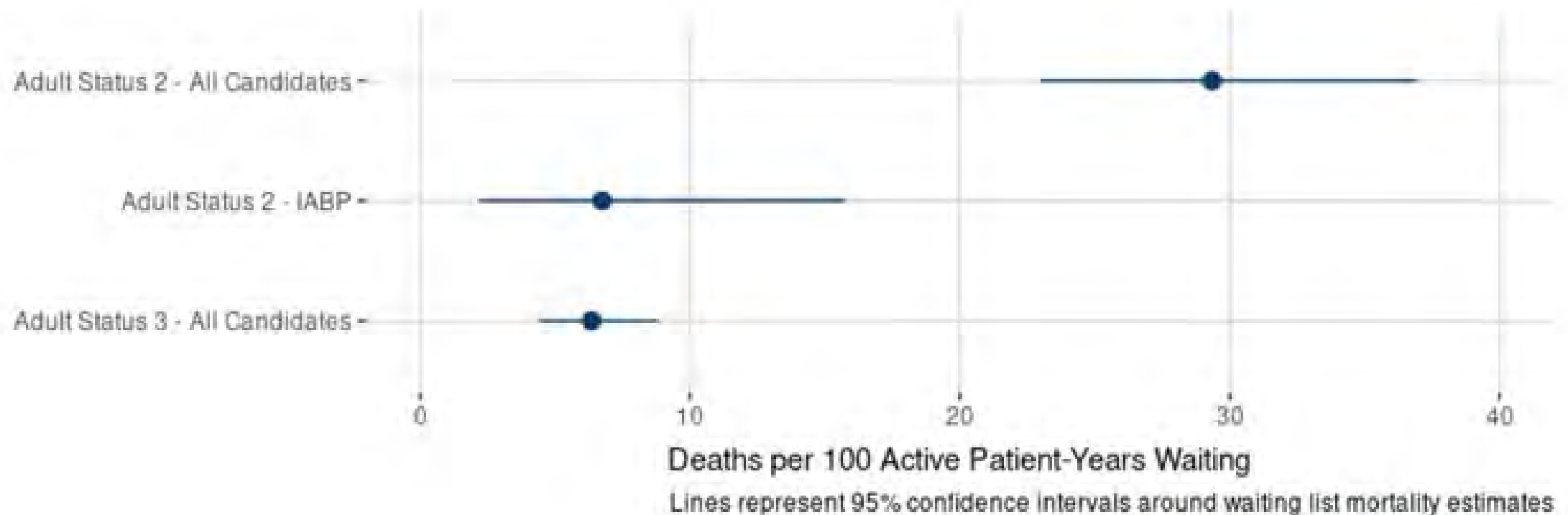
Proposal

- Initiate and show failure of inotropic drug therapy prior to IABP or percutaneous endovascular mechanical circulatory devices use
 - Inotrope levels pulled directly from status 3 heart policy
- Failure to wean off device while on continued inotrope therapy to extend status 2
- Different criteria acknowledges emergent situations

Rationale

- IABP use accounts for 45% of all status 2 registrations
 - Waitlist mortality rates of status 2 IABP is more aligned with status 3
- Current listing criteria for status 2 IABP only requires hemodynamics to be recorded
- If a candidate can be treated with inotropes, they will be listed at status 3
 - Failure of inotropes necessitating the use of an IABP, the candidate can be listed at status 2
- Percutaneous devices included to prevent the issue from occurring with a different device

Comparing Waitlist Mortality Rates



Data represents October 18, 2018-
October 17, 2021

Inotrope Requirements

- A continuous infusion of one high-dose inotrope:
 - Dobutamine greater than or equal to 7.5 mcg/kg/min
 - Milrinone greater than or equal to 0.50 mcg/kg/min
 - Epinephrine greater than or equal to 0.02 mcg/kg/min

OR

- Continuous infusion of two inotropes:
 - Dobutamine greater than or equal to 3 mcg/kg/min
 - Milrinone greater than or equal to 0.25 mcg/kg/min
 - Epinephrine greater than or equal to 0.01 mcg/kg/min
 - Dopamine greater than or equal to 3 mcg/kg/min

