OPTN Pediatric Transplantation Committee
Lost to Follow-Up & Transfers Workgroup
Meeting Summary
August 28, 2025
Conference Call

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Neha Bansal, MD, Vice Chair

Introduction

The OPTN Pediatric Transplantation Committee's Lost to Follow-Up (LTFU) & Transfers Workgroup (the Workgroup) met via WebEx teleconference on 8/28/2025 to discuss the following agenda items:

1. Discuss LTFU criteria and related policy requirements
2. Data submission expectations after a transfer to non-OPTN provider
3. Data collection changes: Collecting reasons for LTFU designation

The following is a summary of the Workgroup's discussions.

1. Discuss LTFU criteria and related policy requirements

The Workgroup met to continue development of policy requirements related to Lost to Follow-up (LTFU) reporting.

Summary of discussion:

Decision #1: The Workgroup recommended that transplant recipients are reported LTFU to the OPTN after one missed follow-up period (i.e., one TRF with patient status of "not seen") and three failed outreach attempts. Outreach attempts would be required.

Decision #2: The Workgroup recommended requiring transplant hospitals to complete the first and third outreach attempts 150 days apart.

Decision #3: The Workgroup recommended requiring transplant hospitals to wait 30 days following the third attempt prior to reporting a recipient as LTFU to the OPTN.

Determining LTFU criteria

Option 1 proposed that a patient be considered LTFU after one missed TRF (i.e., patient status of "not seen"), provided that at least three outreach attempts using distinct methods are unsuccessful. Members supporting this approach emphasized that one missed TRF allows for earlier identification of patients who may be disengaging from care. It was noted that in most cases, one missed TRF corresponds to approximately one year without clinical contact, which aligns with clinical practice since programs are unlikely to continue prescribing medications to recipients absent for that length of time. Several members felt that waiting longer could result in patients being out of care for too long before any intervention occurs.

The Workgroup acknowledged concerns that one missed TRF may yield false positives, citing data showing approximately 60 percent of patients reported as "not seen" on one TRF are later recaptured for follow-up. To address this, members supported pairing one missed TRF with a higher threshold of

outreach attempts—three being the number most discussed in prior meetings. Members expressed that requiring multiple outreach attempts could reduce the risk of prematurely categorizing patients as LTFU while still enabling earlier detection than a two-TRF model.

Option 2 would have required two consecutive missed TRFs before classifying a patient as LTFU, with fewer outreach attempts required. Members noted advantages to this approach, including reduced administrative burden and decreased likelihood of capturing temporary lapses in follow-up as LTFU. However, concerns were raised that waiting for two missed TRFs would delay LTFU designation by up to two years, given the timing of annual follow-up forms. Some members argued this period was too long for patients to go without contact, especially since coordinators and clinical staff would likely no longer be actively managing these patients by that time.

During discussion, multiple participants expressed preference for Option 1. They highlighted that one missed TRF coupled with three outreach attempts strikes a better balance between timeliness and accuracy. Members reasoned that after a year of no contact, programs should begin intensive efforts to reconnect with patients, and if those attempts fail, reporting LTFU is appropriate. The inclusion of three outreach attempts was viewed as sufficient to account for patients who may initially be unresponsive but could still be reengaged.

As discussion concluded, most Workgroup members supported adopting Option 1.

Requirements for outreach attempts

The Workgroup considered parameters for outreach attempts. Members discussed whether policy should prescribe specific intervals following each attempt or allow transplant hospital discretion over the process for completing outreach attempts. Members considered the balance between creating consistency across programs, ensuring adequate attempts to follow-up and avoiding unnecessary administrative burden.

Several participants cautioned that requiring rigid intervals (e.g., exactly 30 days between attempts) could inadvertently place transplant hospitals out of compliance due to calendar variations, such as February having fewer days. Others emphasized that some flexibility is important because different patient populations may respond better to different communication methods and timelines. The Workgroup leaned toward an approach that sets broad parameters without dictating exact spacing between contacts.

