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Public Comment Proposal

Modification of the Lung Transplant Recipient Follow-up Form (TRF) to Better Characterize Longitudinal Change in Lung Function following Transplantation

OPTN/UNOS Thoracic Organ Transplantation Committee

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Modification of the Lung Transplant Recipient Follow-up Form (TRF) to Better Characterize Longitudinal Change in Lung Function following Transplantation

Affected Policies: *N/A*
Sponsoring Committee: *Thoracic Organ Transplantation*
Public Comment Period: *January 22, 2018 – March 23, 2018*

Executive Summary

The current OPTN/UNOS adult and pediatric lung and heart-lung Transplant Recipient Follow-up form (TRF) collects lung graft function status limited to bronchiolitis obliterans syndrome (BOS).[1] The Thoracic Organ Transplantation Committee (Committee) identified two issues with the way graft function data is collected on the TRF, which limits the utility of this data in the context of chronic lung rejection:

- BOS data collection is outdated, incomplete, and inaccurate
- Restrictive allograft syndrome (RAS) is not collected at all

Therefore, the limited data currently collected does not capture all the prognosis possibilities for declining graft function and may not accurately describe the type of rejection a patient is exhibiting. Chronic lung allograft dysfunction (CLAD) is a broader, more contemporary definition of post-transplant lung dysfunction, encompassing both obstructive and restrictive chronic lung rejection. This proposal will modify the adult and pediatric lung and heart-lung TRFs to align with updated professional definitions. Refining the outcomes data the OPTN collects can better inform future policy.

This proposal aligns with the OPTN strategic goal of improving transplant recipient outcomes by collecting more granular data on lung dysfunction to help inform future policies for improving lung transplant outcomes. In addition, it will more accurately characterize longitudinal change in lung function following transplantation. Finally, examining outcomes other than strictly survival (in particular, quality-of-life measures such as pulmonary function) will be important for patients and for program assessment.

Is the sponsoring Committee requesting specific feedback or input about the proposal?

The Committee requests specific feedback regarding the following questions:

- The Committee is proposing keeping the bronchial stricture question on the 6-month and 1-5 year TRFs. Does the community feel this question is of value? If so, please provide input on how the question could be better asked to elicit more meaningful data regarding this short-term complication. If not, please articulate why.
- The Committee welcomes feedback on how many time intervals should be collected for FEV1, FVC, and FEF25-75.

[1] Meyer KC, Raghu G, Verleden GM, Corris PA, Aurora P, Wilson KC et al. An international ISHLT/ATS/ERS clinical practice guideline: Diagnosis and management of bronchiolitis obliterans syndrome. European Respiratory Journal. 2014 Jan 1;44(6):1479-1503.

- Members are asked to comment on both the immediate and long term budgetary impact of resources that may be required if this proposal is approved. This information assists the Board in considering the proposal and its impact on the community.

What problem will this proposal address?

The current OPTN/UNOS adult and pediatric lung and heart-lung Transplant Recipient Follow-up form (TRF) collects lung graft function status limited to bronchiolitis obliterans syndrome (BOS). The Committee identified two issues with the way graft function data is collected on the TRF, which limits the utility of this data in the context of chronic lung rejection:

- BOS data collection is outdated, incomplete, and inaccurate
- Restrictive allograft syndrome (RAS) is not collected at all

BOS data collection is outdated, incomplete, and inaccurate

Programs may be misclassifying RAS patients as having BOS. The lung transplant community recognizes this new phenotype of chronic lung rejection and has asked UNOS how to report RAS or CLAD generally.[1, 2,3,4,5] This data would provide a more complete picture of lung transplant outcomes and help to inform future policy and other projects. Another issue is that there is subjectivity around BOS reporting.[3] The OPTN simply collects the BOS grade the clinician diagnoses the patient with, as well as forced expiratory volume in one second (FEV1). The TRF does not collect other objective clinical parameters that inform diagnosis of BOS. There also may be some subjectivity in the way the data is asked. The TIEDI form is not programmed to calculate BOS by the relevant clinical parameters reported.

The Committee also recognized that the TRF does not collect information on RAS. This leads to two additional problems: the number of and types of outcomes for patients diagnosed with RAS is unknown; and transplant programs have no clear way to report RAS.

Restrictive allograft syndrome (RAS) is not collected at all

<u>The number of and outcomes for patients diagnosed with RAS is unknown</u>
Because it is a new phenotype of chronic lung rejection and is not reported to the OPTN, there is no data repository for this information. Reporting objective measures that can predict RAS will help inform future policy, as well as help the lung transplant community better understand long-term lung transplant outcomes. It may also be useful in managing RAS.

