# OPTN

## *Public Comment Proposal*

# Modify Lung Donor Data Collection

*OPTN Lung Transplantation Committee*

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## Contents

# OPTN

# Modify Lung Donor Data Collection

*Sponsoring Committee:*      *Lung Transplantation*
*Data Collection Affected:*      *OPTN Donor Data and Matching System*
                       *Data System for OPTN*
                       *OPTN Waiting List*
                       *Lung Offer Filters*
*Public Comment Period:*      *January 21, 2025- March 19, 2025*

## Executive Summary

The purpose of this proposal is to promote efficiency of lung allocation by considering changes to OPTN data collection to make it easier for lung programs to respond to lung offers. This proposal aims to streamline communication and information sharing between Organ Procurement Organizations (OPOs) and lung transplant programs as lung transplant programs consider organ offers. **Table 1** shows a summary of the Lung Committee's (the Committee) proposed data changes.

**Table 1. Overview of proposed data changes**

| OPTN Donor Data and Matching System | Deceased Donor Registration (DDR) | OPTN Waiting List | Lung Offer Filters |
|---|---|---|---|
| Add ||||
| • History of Smoking<br>  o Cigarette Smoking History<br>    ▪ Calculation of pack years based on data inputs<br>  o Vape Use History<br>  o Marijuana Smoking History<br>• Peak Inspiratory Pressure (PIP) | • Cigarette Smoking History | • Acceptable donor Predicted Total Lung Capacity (pTLC) range | • Donor cigarette use exceeds |
| Remove ||||
| • Cigarette use (>20 pack years) ever<br>  o And continued in the last six months | • Cigarette use (>20 pack years) ever<br>  o And continued in the last six months | • Accept a donor with cigarette use > 20 pack years ever? | |
| Modify ||||
| • Diagnostic Test Status | | | |

# Purpose

The purpose of this proposal is to promote efficiency of lung allocation by considering changes to OPTN data collection to include the information necessary for transplant programs to respond to lung offers. This proposal aims to streamline communication and information sharing between OPOs and lung transplant programs as lung transplant programs consider organ offers.

# Background

Since the implementation of continuous distribution of lungs in March 2023[1], the Committee has engaged in policy efforts that aim to increase efficiency in lung transplantation.[2] These efforts include the introduction of Lung Offer Filters, new data collection for evaluating offers, and system enhancements to help streamline the allocation process for OPOs and transplant programs. In December 2024, the OPTN Board of Directors approved *Promote Efficiency of Lung Donor Testing*, which will change requirements in *OPTN Policy 2.11.D: Required Information for Deceased Lung Donors* and *Guidance on Requested Deceased Lung Donor Information* once implemented[3] The development of *Promote Efficiency of Lung Donor Testing* was the Committee's response to the community after hearing transplant programs' concerns about the currency and completeness of information in the organ offers they receive. Most often members stated that the donor data available at the time they are expected to review and respond to lung offers is outdated or incomplete. *Promote Efficiency of Lung Donor Testing* aimed to bring more standardization to lung offers by proposing policy updates that require relevant and timely donor information that make it easier for lung transplant programs to make decisions about organ offers.

While the *Promote Efficiency of Lung Donor Testing* proposal addressed policy requirements and guidance, *Modify Lung Donor Data Collection* addresses data collection aimed to improve efficiency during the lung offer and allocation processes. The Committee proposes additional and updated data collection that would provide lung programs with crucial information for making decisions on lung offers. Additionally, the Committee proposes innovative new features to the OPTN Computer System to filter and screen lung donors, in addition to streamlining communication between OPOs and programs.