To identify an appropriate timeframe, members discussed options ranging from three months to a full year. Some suggested quarterly outreach over twelve months, but others expressed concern this would extend the process too long, effectively delaying an LTFU designation for nearly two years from the last patient contact. Ultimately, a majority favored six months as a middle ground, providing sufficient opportunity for meaningful outreach while avoiding excessive delays in LTFU reporting.

Building on this, the group recommended requiring a minimum of three outreach attempts over a period of at least six months. They further refined this by agreeing that the first and last attempts should be at least 150 days apart, ensuring outreach is distributed across the six-month period rather than clustered in a short window. Members also added a 30-day period following the final attempt to allow adequate time for the patient to respond before the program designates them as LTFU.

This structure was seen as both practical and enforceable: it ensures persistence in attempting contact, reflects reasonable clinical practice, and avoids penalizing programs for small timing discrepancies. While members debated whether certified letters should be mandated as one of the attempts, most agreed that methods should remain at the discretion of the transplant hospitals, provided at least two different contact modalities are used.

Flexibility in LTFU criteria

During the discussion of outreach intervals and criteria, several members raised whether transplant centers should retain flexibility to report LTFU sooner or later than the proposed standard of one missed TRF with three unsuccessful outreach attempts. One participant noted that the six-month outreach period should be considered a minimum, emphasizing that centers may wish to continue outreach for up to a year at their discretion before designating a patient as LTFU. Another member observed that while policy could set a baseline, programs should have the option to extend efforts depending on circumstances, ensuring that centers are not restricted from attempting longer follow-up if they believe it appropriate.

Successful vs. Unsuccessful attempts

The Workgroup considered whether a definition of "successful" outreach attempt in the context of LTFU reporting. Members reviewed a suggestion to tie success to whether the transplant program is able to complete the next expected TRF. Under this framework, if the recipient contact results in sufficient information to complete the TRF, the attempt would be deemed successful. Conversely, if the transplant program cannot complete the TRF, the attempt would be considered unsuccessful, even if some communication occurred.

Participants discussed scenarios that illustrate the complexity of this definition. For example, if a patient acknowledges by phone that they should return to clinic but does not attend an appointment, the program would remain unable to complete the TRF; in this case, the outreach would be considered unsuccessful despite confirmation the patient is alive. In contrast, at later follow-up intervals where the TRF may require fewer data points, a brief phone call might provide sufficient data to complete the form, qualifying as a successful attempt. Members noted that while this definition introduces some ambiguity, it keeps the focus on the core goal of ensuring TRF data submission.

The group also reflected on how this approach might help prevent a high proportion of patients from initially being classified as LTFU and later reentering follow-up. By defining success in terms of TRF completion, OPTN data collection could better differentiate between temporary lapses in clinical contact and true LTFU. However, it was acknowledged the definition may delay reporting, as programs may need to wait until the next TRF cycle to determine if outreach had been "successful."

Several members emphasized that this definition should apply specifically to true LTFU cases and not necessarily to related data collection elements, such as reasons for LTFU. It was also noted that incorporating additional drop-down fields for reasons (e.g., patient declined follow-up, unresponsive) could help capture nuance beyond the binary successful/unsuccessful distinction.

In conclusion, the Workgroup tentatively agreed to adopt the TRF-based definition of successful outreach while recognizing that the concept may require further consideration as other definitions and data collection elements are developed. Members also anticipated that site surveyors might rely on this definition when reviewing program compliance, underscoring the importance of clear policy language.

Re-instating follow-up

Members then addressed whether transplant hospitals should be required to report to the OPTN for reinstatement of TRF forms if a patient previously reported as LTFU reenters care. In alignment with current requirements to submit TRF forms for "[e]ach recipient followed by the transplant hospital", the group supported requiring reinstatement to maximize data collection. A member emphasized that this requirement should avoid imposing excessive administrative burden, particularly regarding backfilling missed TRFs.

Next steps

The Workgroup will continue refining proposed LTFU reporting criteria at an upcoming meeting.