<u>Transplant programs have no clear way to report RAS</u>
The TRF does not currently collect RAS, and there is no way for transplant programs to report it. The only option if a patient is experiencing RAS is to report “No BOS,” which is not inaccurate, but vague. The program could select “Unknown,” which is not accurate if a patient is diagnosed with RAS. This situation has prompted programs to contact UNOS and question how RAS should be reported. This could lead to variation in how chronic lung rejection is currently being reported.

Consequently, the limited data currently collected does not capture all the possibilities for declining graft function and may not accurately describe the type of rejection a patient is exhibiting. CLAD is a broader, more contemporary definition of post-transplant lung dysfunction, encompassing both obstructive and restrictive chronic lung rejection.[6] This proposal will modify the adult and pediatric lung and heart-lung TRFs to align with updated professional definitions. In addition, refining the outcomes data the OPTN collects can only serve to better inform future policy.

[2] Verleden GM, Vos R, Verleden SE, et al. Survival determinants in lung transplant patients with chronic allograft dysfunction. Transplantation 2011;27(92):703-8.
[3] Sato M, Waddell TK, Wagnetz D, et al. Restrictive allograft syndrome (RAS): A novel form of chronic allograft dysfunction. J Heart Lung Transplant 2011; 30: 735.
[4] Verleden GM, Raghu G, Meyer KC, et al. A new classification system for chronic lung allograft dysfunction. J Heart Lung Transplant. 2014;33:127–33.
[5] Verleden SE, Ruttens D, Vandermeulen E, et al. Restrictive chronic lung allograft dysfunction: where are we now? J Heart Lung Transplant 2014; Nov 11. pii: S1053-2498(14)01440-5.
[6] Woodrow JP, Shlobin OA, Barnett SD, Burton N, Nathan SD. Comparison of bronchiolitis obliterans syndrome to other forms of chronic lung allograft dysfunction after lung transplantation. J Heart Lung Transplant 2010;29:1159–1164.

Why should you support this proposal?

This proposal will modify the data elements captured within the graft function section of the TRF. The elements selected are objective and standardized. They are easily accessible within a patient's medical record for both clinical and non-clinical coordinators and no interpretation is necessary. This format should improve the accuracy and completeness of reporting. In addition, the modifications to the TRF allow for collection of a new phenotype of chronic lung rejection. This information may inform new policy or strategies that may serve to improve long-term survival after lung transplantation. Finally, this data collection effort is justified by the OPTN Principles of Data Collection, which states that "institutional members must provide sufficient data to OPTN to allow it to: a) Develop transplant, donation and allocation policies;… c) determine member-specific performance."

How was this proposal developed?

UNOS has received questions about how to report CLAD and RAS from several transplant programs which prompted the Committee to discuss this issue. The Lung Subcommittee (Subcommittee) discussed this potential project idea during a breakout session during the fall 2016 in-person meeting and was supportive of pursuing it because improving outcomes for lung transplant recipients is a priority in the lung transplant community. Finally, collecting better data can better inform future policy.

The Subcommittee discussed potential barriers to pursuing this project. Data collection projects are scrutinized to ensure they align with the OPTN Principles of Data Collection and there is sound justification to imposing additional administrative burden on members. Additional data reporting can be burdensome to members if data is difficult to obtain or if the data elements require some level of interpretation by a coordinator. In addition, members are sensitive to the amount of time coordinators spend on data entry. Another concern the Subcommittee anticipated was whether the data could be found elsewhere (e.g. in literature). However, the CLAD nomenclature is relatively recent so information is somewhat limited. Finally, the Subcommittee discussed potentially expanding the project scope to include evaluating and potentially changing the acute lung rejection fields on the TRF. These fields can be as vague and incomplete as the chronic lung rejection data fields. If the scope of the project was expanded, this project may take longer than anticipated to complete. The programming cost was already projected to be significant, so cost/benefit was considered. The Subcommittee ultimately decided to prioritize changing the acute rejection fields with other Committee project ideas at a later time.

The Subcommittee collaborated with the Scientific Registry of Transplant Recipients (SRTR) and the OPTN/UNOS Data Advisory Committee (DAC) during the development of the proposed data fields. The SRTR provided insight into how data could be used for outcomes research, in addition to the aforementioned goals of the project. The Subcommittee sought the DAC's input about the data elements proposed and it endorsed the Subcommittee's due diligence in vetting those elements against the OPTN's Principles of Data Collection.

During public comment, the Committee will seek feedback from the OPTN Transplant Coordinator Committee and professional societies, including but not limited to the International Society of Heart and Lung Transplantation (ISHLT) and the American College of Chest Physicians (CHEST). Finally, the Subcommittee welcomes feedback from patients and patient advocacy groups.

The Subcommittee considered multiple data elements on the current TRFs as it developed this proposal, and ultimately is proposing the following changes to the TRF:

- Modify current FEV1 field and add Forced Vital Capacity (FVC) and Forced Expiratory Flow 25–75% (FEF 25–75) fields
    - All elements collected at three time intervals on each TRF
- Modify Bronchial Stricture and Oxygen Requirement fields

Figure 1 shows each data element and whether it is on the current TRF, as well as each element's proposed status on each TRF.

