Proposal: **Modify Guidance for Pediatric Heart Exception Requests to Address Temporary Mechanical Circulatory Support Equipment Shortage**

ASTS Position: Support

Are the guidance updates approved through the emergency action appropriate for addressing the problem?

The emergency guidance update is appropriate and necessary to protect pediatric candidates during the current shortage of mechanical circulatory support (MCS) devices and equipment. It provides a clear pathway to Status 1A by exception for dilated cardiomyopathy patients who fail inotropes and cannot access durable MCS, ensuring equity and consistency across programs and review boards. The temporary, time-limited nature of the change is reasonable, with reassessment built in. The updates are appropriate and necessary to address a patient safety concern. We do not "strongly support" because this is a temporary measure, and its continued relevance should depend on ongoing monitoring of device availability and outcomes.

Proposal: [Require Patient Notification for Waitlist Status Changes]
ASTS Position: Oppose

Executive Summary/General Comments:
The American Society of Transplant Surgeons (ASTS) acknowledges and supports the intent behind the Transplant Coordinators Committee (TCC) proposal to require patient notification for waitlist status changes. We agree that patients must be fully informed of their listing status and recognize the critical importance of comprehensive education, shared decision-making, and effective collaboration between patients and programs as these efforts are essential to ensuring candidates remain active on the waitlist and are eligible to receive life-saving organ offers.

However, ASTS does not believe the proposal as drafted achieves this goal. Instead, it reflects an outdated, compliance-driven approach that adds administrative burden without delivering meaningful benefit to patients. Requiring a written letter within 10 business days of a status change is unlikely to enhance understanding or support timely action, and risks reducing patient engagement to a box-checking exercise rather than fostering true, patient-centered care.

Concerns with Written Notification
Insufficient.Detail.and.Lack.of.Actionable.Information¿The proposed requirement mandates only that patients be notified when their status changes to active or inactive. Critically, it does not require an explanation of the rationale for the status change, what it means for their ability to receive organ offers, or steps required to resolve an inactive status. Moreover, the absence of detail ignores best practices in patient-centered communication, which emphasize tailoring information to individual circumstances, confirming comprehension, and empowering patients to take corrective action. A generic letter that reports only a status change is unlikely to achieve these outcomes and, in some cases, may undermine trust in the transplant system.

Low.effectiveness.of.mailed.communication¿Studies consistently show that patients often discard or fail to act on mailed correspondence, particularly those with limited health literacy or competing life stressors (Volandes et al., 2009; Sudore et al., 2006). A Pew Research survey found that only 55% of adults reported regularly opening and reading all their postal mail, compared with 85% reporting daily use of text messaging and 75% reporting daily email use (Pew Research Center, 2021).

Arbitrary.timeframe.and.timeliness.risks¿The proposed 10-business day notification period is arbitrary, borrowed from existing OPTN policies without evidence that it benefits patients in the context of status changes. In practice, this approach risks causing real harm: hospitalized patients may be unable to receive or respond to mailed notices, and in the most tragic cases, families may be left to open a letter about inactivation after the patient has died—transforming a policy meant to promote engagement into one that delivers confusion and distress.

Equity.and.Language.Access.Concerns¿Compounding the broader concerns with this proposal, current EMR and communication system limitations make it likely that written letters would default to English rather than a patient's preferred language. While state and federal requirements—such

as Title VI of the Civil Rights Act and the HHS Office of Minority Health's National Standards for Culturally and Linguistically Appropriate Services (CLAS Standards)—mandate that patients receive communication in their preferred language, the reality is that mailed letters often fail to meet this obligation in practice.

Beyond language, health literacy is a critical barrier. Nearly 9 out of 10 adults in the United States struggle with health literacy (Kutner et al., 2006), and transplant candidates face especially complex information related to listing, inactivation, and reactivation. A written letter—often highly technical, impersonal, and without opportunity for clarification—does little to ensure patient understanding. Instead, it risks widening disparities by privileging those who already have higher literacy or greater access to support systems.

