

Escalation of Status for Time on Left Ventricular Assist Device

OPTN Heart Transplantation Committee

Purpose of Proposal

- Provide pathway to higher priority on the waiting list for adult candidates supported by dischargeable left ventricular assist device (LVAD)
- Increase transplant opportunities of those supported by LVAD prior to developing a complication
- Transplant stable candidates and improve post-transplant outcomes

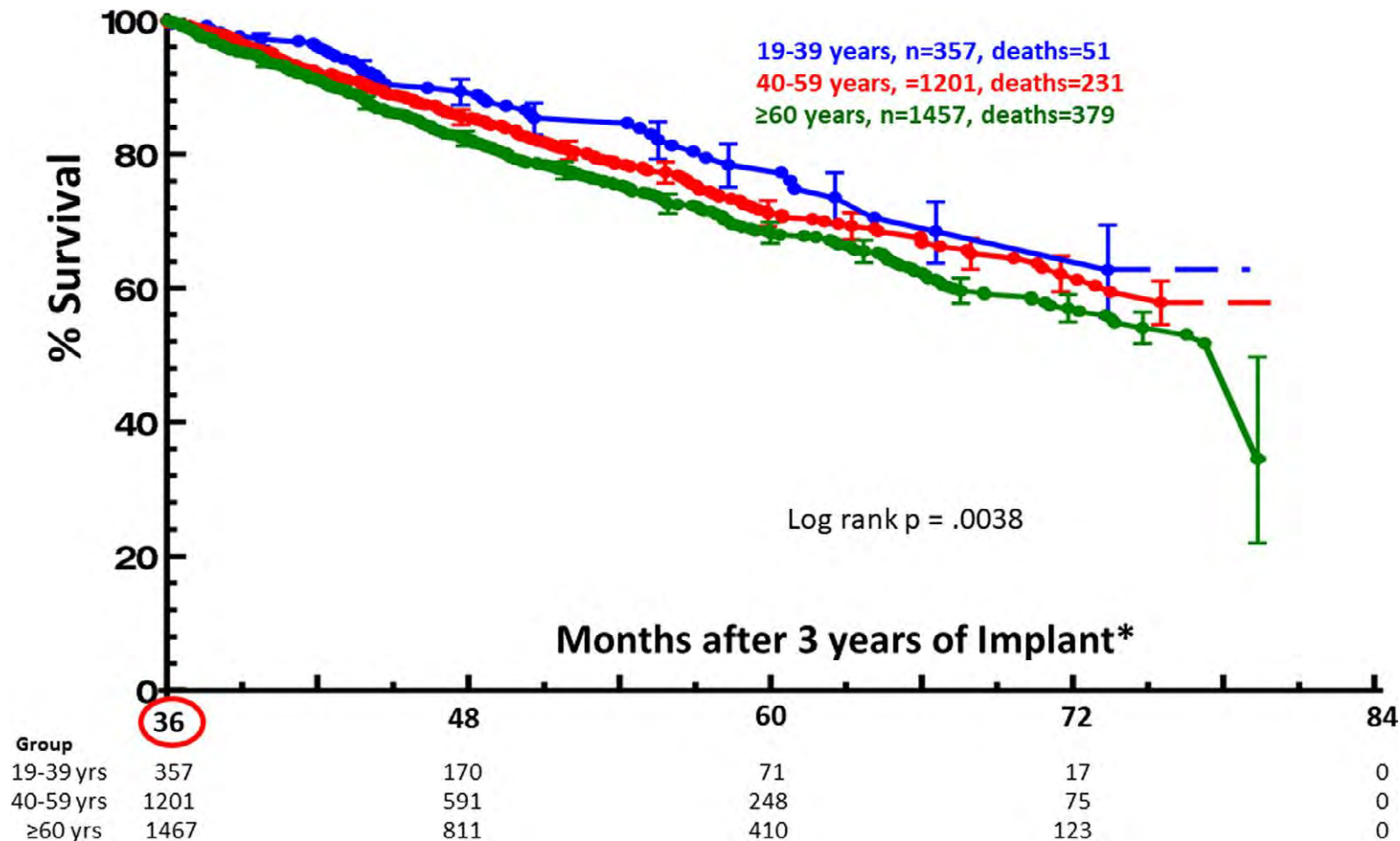
Proposal

- Adult heart candidates supported by dischargeable LVADs for extended periods of time will be eligible to transition to statuses 2 or 3
- Specifically, a candidate whose device was implanted at least:
 - Six years prior will be eligible for status 3
 - Eight years prior will be eligible for status 2
- 18 months after implementation, the timeframes waiting after device implant will be shortened. A candidate whose device was implanted at least:
 - Five years prior will be eligible for status 3
 - Seven years prior will be eligible for status 2