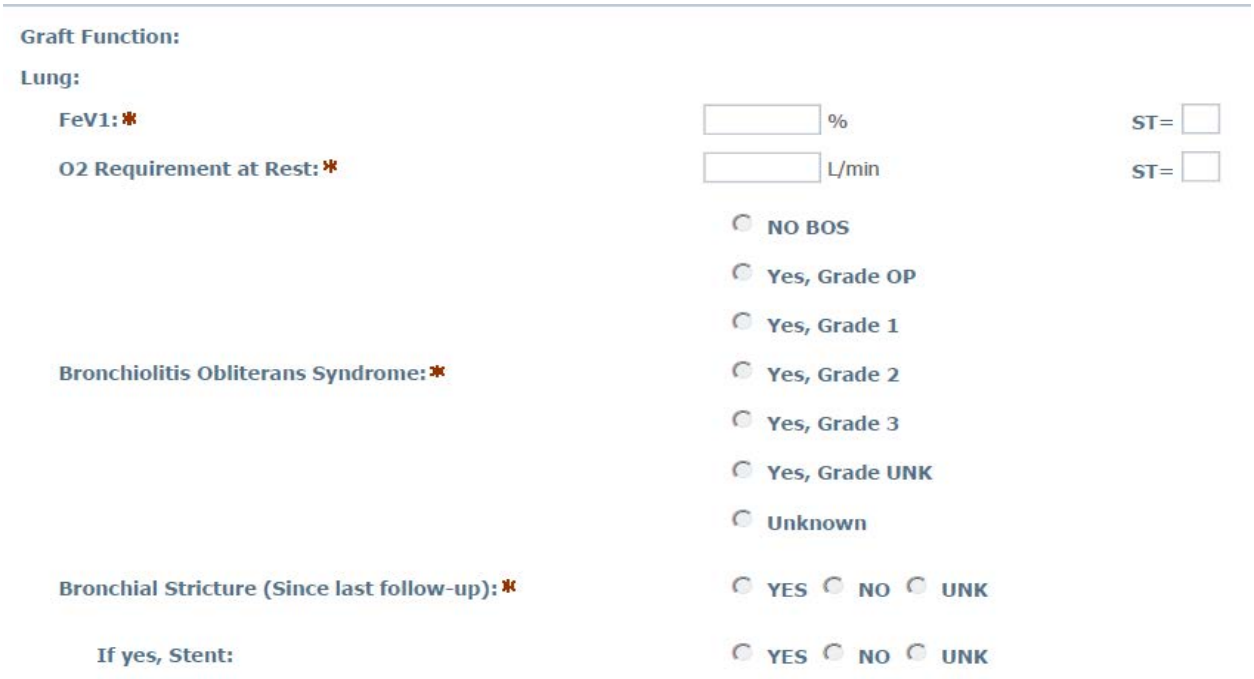
Figure 1: Data Element on Each Adult Lung Transplant Recipient Follow-up Form (TRF)

Element	Current form	6 month form	1-5 TRF	6+ TRF	Interim Forms
FEV 1	Yes	Yes-modified	Yes-modified	Yes-modified	Yes
FVC	No	Yes-New	Yes-New	Yes-New	Yes
FEF25-75	No	Yes-New	Yes-New	Yes-New	Yes
Bronchial stricture	Yes	Yes-modified	Yes-modified	No	
Oxygen requirement	Yes	Yes-modified	Yes-modified	Yes-modified	

Modify current FEV1 field and Add Forced Vital Capacity (FVC) and Forced Expiratory Flow 25–75% (FEF 25–75) Fields

The Subcommittee began by reviewing the current TRFs (Figure 2).

Figure 2: Adult Lung Transplant Recipient Follow-up Form (TRF)



The Subcommittee agreed on collecting FEV1 and FVC values, while one member raised the possibility of recording creatinine and another proposed collecting a range of pulmonary function test (PFT) values over a certain timeframe. The Subcommittee settled on collecting FVC, FEV1, and the FEV1/FVC ratio. These three data points would also enable the detection of patients who develop obstructive versus restrictive CLAD.[3] The Subcommittee discussed whether to gather data for percent predicted for FEV1, but agreed not to because percent predicted can be calculated using other data already collected on the

forms, such as height, race, date of birth, and gender. The Subcommittee felt that requesting data for percent predicted could negatively affect the data, as well as add unnecessary work for those filling out the forms.