Hemodynamic Not Obtained

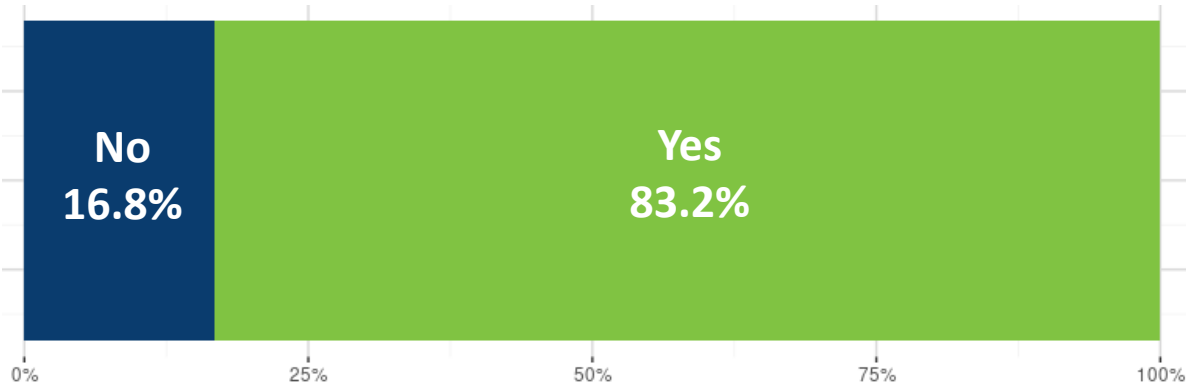
- Within a 24-hour period:
 - CPR was performed on the candidate
 - Systolic blood pressure less than 70 mmHg
 - Arterial lactate greater than 4 mmol/L
 - Aspartate transaminase (AST) or alanine transaminase (ALT) greater than 1,000 U/L

Extension at Status 2

- Inotropic therapy must continue
- Candidate must meet one of the following to demonstrate a failure to wean:
 - Mean arterial pressure (MAP) less than 60 mmHg
 - Cardiac index less than 2.0 L/min/m²
 - Pulmonary capillary wedge pressure greater than 15 mmHg
 - SvO₂ less than 50 percent measured by central venous catheter

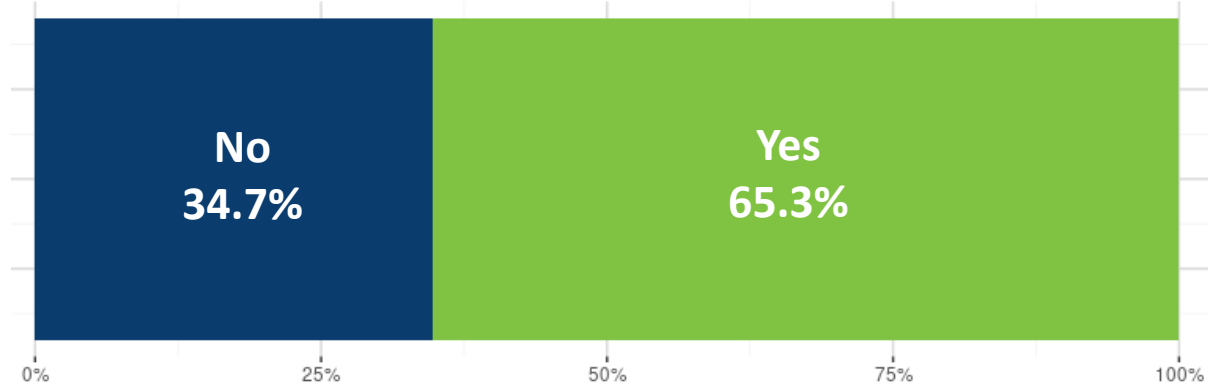
How many IABP candidates would no longer qualify for Status 2?

Lack Requirements in Justification Form Data



83% of Status 2 IABP candidates never applied for Status 3 based on inotropes

Lack Requirements in Risk Stratification Data



65% of Status 2 IABP candidates never entered multiple inotropes/single high-dose inotrope in the risk stratification data

- Analysis did not require conditions to have been met within seven days as in proposed policy; may underestimate candidates who would not qualify
- **Conclusion:** Up to 65%-83% of current Adult Status 2 candidates may not qualify for Status 2 under the revised requirements

Member Actions

- Transplant Hospitals
 - Will need to be aware of this change
 - Be prepared to report use of inotropes prior to the IABP or percutaneous device for initial listing
 - Be prepared to report use of inotropes to demonstrate a failure to wean a candidate off an IABP or percutaneous device on status 2 extension forms

What do you think?

- Does this proposal sufficiently address the issue?
- Are the inotropic levels that are listed within the policy appropriate for use prior to the placement of an IABP? If not, what levels would be more appropriate and why?