# Overview of Proposal

The Committee proposes the addition of new data collection to include History of Smoking (Cigarette Smoking History, Vape Use History, Marijuana Smoking History), Peak Inspiratory Pressure (PIP), and Acceptable donor Predicted Total Lung Capacity (pTLC) range. The Committee proposes modifying current Diagnostic Testing data collection by adding Diagnostic Test Status. Additionally, the Committee proposes an addition to Lung Offer Filters, which would allow programs to bypass offers with donors that exceed a cigarette pack year threshold of their choosing. Lastly, the Committee proposes removing the data fields that indicate if a donor smoked greater than 20 pack years and if the program would

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[1] "Establish Continuous Distribution of Lungs," OPTN, Policy Notice, available at https://optn.transplant.hrsa.gov/media/b13dlep2/policy-notice_lung_continuous-distribution.pdf.
[2] "Promote Efficiency of Lung Allocation", OPTN, Policy Notice, accessed November 20, 2024, https://optn.transplant.hrsa.gov/media/sbvpaop1/lung_efficiency-of-lung_june-2024_pn.pdf.

accept a donor with greater than 20 pack years smoking history.[4] This cigarette smoking data collection is proposed for removal because it is being replaced with the proposed cigarette smoking data collection which aims to be more comprehensive and provide additional utility for screening.

## OPTN Donor Data and Matching System

**Table 2** displays the proposed data collection changes to the OPTN Donor Data and Matching System for deceased lung donors, including History of Smoking (Cigarette Smoking History, Vape Use History, Marijuana Smoking History) in addition to PIP and Diagnostic Test Status.

**Table 2. Proposed changes to OPTN Donor Data and Matching System**

| Action | Data Field | Child Field | Response Option/ Data Entry Description |
|---|---|---|---|
| **Add** | History of Smoking | | <ul><li>Yes</li><li>No</li><li>Unknown</li></ul> If Yes- <ul><li>Cigarette Smoking History</li><li>Vape Use History</li><li>Marijuana Smoking History</li></ul> |
| **Add** | | Cigarette Smoking History | <ul><li>Current cigarette smoker</li><li>Former cigarette smoker</li><li>Never smoked cigarettes</li><li>Cigarette smoking history unknown</li></ul> If Current cigarette smoker, or if Former cigarette smoker- <br><br>Frequency of cigarette smoking: <ul><li>Packs per day</li><li>Cigarettes per day</li><li>Unknown</li></ul> How many years did the donor smoke?: <ul><li>Enter years in open text field</li><li>Unknown</li></ul> Cigarette pack years calculated and displayed. |
| **Add** | | Vape Use History | <ul><li>Current vape user</li><li>Former vape user</li><li>Never vaped</li><li>Vape history unknown</li></ul> |

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[4] See Lung Transplantation Committee meeting summary, November 14. 2024. Available at https://optn.transplant.hrsa.gov/media/2ode2rtz/20241114_lung_summary.pdf

| Action | Data Field | Child Field | Response Option/ Data Entry Description |
|---|---|---|---|
| | | | If Current vape user or Former vape user- <br><br> Frequency of vape use <br> • Every day <br> • Every week <br> • Less than weekly <br> • Unknown <br><br> How many years did the donor vape?: <br> • Enter years in open text field <br> • Unknown |
| Add | | Marijuana Smoking History | • Current marijuana smoker <br> • Former marijuana smoker <br> • Never smoked marijuana <br> • Marijuana smoking history unknown <br><br> If Current marijuana smoker or Former marijuana smoker- <br><br> Frequency of marijuana smoking: <br> • Every day <br> • Every week <br> • Less than weekly <br> • Unknown <br><br> How many years did the donor smoke?: <br> • Enter years in open text field <br> • Unknown |
| Add | Peak Inspiratory Pressure (PIP) | | Enter PIP in open text field in centimeters of water pressure (cm $H_2O$). |
| Modify | Diagnostic Test Status[5] | | Select test status: <br> • Complete <br> • Pending (awaiting result) <br> • Unable to complete <br><br> If status is Unable to complete, select all reasons that apply: <br> • Capacity/workflow issue <br> • Proxy refusal <br> • Expertise issue <br> • Equipment issue <br> • Other, specify - free text |
| Remove | Cigarette use (>20 pack years) ever | | • Yes <br> • No |