Since the Subcommittee agreed that the FEV1 and oxygen requirements were pertinent to the CLAD definition and should be retained, it focused on the BOS data field. The Subcommittee discussed possible reasons for inconsistency in data reporting, such as:

- Transplant program staff may be utilizing different definitions of BOS
- Non-clinical coordinators might not understand what BOS is
- It can be difficult even for experts to classify people correctly due to symptoms
- Definitions of disorders change over time; BOS itself used to be considered an irreversible airway disease
- There might be logistical issues contributing to the inaccuracy, such as difficulty in locating pertinent information in patient charts

The group quickly came to consensus that this field may be prone to subjectivity based on the way it is being asked, and agreed to evaluate further.

To determine the accuracy and completeness of data currently collected on the TRF, the Subcommittee requested data showing the distribution of responses to the BOS field on the TRF generated and validated 1-5 years post-transplant, by form anniversary type (1 year – 5 year, Death, and Graft Failure forms). In addition, Subcommittee members requested the number of lung transplant recipients that progressed to higher BOS stages as represented through the follow-up reporting and the types of progressions that were reported. Table 1 provides a summary of the number of increases reported in BOS status by max status reported for adult lung alone transplant recipients from 2009 through 2015. Table 2 summarizes the number of decreases reported in BOS status by max status reported for the same cohort.

Table 1: Number of Increases Reported in BOS Status by Max Status Reported

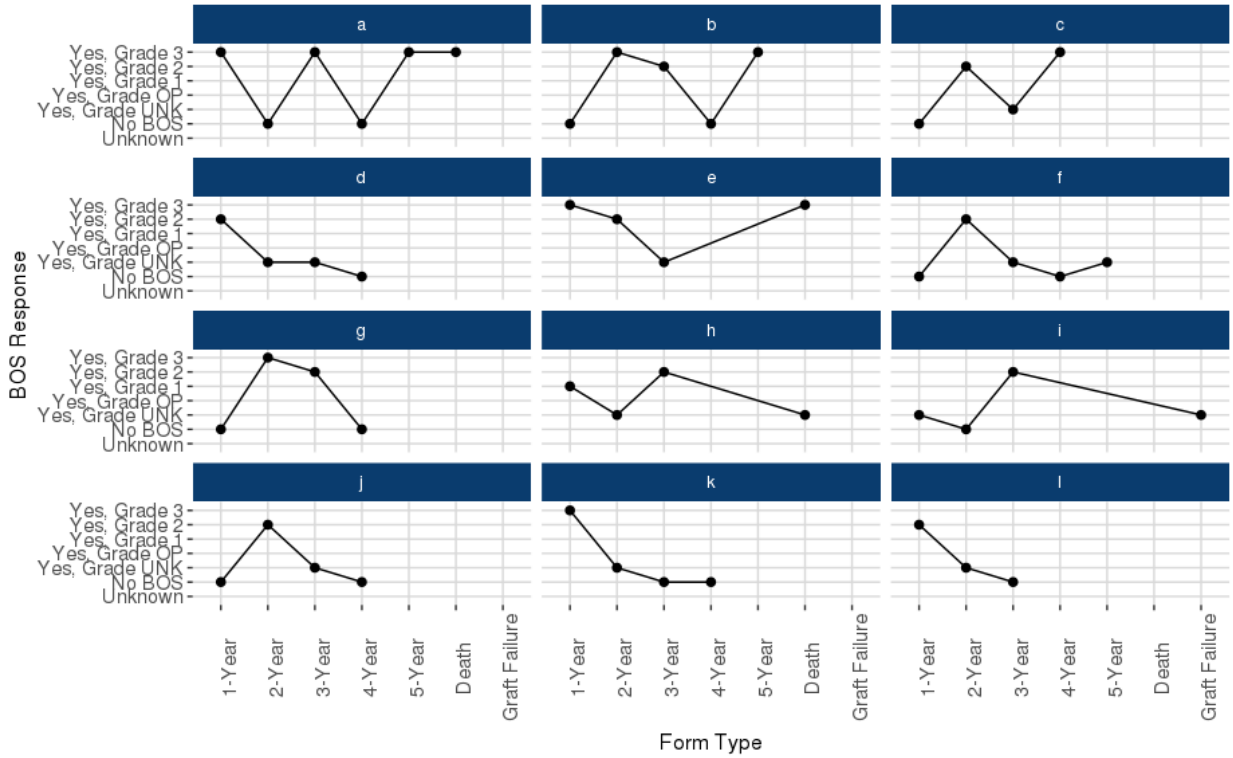
	0	1	2	3	Total
Grade OP or UNK	391	1366	52	0	1809
Grade 1	105	407	100	7	619
Grade 2	53	206	110	8	377
Grade 3	116	493	245	19	873
Total	665	2472	507	34	3678

Table 2: Number of Decreases Reported in BOS Status by Max Status Reported

	0	1	2	Total
Grade OP or UNK	1146	647	16	1809
Grade 1	338	255	26	619
Grade 2	246	113	18	377
Grade 3	674	181	18	873
Total	2404	1196	78	3678

At least one decrease in BOS status was reported for 34.6% of adult lung alone transplant recipients that ever had a post-transplant positive BOS from 2009 through 2015. Below, Figure 3 shows BOS reporting for randomly selected individuals with a max BOS reported as at least Grade 2 and at least two decreases reported.