A Better Approaches to Patient Engagement

ASTS strongly believes that the benefit the TCC desires is best achieved through real-time, personalized communication between transplant teams and patients; conversations that provide not only information, but also the opportunity for the patient to ask questions, clarify next steps, and ensure true understanding.

Research on health communication and patient education consistently shows that interactive strategies, such as the "teach-back" method, significantly improve comprehension and retention of complex medical information (Ha Dinh et al., 2016). These methods ensure that patients can accurately explain information back to the provider, confirming both understanding and readiness to act. By contrast, relying solely on mailed written communication denies patients the chance to seek clarification or context in the moment. This one-way approach not only risks misunderstanding but can also deepen inequities in access, particularly for patients with limited literacy, language barriers, or less social support.

Effective communication about waitlist status must be dynamic, patient-centered, and documented in the medical record as part of standard practice. This ensures that programs fulfill their duty not just to inform, but to equip patients and families with the knowledge and confidence needed to remain active participants in their transplant journey

Responses to Committee Questions

- **Do community members think that written notification is necessary, or would documentation of notifications, including conversations, be sufficient?**
  Documentation of direct, real-time conversations should be sufficient and preferable. This ensures patients not only receive information but also comprehend it. If the program is unable to contact the patient within a reasonable timeframe (perhaps this is where the 10-day period should apply) patient portals, secure messaging, and SMS/text notifications have demonstrated efficacy in improving patient engagement and adherence (McInnes et al., 2010). These tools are far more effective than mailed letters. The best method of communication may also vary from patient to patient. Programs should be required to develop patient notification protocols and demonstrate adherence to them.

- **Do patients & patient families and caregivers support notifying candidates when their waiting list status changes?**
  Yes, patients and families should be informed, but communication must include reasons for inactivation, its implications, and actionable next steps. A binary "active/inactive" notice is inadequate.

- **Is there additional information that would be helpful to include in the patient notification, other than waiting list status?**
  Clear explanations of what active or inactive status means, how it affects organ offers, and how patients can regain active status should be included.

- **This proposal lays the groundwork for future efforts to improve patient awareness and engagement in their transplant journey. Are there additional tools or efforts, such as a patient portal, that you feel would be helpful to better inform and engage patients in the future?**
  There are ongoing developments in electronic medical record platforms that increasingly allow patients to view their transplant journey directly, including evaluation milestones and listing status. Coupled with patient portals, secure messaging, and SMS/text notifications which have been shown to improve engagement and adherence (McInnes et al., 2010) these tools represent an important opportunity to enhance transparency, patient understanding, and active participation in care. Different patients learn, understand, and engage in unique ways, and it is contrary to the goals of both patients and providers for the OPTN to mandate a single communication method when a range of approaches is necessary to meet diverse patient needs.

- **What education or guidance would be helpful for patients & patient families and caregivers?**
  Both general and specific education about the waitlist process are essential, and this education must be delivered on an ongoing basis throughout a patient's transplant journey. General education should ensure patients and families understand core concepts such as active versus inactive status, what inactivation means for organ offers, and the steps required for reactivation. Specific education should be provided at each point of status change or clinical decision, tailored to the patient's individual circumstances. Importantly, this education must be iterative, reinforcing key concepts over time and allowing opportunities for questions to ensure true comprehension and engagement.

- **Do transplant programs feel that this notification change is feasible or have concern about the level of burden? If there is concern about burden, please specify.**
  Many, if not most, transplant programs already have processes in place to notify patients and families of changes in waitlist status. However, mandating such communication in this narrow, prescriptive manner does not meet the stated goal. If the field is to truly improve transparency, patient engagement, and ultimately trust, we must rethink our approach.

Patient-centered care cannot be reduced to a single mandated notification requirement. It requires flexible, real-time communication strategies that prioritize understanding, responsiveness, and equity over administrative compliance.