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[5] Diagnostic tests include Angiography; Bronchoscopy; Cardiac catheterization; Chest x-ray; CT/MRI; Echocardiograms; EKGs; Ultrasounds; Other specify.

| Action | Data Field | Child Field | Response Option/ Data Entry Description |
|---|---|---|---|
|  |  |  | • Unknown<br><br>If yes- And continued in the last six months?:<br>• Yes<br>• No<br>• Unknown |

*Add*

### History of Smoking

The Committee proposes adding more granular data collection on Cigarette Smoking History. They also propose adding new data collection on Vape Use History and Marijuana Smoking History. Though difficult to quantify, donor Vape Use History and Marijuana Smoking History are clinically relevant for offer evaluation and would expand research on the impact of donor smoking history on post-transplant outcomes.[6, 7]

If yes is selected for the History of Smoking field, additional fields will ask the user to indicate cigarette smoking history, vape use history, and marijuana smoking history.

### Cigarette Smoking History

The Committee proposes data collection on Cigarette Smoking History to include donor smoking status (current, former, never, unknown). If the donor is a current or former cigarette smoker, the OPO will be required to enter frequency of cigarette smoking (packs per day, cigarettes per day, unknown) and years the donor smoked (open text field, unknown). The Committee proposes that if both the frequency and years fields are completed with responses that are not unknown, the OPTN Donor Data and Matching System will automatically calculate the number of pack years the donor smoked.[8]

Currently, the OPTN Donor Data and Matching System captures whether a donor smoked for greater than 20 pack years and if cigarette smoking had continued in the last six months. Promote Efficiency in Lung Allocation Workgroup (Workgroup) members from lung transplant programs reported that this information is unhelpful in evaluating offers. To be more clinically valuable, lung transplant program representatives expressed the need for additional detail on the number of pack years a donor smoked.[9] Initially, the Workgroup discussed capturing donor cigarette smoking history in smaller pack year categories with data collection that would allow an OPO to indicate if the donor had a cigarette smoking history of less than 5 pack years, 5-10 pack years, 10-20 pack years, 20-30 pack years, 30-40 pack years, or greater than 40 pack years.[10] Ultimately the Committee recommends collection of the raw data to

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[6] See Promote Efficiency of Lung Allocation Workgroup meeting summary, June 11, 2024, available https://optn.transplant.hrsa.gov/media/jiifq0ws/20240611_lungefficiencywg_ms.pdf.

[7] Rappaport JM, Siddiqui HU, Thuita L, Budev M, McCurry KR, Blackstone EH, Ahmad U; Cleveland Clinic Lung Transplantation Center. Effect of donor smoking and substance use on post-lung transplant outcomes. J Thorac Cardiovasc Surg. 2023 Aug;166(2):383-393.e13. doi: 10.1016/j.jtcvs.2023.01.028. Epub 2023 Feb 7. PMID: 36967372.

[8] See Lung Transplantation Committee meeting summary, November 14, 2024, available https://optn.transplant.hrsa.gov/media/2ode2rtz/20241114_lung_summary.pdf

[9] See Lung Transplantation Committee meeting summary, June 11, 2024, available https://optn.transplant.hrsa.gov/media/jiifq0ws/20240611_lungefficiencywg_ms.pdf.