Figure 3: Randomly Selected Individuals to Depict the Variation in BOS Reporting



This data illustrates the inconsistency in data reporting for BOS on the current TRF. The evidence shown in the analysis supports the claim that the current subjective criteria that is collected on the TRF using the BOS field does not always adequately represent the staging of rejection in lung transplants. Trends shown in this report indicate that centers likely do not see the progression through BOS stages the same way, and the data is not collected consistently within each center or patient year to year. The Subcommittee felt this evidence supports efforts for more precise data collection focused on objective data fields, including FEV1 and FVC.

Subcommittee members discussed whether it would be sufficient to collect very general information, similar to how BOS is currently collected, or whether there is more value in collecting more granular data. While simply asking whether the patient has CLAD and then selecting “BOS” or “RAS” could be adequate, collecting high-level information is vulnerable to the same subjectivity issues as the way BOS is currently collected. The data may end up being too broad to be useful for future policy development. Some members favored more specific data elements, and perhaps even programming UNet^{SM} to calculate BOS (or RAS). This would enable the OPTN to better monitor changes over time, especially if the condition was calculated rather than reported by a data coordinator. Subcommittee members acknowledged that increased data collection and reporting may not be well received by the community, but if the community believes in the value of having this information that might mitigate concerns over the administrative burden.

Due to the problems associated with collecting high level BOS and RAS data, the Subcommittee reached consensus to instead modify the way in which forced expiratory volume in one second (FEV1), forced vital capacity (FVC), and FEV1/FVC ratio are collected. Subcommittee members generally agreed that most centers do not collect total lung capacity data on a regular basis; rather, this data is collected only if there is a specific issue. Programs tend not to collect this data because of the high volume of patients, which makes it difficult to get PFTs done in clinic. As a result, including a total lung capacity field might pose a problem. The Subcommittee considered collecting total lung capacity if there is chronic decline, but there was consensus not to add this element.

The Subcommittee opted to replace FEV1/FVC ratio with forced expiratory flow during middle one half of the FVC (FEF25-75). The members agreed that the FEV1/FVC ratio doesn't need to be requested since

the system can calculate it based on provided information. Participants debated the relevance of confounding conditions that may affect proposed data points in establishing a CLAD diagnosis, including reflux/fundoplication surgery, airway stenosis, and the presence of an infection on the date of PFT collection. The Subcommittee agreed that information about fundoplication surgery likely doesn't need to be collected. The Subcommittee also agreed that both airway stenosis and infection represent reversible conditions whereas CLAD is a progressive syndrome. Ultimately, the Subcommittee agreed on collecting FEV1, FVC, and FEF25-75 on each TRF in place of the current BOS field.

Modify Bronchial Stricture and Oxygen Requirement Fields

The Subcommittee evaluated whether to keep the remaining two questions from the *Graft Failure* section of the TRF:

- "Bronchial Stricture (since last follow-up)"
    - "If yes, stent?"
- "O2 Requirement at Rest"

Subcommittee members asked whether members were currently reporting this data, as at least one member indicated the O2 requirement at rest wasn't being utilized. The Subcommittee member advocated eliminating it if the data is not purposeful. SRTR shared that it does not use it in the annual data report, but thought that investigators do use it in survival analyses. The Committee discussed whether to modify or remove the "bronchial stricture" and the oxygen at rest questions. While these data elements don't directly contribute to the lung allocation score (LAS), they can help identify risk factors that do inform the LAS.

The Subcommittee requested information on complete data reporting for bronchial stricture and oxygen requirement at rest on the TRFs to aid in the discussion of the project. For bronchial stricture reporting, Figure 4 demonstrates that data showed a gradual increase in missing values and therefore a decrease in reported values across the year 1-5 TRFs.

Figure 4: Bronchial Stricture Data Completeness

Form	Missing (%)	Recorded Value (%)
1-year	1.4	98.6
2-year	1.6	98.4
3-year	2.6	97.4
4-year	4.1	95.9
5-year	5.0	95.0
Death	16.7	83.3
Graft failure	12.2	87.8

A majority of responses for this question were "no," with a higher percentage of affirmative responses reported on the 1-year TRF and a decreasing trend over time. Bronchial stricture reporting dropped noticeably at the time of reporting death or graft failure. For O2 requirement at rest, Figure 5 shows that within 5-years of transplant for all adult lung alone transplants 2009-2015, approximately 20% of values were missing.