2. Data submission expectations after a transfer to non-OPTN provider

The Workgroup next discussed discrepancies in existing guidance regarding LTFU in the context of transfers to non-OPTN providers. Current policy requires TRF submission until graft failure or death but does not specify expectations after transfer to non-OPTN providers, and existing guidance language is inconsistent on the matter.

OPTN Guidance on Pediatric Transplant Recipient Transition and Transfer indicates that transplant hospitals remain responsible for TRFs after transfer, while OPTN Data System guidance suggests such patients should be reported as LTFU immediately. It is also noted that OPTN Guidance on Pediatric Transplant Recipient Transition and Transfer contains outdated language related to former OPTN data processes that should be updated as part of this project.

Summary of discussion

Decision #1: The Workgroup recommended that OPTN policy specify recipients are reported as LTFU following transfer to a non-OPTN provider only when follow-up data can no longer be obtained.

Members discussed the implications of these discrepancies. It was noted that a substantial portion of follow-up data currently comes from recipients followed outside of OPTN member hospitals. Per the data request for this project, by five years post-transplant, approximately 10 percent of follow-up data originates from non-transplant providers. If policy required automatic reporting of LTFU upon transfer, this data stream would be lost, creating significant gaps. It was noted that this approach could introduce bias into OPTN data, since recipients who transfer to non-OPTN providers may differ demographically or clinically from those retained at transplant hospitals.

The Workgroup considered an alternative approach: requiring that recipients transferred to non-OPTN providers only be reported as LTFU if the transplant hospital is no longer able to obtain follow-up data from the outside provider. Several members expressed support for this option, noting that it provides needed clarity while allowing flexibility for hospitals with different capacities and relationships with outside providers. They emphasized that it encourages reporting of follow-up data whenever feasible without imposing excessive administrative burden, such as repeatedly contacting community physicians who are unresponsive. One participant described this as a "flexibility" approach—if programs can obtain data, they should report it, but if not, they can designate the patient as LTFU.

There was also discussion of creating a specific reporting category, such as "transferred to non-OPTN provider," to distinguish these cases from true LTFU where no clinical information is available. This was seen as important to differentiate between patients who remain in medical care but outside the OPTN system, and those who are no longer engaged in any follow-up.

In conclusion, the Workgroup recommended that policy specify recipients are reported as LTFU following transfer to a non-OPTN provider only when follow-up data can no longer be obtained, rather than automatically at the point of transfer.

3. Data collection changes: Collecting reasons for LTFU designation

In addition to standardizing LTFU reporting and clarifying responsibility for follow-up data submissions when a recipient can no longer be followed, this project aims to better understand factors contributing

to LTFU designation in OPTN data. The OPTN Pediatric Transplantation Committee proposed adding new data collection on why a recipient is being reported as LTFU.

Summary of discussion

No decisions were made.

The Workgroup reviewed a draft list of potential LTFU reasons to capture data collection, including transfers to non-OPTN providers, patient/family declining follow-up, unresponsiveness to contact attempts, relocation (domestic or international), insurance or financial barriers, geographic challenges, and language barriers. There was some discussion around distinguishing patient versus family decisions, and a suggestion to separate domestic and international relocation. Members also raised questions about whether reasons should be collected as multiple selections and how to account for overlapping factors.

Next steps

The Workgroup will continue to discuss this topic at upcoming meetings.

Upcoming Meetings

- September 25, 2025, 4-5 PM ET, teleconference

Attendance

- **Workgroup Members**
  - Rachel Engen
  - Allen Wagner
  - Rebecca Baranoff
  - Whitney Holland
  - Susan Stockemer
  - Katrina Fields
  - Shawn West
  - Jennifer Vittorio
  - Ryan Fischer
  - Katherine Robinson
  - Jill McCardel
- **HRSA Representatives**
  - N/A
- **SRTR Staff**
  - Avery Cook
- **UNOS Staff**
  - Leah Nunez
  - Matt Cafarella
  - Dzhuliyana Handarova
  - Asma Ali
  - Tory Boffo
  - Nadine Rogers
  - Eric Messick