[10] Ibid.

calculate pack years (packs per day or cigarettes per day and number of years smoked). This option is even more granular than categorical collection because it allows OPOs to more accurately report the information they receive from donor historians, as opposed to selection from pack year ranges. The Workgroup discussed that collection of the raw data and the automatic calculation of pack years would accommodate OPOs and reduce potential errors resulting from miscalculation during unit conversion.[11] The Committee proposes that the system allows either packs per day or cigarettes per day be entered into the frequency field.[12] This aims to allow for more flexible data entry, especially when a donor smokes only a few cigarettes a day or week. For example, if a donor smoked 3 cigarettes a week (3 cigarettes per 7 days), the user would enter 0.4 cigarettes per day.[13]

The calculations for pack years are as follows:
- Packs per day:

$$Number\ of\ packs\ smoked\ per\ day \times Number\ of\ years\ the\ person\ smoked$$

- Cigarettes per day:

$$\frac{Number\ of\ cigarettes\ smoked\ per\ day}{20} \times Number\ of\ years\ the\ person\ smoked$$

The Committee considered including data on how long ago a donor quit smoking, but members agreed that this was less clinically relevant to the offer evaluation, especially when compared to data regarding pack years.[14]

### Vape Use History

Vape use refers to the inhalation of vapor through the mouth, usually from a battery-operated electronic device (such as an electronic cigarette) that heats up and vaporizes a liquid or solid.[15] The Committee proposes data collection on Vape Use History to include donor use status (current, former, never, unknown). If the donor is a current or former vape user, the OPO will be required to enter frequency of vape use (every day, every week, less than weekly, unknown) and years the donor vaped (open text field, unknown).

Before deciding on the frequency of vape use data field, the Workgroup investigated available methods for quantifying vape use. The Workgroup found that current research methods for quantifying vape use include number of cartridges per day and number of uses per day. Members agreed that this level of detail would be too granular to collect accurately from donor historians. When determining response options for frequency of vape use, the Workgroup discussed the inclusion of "multiple times daily" and "less than monthly" but agreed these should be removed because such granularity is not clinically meaningful and could be overly burdensome to OPOs and the donor historians.

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[11] See Promote Efficiency of Lung Allocation Workgroup meeting summary, July 9, 2024, available https://optn.transplant.hrsa.gov/media/pedjajhi/20240709_lungefficiencywg_ms.pdf.
[12] See Promote Efficiency of Lung Allocation Workgroup meeting summary, July 9, 2024, available https://optn.transplant.hrsa.gov/media/pedjajhi/20240709_lungefficiencywg_ms.pdf.
[13] See Promote Efficiency of Lung Allocation Workgroup meeting summary, October 15, 2024, available https://optn.transplant.hrsa.gov/media/y3llfkgy/20241015_lungefficiencywg_ms.pdf.
[14] See Promote Efficiency of Lung Allocation Workgroup meeting summary, August 20, 2024, available https://optn.transplant.hrsa.gov/media/2ijd40r5/20240820_lungefficiencywg_ms.pdf.
[15] American Cancer Society, What Do We Know About E-cigarettes?, https://www.cancer.org/cancer/risk-prevention/tobacco/e-cigarettes-vaping/what-do-we-know-about-e-cigarettes.html. Accessed October 23, 2024.

The Workgroup agreed that the extent of the impact of vaping is not currently known, but this information would prompt programs to examine donor chest imaging more closely.[16, 17] The Workgroup considered adding vape type, such as with marijuana and with or without nicotine. Though such granularity in data collection would be useful to future research, members agreed that information on vape type would not impact efficiency of offer evaluation.[18] However, the Committee proposes that if a donor vaped marijuana or Tetrahydrocannabinol (THC), it should be entered under Vape Use History instead of Marijuana Smoking History.

### Marijuana Smoking History

Similar to proposed data collection for Vape Use History, the Committee proposes data collection on marijuana smoking history to include donor smoking status (current, former, never, unknown). If the donor is a current or former marijuana smoker, the OPO will be required to enter frequency of marijuana smoking (every day, every week, less than weekly, unknown) and years the donor smoked (open text field, unknown).