Figure 5: O2 at Rest Data Completeness

Form	Missing (%)	Recorded Value (%)
1-year	18.3	81.7
2-year	18.6	81.4
3-year	19.4	80.6
4-year	18.9	81.1
5-year	19.4	80.6
Death	41.1	58.9
Graft failure	22.1	77.9

The Subcommittee also viewed variation in reporting oxygen requirement at rest. Data indicated a majority of programs complete this field, and only an outlying minority account for 20% of the missing data. Finally, data showed that the oxygen requirement at rest increased over time.

The Subcommittee discussed the possible implications of the data reported.

Bronchial Stricture

The Subcommittee acknowledged that the response options for “bronchial stricture” (“yes,” “no,” or “unknown”) were not entirely useful, and may not be the best choices for this condition. Since strictures typically occur early post-transplant, it may only be logical to retain the question on the 6-month and 1 year TRF. The data presented supports this idea. UNOS staff encouraged the Subcommittee to keep the 1-5 year TRF standardized to the extent possible.

There was some debate on whether to only capture stenosis on the 6-month form, not capture it at all, or capture it for a limited time beyond 6-months (1 or 2 years). When evaluating for chronic lung rejection, ruling out presence of bronchial stricture is required. One member mentioned that ISHLT might be examining stenosis more critically to better define and report it. The group acknowledged that multiple factors could impact strictures, such as the surgery itself, ex vivo lung perfusion (EVLP), or recipient factors. While it may not impact survival, it does interplay with quality of life and lung function. The Committee agreed that the way the bronchial stricture questions were asked likely contributed to the inability to interpret the data and the question in its current form should be eliminated. However, the Committee could not come to consensus on how to reword the question, so it instead proposed retaining the field, but asking the community for feedback about how to word this question during public comment.

Oxygen Requirement at Rest

The Subcommittee was interested in data for oxygen requirement at rest. There was consensus that this variable is important, as supplemental oxygen need may be used in survival analyses and should be retained. For example, oxygen requirement may be indicative of medical urgency: one member gave the example of a patient who did not need oxygen at rest, but did with exertion. The Subcommittee believed the question needed to be modified to elicit more meaningful information. One member suggested that the “at rest” information may be subjective, since it may be self-reported, the actual need at the time of the clinic visit, what is prescribed, or what is required on a six minute walk test. One member suggested mirroring how the question is asked upon registration by eliciting what the oxygen requirement is at rest and with exercise. Several members commented that additional clarification would be helpful to coordinators (e.g. room air = 0 L/min). There was consensus to keep the oxygen at rest field because it is important for survival analysis, but the Committee agreed to add additional fields under oxygen requirement: at rest and with exercise.

Data Element Review

The Subcommittee walked through the Data Advisory Committee's Data Element Standards of Review to ensure that a strong case could be made to request modification to the TRF fields. These questions may come up during the Policy Oversight Committee's review or during public comment.

Figure 6: Data Element Standards of Review Analysis

Component or Measure	Criteria & Response
OPTN Data Collection Principles	*Is the proposal for collection of this element consistent with at least one of the principles?* Yes, the Subcommittee confirmed the purpose for collecting new data elements is to inform future policy.
Purpose, Population and Outcomes	*Have the purpose, population, and intended outcomes of collecting this element been clearly articulated?* The Subcommittee vetted the problem, impacted population, and intended outcomes of collecting new data at a previous meeting. Subcommittee members agreed that the data is being collected in a way that isn't interpretable, so the goal is to optimize the data that is already being collected.
Definition and Reliability	*Is the data element definition sufficiently clear to enable consistent entry? Is the element and collection mechanism designed to consistently reproduce the same results? Are there variations in interpretation that would reduce the utility?* The proposed elements are objective and consistent across all programs, thus minimizing confusion.
Face Validity	*Is the element capable of eliciting the data we seek? Is the data a proxy for the concept you're trying to measure?* The proposed data elements are included in the definition of CLAD.
Availability	*Is this element widely available for the population of patients for which it is sought to be collected?* All of the proposed elements are consistently collected and reported by transplant centers.
Alternative Data Sources	Have alternatives to collecting this by the OPTN been explored? Is this element already available via an external source? *There are no alternatives to collecting it directly from the patient population.*

During the data review, the Subcommittee posited that the Yes/No variable for BOS scoring is likely correct, but the grading may need adjusting to attain more consistent reporting among centers. The Subcommittee was in agreement that any data that needs interpretation before being captured is less reliable. To determine who has BOS with some degree of confidence, data needs to be objective rather than subjective. Therefore, it was suggested that rather than asking for a BOS diagnosis on the forms, a better approach might be to ask for raw numbers at certain timeframes. UNet could then calculate when patients meet BOS criteria. By taking the subjectivity out of data collection, this approach would make it easier for nonclinical staff, such as data coordinators, to enter information accurately. It would also make data reporting more efficient. Finally, this approach could also use the raw data collected to refine definitions of both RAS and BOS.