- **What education or guidance would be helpful for programs to support the implementation of this proposal?**
  Guidance should focus on communication best practices, such as teaching-back, cultural and linguistic competency, and integration of electronic patient engagement tools.

While ASTS supports the intent of the proposal to improve transparency and patient empowerment we cannot support the proposal as drafted. By mandating a written notification without meaningful content or patient-centered delivery methods, this policy risks becoming a compliance exercise rather than a tool for true patient engagement.

ASTS encourages the Committee to reframe the policy to emphasize real-time, personalized communication, effective use of digital platforms, and documentation of meaningful encounters rather than perfunctory written notification.

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Proposal: [Require West Nile Virus Seasonal Testing for All Donors]

ASTS Position: Oppose

The proposal would mandate WNV NAT testing for all potential living and deceased donors within seven days of planned recovery. This mandate would include the entire nation and would be in effect only during peak WNV prevalence periods of July 1 to October 31 each year. While ASTS conceptually supports the goal of preventing WNV transmission, we have significant concerns about the unintended adverse consequences of this policy.

This proposal has been controversial even in the transplant infectious disease community. Much of the data and evidence supporting WNV NAT screening is derived from the blood donor population - a fundamentally different population without the biological, logistical, and operational time constraints associated with deceased organ donation.

In the blood donor population, positive screening tests can be confirmed or the blood in question discarded with minimal impact. Additionally, testing on donated blood is usually batched (multiple donor samples batched). For organ donors, batching tests is not feasible, reflex testing is frequently impossible within the short timelines, and false-positive results carry a direct risk of organ loss. While blood donation itself is lifesaving, it is not comparable to the urgency and irreplaceability of organ donation. Importantly, WNV transmissions through transplantation are rare; seem approximately one every two years. Anticipated false positive rates for WNV NAT which vary with prevalence, could therefore outweigh the actual risk of transmission, particularly if OPOs adopt year-round testing.

In practice, OPOs are likely to default with justification to continuous testing rather than navigating seasonal start/stop dates, retraining staff, and managing compliance risk. The results of this straightforward behavioral economics-based outcome are that costs will massively increase, and false-positive rates will dramatically rise because testing will be carried out during times of both high and low prevalence.

Operationally, the testing requirement could delay or cancel organ recovery, particularly in abdominal-only or DCD cases, leading to preventable organ loss. The cost in lost organs is therefore not simply related to the false positive testing rate, but also the time constraints that will lead to decline of organs or shutdowns of potential donors

The financial burden is also significant. For deceased donors alone, given approximately 45,000 donors per annum at approximately $225 per initial test, direct testing costs are estimated at more than $10 million annually, with higher actual costs likely once testing of potential (not just realized) donors and repeat or confirmatory testing are factored in. These estimates exclude living donor testing, OPTN programming, and OPO and Transplant Hospital compliance costs, all of which will add substantial additional burden.

Because the prevalence of WNV even during peak seasons is very heterogeneous across areas of the country, the proposed policy would create inequitable impact across OPTN regions and states, with some areas bearing disproportionate costs and risk despite low or negligible WNV activity.

ASTS recommends a more measured approach, beginning with testing living donor candidates only. This would avoid many of the pitfalls and unintended but predictable harms of the current proposal, while generating valuable real-world data on the operationalization and recipient impact of WNV NAT screening in the organ transplant population that would then better inform future iterations of this policy.

Again, we recognize the complexity of this issue and are grateful for the opportunity to contribute to the broader dialogue as the community works towards solutions that balance patient safety, system efficiency and societal equity.

Considerations for the Community

Is the proposed requirement to have living donors tested for WNV within seven days or as close as possible to organ recovery an appropriate testing timeframe?