Rationale

- Allocation changes implemented in October 2018 increased granularity of adult candidates' prioritization on the waiting list, resulting in:
 - Better aligned candidates with waitlist mortality rates
 - Shorter median waiting times while not adversely impacting waiting list mortality of post-transplant outcomes for all adult heart candidates
- Unfortunately, changes also resulted in decreased use of LVADs as bridge-to-transplant therapy and fewer LVAD-supported candidates being transplanted
- Evidence suggests LVADs provide stable transplant alternative, but risks of stroke, infection, and bleeding grow the longer device is implanted
- As a result, LVAD use is considered a 'bridge to complication'

Rationale (Continued)



Source: Hariri, Imad M., et al., “Long-Term Survival on LVAD Support: Device Complications and End-Organ Dysfunction Limit Long-Term Success,” *The Journal of Heart and Lung Transplantation* 41, no. 2 (2022): p. 165. <https://doi.org/10.1016/j.healun.2021.07.011>

Member Actions

- Transplant Hospitals
 - Will need to be aware of the changes and the two implementation phases
 - Review the device implant dates for each candidate supported by a dischargeable LVAD
 - Determine whether changing status assignments is appropriate for each candidate

What do you think?

- The Committee seeks your feedback about the appropriateness of the proposed changes in context of the following:
 - Does clinical evidence support the need to give greater prioritization to candidates who have waited an extended period of time for a transplant?
 - Should stable, non-hospitalized candidates be given the same priority as candidates who experienced stroke, infection, or device malfunction?
 - From the perspective of patients, donors, and their families and caregivers, is the tradeoff between potentially transplanting fewer sicker patients versus transplanting more patients before they get sicker appropriate?
- Should the Committee wait until after the allocation changes associated with the *Amend Adult Heart Status 2 Mechanical Device Requirements* have been implemented and monitoring results are available before making the proposed changes?
- Should the Committee include the proposed ‘step-down’ provision granting status 2 and 3 eligibility after seven- and five-year following device implant, respectively, or wait for monitoring results to determine effectiveness before shortening the timeframes?

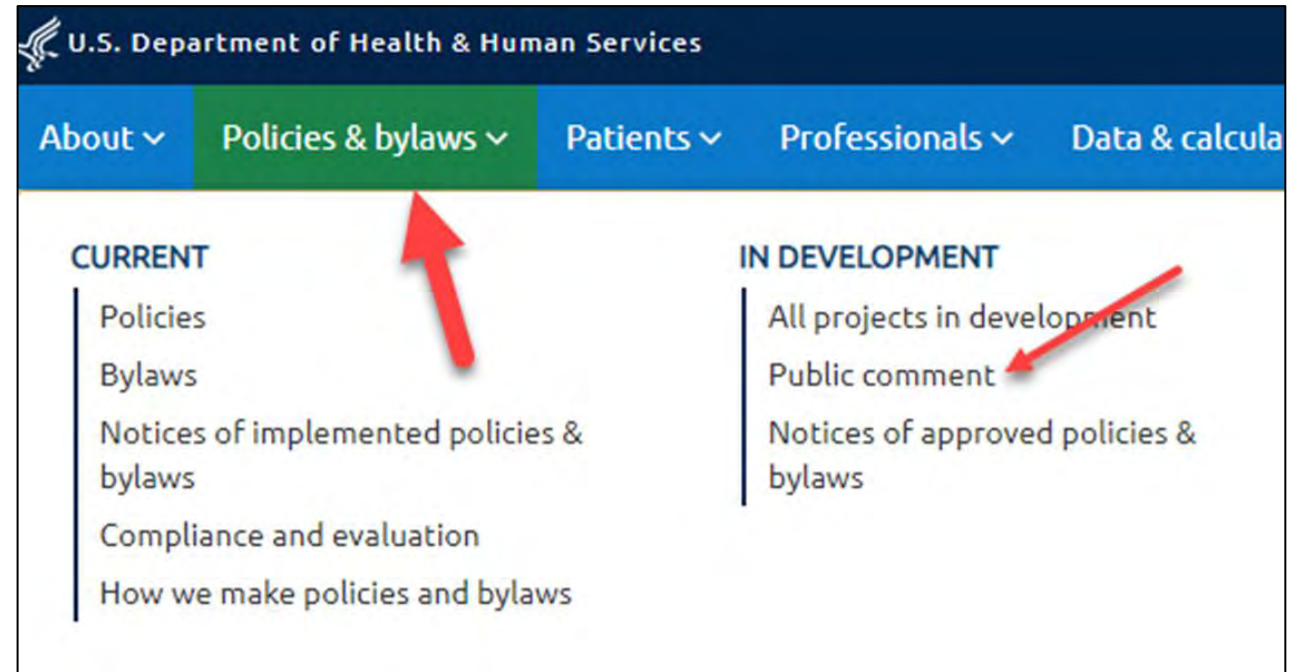
Additional Questions?

- Please direct all questions concerning the proposal to Eric Messick at Eric.Messick@unos.org

Provide Feedback

Submit public comments on the OPTN website:

- January 21 – March 19, 2025
- **optn.transplant.hrsa.gov**



FAQs