The OPTN/UNOS Data Advisory Committee (DAC) provided feedback to the Lung Subcommittee on November 8, 2017. As a result of their review, there was no substantive feedback on necessary changes. DAC members found the proposal to be thoroughly vetted with well-selected data fields that could inform future policy. However, the DAC did note that the status (ST) drop-down field, which permits a program to enter "unknown," could lead to unclear data. The DAC did acknowledge that this field is used across all forms and organ-types, thus modifying it should be part of a larger effort.

Pulmonary Function Tests

During proposal development, the Subcommittee discussed additional ways to utilize PFT data. One idea was to have UNet calculate whether the values indicated BOS or RAS from baseline PFT results which would consist of two highest values for FEV1, FVC and FEF25-75, collected at least three weeks apart. These values would then carry forward to subsequent TRFs. Members wanted these fields to be editable, so they could be updated if the patient had higher values in year two (versus year one). Members proposed another field to collect the most recent PFT values, closest to the patient's anniversary. In subsequent years, these fields (baseline + most recent values) would pop up and ask whether the patient's highest PFTs have changed or not.

The Subcommittee also revisited a previous decision regarding having more recent spirometric values replace the initially reported baseline values if they are greater. On the 6-month TRF, programs would report the two highest values of FEV1, FVC and FEF25-75, collected at least three weeks apart post-transplant regardless of test date. These will be considered the baseline values. On subsequent forms, the two highest values previously reported would carry over, and programs would report the "most recent" data for FEV1, FVC and FEF25-75. If more recent spirometric values were greater than the previous highest baseline values, the new value would adjust to become the new baseline. Although there was some consensus during a previous meeting that operationalizing this decision was making programming too complicated and could potentially impact the accuracy of the data, the Subcommittee made the decision to proceed with this idea.

UNOS staff and SRTR questioned the Subcommittee's rationale behind UNet performing this analysis function. From a programming and data analysis perspective, UNOS staff recommended keeping functionality simple and only collect the data. They questioned the value of having UNet perform this analyses, and what value coordinators would get out of viewing updated baseline values. SRTR shared concerns about having UNet perform any type of analyses based on these data elements. Only including the "best" PFT values runs the risk of skewing the data so outcomes look better than they are early on post-transplant and perhaps worse later. Including only the "worst" PFTs would be subject to the same bias. If data is collected in an organized way with well-defined data points at well-defined intervals, the overall behavior of the group will be detected in a large cohort. Choosing the "best" or "worst" PFTs would dilute the value of the data especially in a case like CLAD where definitions are evolving. SRTR suggested collecting data at additional points in time, such as 2-4 time intervals for the second year and beyond. These data points would be the data collected closest to each respective time interval.

The Subcommittee agreed that reporting "best" or "worst" values may introduce additional administrative burden for coordinators and may bias results. One Subcommittee member asked whether reporting values from an internal transplant center lab versus an outside lab would lead to variability. Other members noted spirometry testing was reproducible and standardized so that might not be an issue. A potential solution to mitigate this concern is to limit reporting PFT values to those collected by the transplant center.

A Committee member asked how the peak PFT results would be captured. The Lung Subcommittee Chair explained that the Subcommittee debated asking for peak PFT results, but felt that the result would be biased if just the best results were reported. Asking for results across several time intervals should capture peak results, but perhaps not on an individual level.

After these discussions, the Committee agreed not to have UNet calculate BOS or RAS in the background. Calculations of BOS or RAS from the raw data could be part of the post-implementation evaluation, but these will not display on the TRFs.

Time Intervals

The Subcommittee proposed collecting dates for these values, although this is not current practice on TIEDI forms. Dates are informative by providing information on time to peak spirometric values, or may identify how many recipients have their best lung function several years after transplantation. If dates are not collected, more assumptions may have to be made (e.g. on an annual form, an assumption might be that the values were obtained on the date of form submission). Collecting dates could provide more granularity, accuracy, and consistency. From an outcomes perspective, the Subcommittee may be interested in the rate of decline in FEV1 as a predictor of death; if so, it is best to collect dates.

The Subcommittee agreed that discussion around operationalizing the best values and replacing old values in the system was making the reporting and programming too complicated. Asking coordinators to retrospectively determine the best values may be an added layer of administrative burden that could potentially impact the accuracy of the data. A member suggested adding an extra standardized point in time during which programs report data; this would standardize reporting and add additional data points to analyze. For example, on the one-year TRF, programs would report values at 9 and 12 months; on the 2-year TRF, they would report values from 18 and 24 months, etc. Dates would still be captured. This would also address the Subcommittee's concerns regarding collecting very limited data (annual reporting).