The timeframe is reasonable in terms of the biology of WNV transmission, but we have serious concerns about the ability to obtain results in a timeframe that will not lead to increases in organ discard or abandonment of potential deceased donors. We note that the proposal is problematic for the reasons detailed above and refer you to our public comment document.

Proposal: [Update and Improve Efficiency in Living Donor Data Collection]

ASTS Position: Oppose

ASTS Public Comment:
The OPTN Living Donor Committee proposes several policy changes with the intent of improving data collection about living organ donors and intended donors who do not proceed with donation.

First, the proposal seeks to modernize and expand data collection on living organ donors and potential donors who do not proceed with donation. Studies on the short-term and long-term safety and outcomes in a variety of domains affecting living donors have been long plagued by a lack of an adequate 'comparator group.' Living donors are healthy and may not be best compared to members of the US general population. The ASTS supports robust improvement in living donor data collection in order to improve informed consent, enhance donor protections, reduce barriers to donation, and to employ a data-driven approach to future living donor policy making. The addition of the new Living Donor Non-Donation Form would add to the transplant community's understanding of barriers to living donation and aid in driving initiatives and policies around improving access. Additionally, the cohort of potential but unrealized donors could serve as a more appropriate comparator group when evaluating the long-term outcomes of actual living donors. This will certainly constitute additional data submission requirements for centers, but centers are currently engaged in the practice of documenting reasons for decline and providing it back to donors. Data collection will provide significant value to the transplant community and potential and actual living donors, but post-implementation monitoring of the data submission hurdles and data yield is warranted.

For long-term follow-up related data collection, the proposal suggests transitioning the responsibility to the SRTR from the OPTN. The transfer of long-term follow-up responsibilities is presented to unburden the OPTN and transplant centers from the data collection, given that clinical follow-up is not clinically necessary for donors or non-donors beyond the initial period of mandated follow-up. As highlighted in the proposal, existing studies and community consensus acknowledge that there are existing gaps in our understanding of donors and non-donors clinically, psychologically, socially and financially in the long-term. We therefore support the committee's effort to address these gaps through expanded data collection.

While we support the ideals of the proposal, it is necessary to understand that the proposal calls for new data collection by transplant centers of non-donors which constitutes greater workload and costs to centers and could divert resources from clinical care. Additionally, removing the OPTN-mandated two-year follow-up and shifting to indefinite SRTR follow-up imposes a significant risk of missing data. Current living donor follow-up at 2 years already demonstrates significant missing data. While SRTR has patient-centered tools and experience with voluntary registries, the proposal is bold in its outline but may not be fruitful through a voluntary mechanism. The question remains

as to how living donors who may be several years out from donation or non-donors will interact with data collection tools if they have no specific incentive to do so.

While ASTS supports the intent of this bold proposal and agrees that improved data collection is essential, we must oppose the proposal as written. We caution that candidates for living donation who do not donate are unlikely to be a suitable comparator group to realized living donors. We stress that this proposal will produce undue negative impact on transplant centers and the transplant ecosystem. We question the likelihood of efficacious data collection in donors and donor candidates who did not donate that relies on voluntary registry data. New data collection efforts without complete capture represent a potential increase in cost without any benefit.

Considerations for the Community

1. **Living Donor Non-Donation form:**
    - **a. Do the proposed data fields support the goals of this project?**
        The proposed data fields support the goal of this project to obtain basic initial and long-term data on both living donors and potential donors.
    - **b. Should all data fields be mandatory or should some be optional?**
        While data completeness would be benefited by all inputs being mandatory, this may prove a barrier to patient response. Therefore, we would support allowing optional fields.

2. **Reporting Requirements:**
    - **a. In this proposal, if the potential donor is approved to donate but does not donate, the recovery center has 30 days after the decision to not donate to submit the Living Donor Feedback form. Do you agree with this turnaround timeframe of 30 days?**
        No, this is not a reasonable time frame for reporting decisions not to donate from an administrative standpoint. It would be more efficient and less burdensome to for centers to submit both Living Donor Feedback form and Living Donor Non-Donation form at the same time (i.e. within 90 days).
    - **b. Is the 90-day turnaround an appropriate timeframe to submit the Living Donor Non-Donation form?**
        Yes, this is a reasonable time frame.

3. Are there any concerns related to barriers to donation or long-term outcomes not addressed among members of the living donor community?

No, barriers to donation are addressed by the current proposed data forms.

4. Do you endorse removal of the current two-year required OPTN follow-up data collection and submission for living donors, to be changed to a voluntary annual follow-up administered by the SRTR (centers are still encouraged to follow up with patients, but no data submission would be required)? Do you endorse the SRTR contacting the patient directly?

We have reservations on the removal of 2-year follow up data requirements on living donors from mandatory and under OPTN purview to voluntary and administered by

the SRTR, with the concern that this may decrease 2-year data at least in the short term. Sufficient data collection requires expansion of the SRTR Living Donor Collective to all living donor transplant centers. If this transition is successful, however, having one body collecting all long-term data would be beneficial. We endorse the SRTR contacting patients directly, as this has been successful in their pilot program.

5. Are there any educational considerations that you believe would be helpful for living donors to understand these potential changes?

Donors should be made aware of how often and by whom they will be contacted and educated as to the use of the provided data and the importance to the transplant community.

Policy: [Establish Comprehensive Multi-Organ Allocation Policy: Request for Feedback]

Executive Summary/General Comments:
The ASTS strongly supports efforts to standardize organ allocation order across match runs and develop a policy solution that standardizes the approach to allocation of organs to multi-organ transplant candidates. We recognize the challenges inherent in this effort, given the absence of a current standard to guide OPOs regarding which match run is completed first and the variability in determining the appropriate order for the match run based on specific donor characteristics. This proposal has identified specific donors which would be eligible for organs offered through this proposed standard approach, which would be inclusive of approximately 98% of the donors currently allocated to and used in multi-organ recipients and cover approximately 78% of the multi-organ recipients receiving organs from those donors.

Donor organs which do not meet the prespecified criteria would be allocated according to OPO preference on which match run order and then to both single organ and multiorgan recipients who appear on those match runs, in the order they appear for whichever organs are not yet allocated. The ASTS recognizes the ambiguities inherent in lung allocation regarding the lung continuous allocation system score which will be finalized and adopted to prioritize lung within this framework.

We recognize the need for pediatric priority for deceased donor kidney transplant and would advocate for a continued focus on this vulnerable group and would support a higher priority than is being proposed. However, we are also concerned that moving kidney-alone candidates (Kidney 6: pediatric, 250 NM) priority *above* Pancreas or Kidney-Pancreas Classification 4 (250 NM) as proposed would potentially choke off pancreas access to a majority of P and K/P candidates (we note that the Pancreas Classifications above Kidney Classification 6 have a median match run appearance of zero each, while P-K/P Classification 4 has a median appearance number of 28.

We appreciate the competing priorities posed by these two vulnerable populations and recognize that compromise is required. An additional population of concern are patients with end-stage renal disease on long-term dialysis who also have cirrhosis but a low MELD score. How this group may access combined liver kidney transplant is not addressed in the current policy. Finally, we note that in cases where expediated placement is required due to donor instability, more potential candidates will be bypassed under this new proposal, which may be of concern with the current focus on reducing out-of-sequence allocations, even if the actual number of donors who require this pathway is not increased.

An additional concern is that intestine transplant candidates are inappropriately omitted from considerations as currently written. Although this is a very small and diverse group of candidates often needing multiple organs with the intestine (stomach, duodenum, pancreas, liver and/or colon), we have observed a significant decrease in the transplantation of intestine containing allografts after prior allocation changes and considerable issues with getting grafts that contain all of the necessary organs for this group of diverse patients. We further recognize that the MELD score is not an accurate assessment of the risk for mortality relative to liver alone transplant candidates and due to the high degree of preservation injury leading to mucosal damage from even

brief periods of ischemia (leading to postoperative translocation of bacteria), there is a limit to the pool of appropriate donors (for example DCD donors or those with long episodes of CPR are not appropriate). We therefore need to prioritize this small group of patients for grafts that are appropriate and not create an allocation system that prevents transplantation of intestine candidates.