The Subcommittee debated including two, three, or four time intervals on each form. Subcommittee members were sensitive in attempting to balance the administrative burden of reporting PFT values at multiple time intervals with getting useful data. One suggestion was to collect more data immediately post-transplant (1- and 2-year TRF) as that is when patients experience the most variability in lung function. Members acknowledged this made sense as most patients perform frequent testing in the first year, with a decreased frequency over time if the patient is stable. However, if a clinician detects a change or decline in lung function, testing will increase. In addition, early changes (<1 year) in lung function are not likely to be associated with CLAD.

After additional discussion, the Subcommittee determined that since the TRF is a government-approved form, it is best practice to keep the data fields as standardized as possible. In light of these limitations, there was broad consensus to include at least two time intervals on each form. Coordinators are likely to support reporting of simple raw data rather than an interpretation or attempting to list the "best" values. The Subcommittee ultimately compromised on three time intervals. The group acknowledged that the further out from transplant the patient is, the more likely the coordinators may not be able to report three data points. The Subcommittee was okay with this as long as at least two values were reported. The group agreed to include three time intervals on the 6-month TRF and the 6+ year TRFs. There was strong consensus to include a detailed explanation of the time intervals, as the labels should be standardized across the forms. UNOS staff confirmed this information could be included in UNet Help Documentation and possibly on the form itself.

The Committee voted unanimously to approve the proposal for public comment in spring 2018 (13 Approve, 0 Oppose, 0 Abstentions).

How well does this proposal address the problem statement?

This proposal makes better use of the lung graft function data fields by utilizing data already available through PFTs. By modifying existing fields and adding FVC and FEF25-75, the data will better characterize longitudinal changes in lung function following transplantation.

Which populations are impacted by this proposal?

This proposal impacts information collected for all recipients post lung or heart-lung transplant. Table 7 shows the number of lung and heart-lung transplants performed in 2017:

Table 7: Number of Lung and Heart-Lung Transplants Performed from January 1, 2017 to December 31, 2017 by Recipient Age

Age	Lung	Heart-Lung	Total
< 18 Years	44	1	45
18 + Years	2405	28	2433
Total	2449	29	2478

How does this proposal impact the OPTN Strategic Plan?

Increase the number of transplants: There is no impact to this goal.

Improve equity in access to transplants: There is no impact to this goal.

Improve waitlisted patient, living donor, and transplant recipient outcomes: This proposal collects more granular data on lung dysfunction to help inform future policies for improving lung transplant outcomes.

Promote living donor and transplant recipient safety: There is no impact to this goal.

Promote the efficient management of the OPTN: This may increase efficient management of the OPTN in that it should reduce the number of questions the OPTN fields about how to report RAS.

How will the OPTN implement this proposal?

This proposal will require an additional public comment posted in the Federal Register sponsored by the Health Resources and Services Administration (HRSA) to adhere to the Office of Management and Budget's guidelines for collecting additional information. This proposal requires programming in UNet^{SM} as it involves modification of TIEDI forms. The 6-month, 1-5 year, and 6+ year TRFs will be modified for both adult and pediatric lung and heart-lung. Changes will also be made to interim forms.

This proposal may require an instructional program and will be monitored for specific needs throughout development and implementation to determine the appropriate education for members.

The OPTN will follow established protocols inform members and educate them on any policy changes through Policy Notices posted on the OPTN website and in Transplant Pro.

How will members implement this proposal?

This proposal will impact lung and heart-lung transplant programs.

Transplant Hospitals

Upon implementation, transplant programs will be required to provide new graft function data to the OPTN for all adult and pediatric lung and heart-lung transplant recipients on the relevant TRF. Administrative burden is mitigated by the fact that the new data elements are standard measures obtained during PFT and readily obtainable to both clinical and non-clinical data coordinators in medical records. Minimal staff training may be required.

Will this proposal require members to submit additional data?

Additional data collection of FVC and FEF25-75 will be required as a result of this proposal. This data collection effort is justified by the OPTN Principles of Data Collection, which states that "members must provide sufficient data to OPTN to allow it to: a) Develop transplant, donation and allocation policies;… [and] c) determine member-specific performance." These data elements are accessible within a patient's medical record for both clinical and non-clinical coordinators and no interpretation is necessary.

How will members be evaluated for compliance with this proposal?

The proposed language will not change the current routine monitoring of OPTN members. Any data entered in UNet may be subject to OPTN review, and members are required to provide documentation as requested.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

This proposal is designed to capture information about the longitudinal change in lung function in transplant recipients. The data fields were developed to be an improved marker of post-transplant lung function and allow for a broader understanding of graft failure. Summaries will be provided at approximately 6 months after implementation, and then annually thereafter as part of the review of the LAS system for 2-3 years as the Committee sees fit. A summary of the five data elements, including monitoring their use, will be provided for lung transplant recipients following implementation of the TIEDI form changes. As requested, calculations of BOS and RAS will be performed using the collected data. Tabulations of the number of patients with BOS and RAS will also be reported. These will be provided overall and by form type when possible.