Despite these noted concerns, we are overall highly supportive of the proposed policy and recognize the extensive effort required to create this proposal. We understand the OPTN's rationale on lack of modeling and recognize it is unavoidable absence in this particular case because of the absence of historical data points to inform the modeling. We advocate for stringent post-implementation monitoring with a commitment to further revision as required.

Overall recommendation: ASTS supports this proposal.

Considerations for the Community:

1. **Does ASTS support the donors covered by multi-organ allocation?**
   Yes.

2. **Does ASTS support the candidate groups covered by the multi-organ allocation tables?**
   Yes.

3. **Does ASTS support the priority of candidate groups in the multi-organ allocation tables?**
   We have the concerns detailed above regarding potential significant impairment of access for Pancreas-Kidney Pancreas candidates. We understand the dynamic tension between competing vulnerable populations and generally agree with the proposed balance between multi-organ and single organ allocation. We recognize that there will inevitably be some level of disagreement in the community over how to optimize the prioritization of SOT and MOT candidates. We support a standardized and evidence-based system that attempts to balance competing needs and meets a community consensus on validity and equity). In addition, we recommend serious consideration to requiring that kidney alone offers that are prioritized ahead of MOT must be definitively accepted prior to the procurement OR.

4. **Does ASTS support the moving to a "must/must not" offer framework for candidates…… and removing "permissible" multi-organ offers?**
   Yes.

5. **Does ASTS support removing priority for some H-K, LI-K, LU-K and K-P candidates above kidney-alone candidates?**
   Yes, with the caveats noted above in item 3 and in our summary statement.

6. **Does ASTS support the proposed policy on which organs would follow the primary organ on each match run?**
   Yes.

7. **Does ASTS support the proposed revisions to Policy 5.6.D: Effect of Acceptance?**
   Yes.

8. **Does ASTS support the timing for running the allocation plan relative to executing match runs and making offers to primary PTRs?**
   Yes.

9. **Would it be feasible to report HLA Typing prior to generating a multi-organ allocation plan?**
   It would be ideal to have HLA available when generating a multi-organ allocation plan, as this information supports the most informed decision-making and efficient organ placement. However, it is not always feasible to obtain HLA typing in advance due to logistical and timing constraints. As long as the HLA information is available and reviewed prior to final acceptance of the organ(s), this should be considered acceptable and consistent with safe and appropriate allocation practices.

   HLA typing remains meaningful in non-liver cases where a second organ is included, or in the case where unacceptable antigens are present. It should be feasible to report HLA to allow for virtual crossmatch in most cases, but this may be an issue if the center utilizes a physical crossmatch, where donor cells and recipient cells are needed.

10. **What challenges are anticipated if this policy is implemented and how should the OPTN support members to ensure successful implementation and promote compliance?**
    Education in advance of implementation. Education and discussion with transplant programs and OPOs on the upcoming changes are critical to ensure smooth implementation. Discussion should occur at the OPTN Regional meetings to both educate the community and to provide community feedback to the OPTN Committees and Board. Materials to educate transplant professionals on the new scheme should be a part of the policy implementation bundle, so that transplant programs are equipped to educate patients and determine how best to counsel them on their options given their clinical conditions. Stringent monitoring for adverse unintended consequences is required. Existing compliance mechanisms should provide a compliance framework.

11. **Are there other groups or topics that should have additional post-implementation monitoring to help identify and remediate any unintended impacts?**
    All the identified populations listed in 11 a. through 11 e. require stringent post-implementation monitoring.