The Workgroup was also interested in methods for quantifying marijuana use. After discussing this idea with OPO representation on the Workgroup, members agreed that current research methods for quantifying marijuana use which involve joint-years, gram-years, and other estimates of usage, are either not applicable to all forms of marijuana smoking or too granular to collect accurately from donor historians.[19] The Workgroup also discussed collecting marijuana smoking methods (e.g. joint, bong, etc.), but ultimately decided against it after agreeing that currently there is no demonstrated clinical significance, and it would not impact efficiency of offer evaluation.[20] Additionally, the Workgroup discussed the inclusion of "multiple times daily" and "less than monthly" in the response options for frequency of marijuana smoking history, but agreed these should be removed because such granularity is not clinically meaningful and could be overly burdensome to OPOs and the donor historians.[21]

### Peak Inspiratory Pressure (PIP)

The Committee proposes the addition of data collection on the Peak Inspiratory Pressure (PIP). PIP would be entered in centimeters of water pressure (cm $H_2O$). Upon implementation of *Promote Efficiency of Lung Donor Testing, OPTN Policy 2.11.D: Required Information for Deceased Lung Donors* would require the PIP to be reported with the ventilator settings at the same frequency as Arterial Blood Gases (ABGs).[22]

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[16] See Promote Efficiency of Lung Allocation Workgroup meeting summary, August 13, available https://optn.transplant.hrsa.gov/media/krqlhko2/20240813_lungefficiencywg_ms.pdf

[17] Honeycutt L, Huerne K, Miller A, Wennberg E, Filion KB, Grad R, Gershon AS, Ells C, Gore G, Benedetti A, Thombs B, Eisenberg MJ. A systematic review of the effects of e-cigarette use on lung function. NPJ Prim Care Respir Med. 2022 Oct 22;32(1):45. doi: 10.1038/s41533-022-00311-w. PMID: 36273009; PMCID: PMC9588082.

[18] See Promote Efficiency of Lung Allocation Workgroup meeting summary, August 13, available https://optn.transplant.hrsa.gov/media/krqlhko2/20240813_lungefficiencywg_ms.pdf.

[19] See Promote Efficiency of Lung Allocation Workgroup meeting summary, July 9, 2024, available https://optn.transplant.hrsa.gov/media/pedjajhi/20240709_lungefficiencywg_ms.pdf.

[20] See Promote Efficiency of Lung Allocation Workgroup meeting summary, August 13, available https://optn.transplant.hrsa.gov/media/krqlhko2/20240813_lungefficiencywg_ms.pdf.

[21] See Promote Efficiency of Lung Allocation Workgroup meeting summary, September 10, 2024, available https://optn.transplant.hrsa.gov/media/fy2hobmk/20240910_lungefficiencywg_ms.pdf.

[22] See Lung Transplantation Committee meeting summary, November 14, 2024, available https://optn.transplant.hrsa.gov/media/2ode2rtz/20241114_lung_summary.pdf

*Public Comment Proposal*

PIP is an indirect measure of donor lung compliance[23] and a fundamental metric captured on ventilators, making it easy to obtain for reporting purposes.[24, 25] OPO representatives on the Workgroup agreed that the PIP is easily obtainable and many OPOs currently enter this data for offer evaluation.[26] The Workgroup discussed that collecting plateau pressure (Pplat) may be more desirable as PIP is the surrogate value for Pplat; however, data for Pplat is often less reliable due to the variability in how it is measured by clinical staff.[27] The Committee proposes PIP values be reported with Arterial Blood Gases (ABGs), as PIP values would be inaccurate if they were reported during lung recruitment.[28]

*Modify*

### Diagnostic Test Status

The Committee proposes modifying the current data collection on Diagnostic Testing to include Diagnostic Test Status. This modification would allow an OPO to indicate if diagnostic testing collected in the OPTN Donor Data and Matching System (including Angiography; Bronchoscopy; Cardiac catheterization; Chest x-ray; Computed tomography (CT)/Magnetic Resonance Imaging (MRI); Echocardiograms; Electrocardiogram (EKGs); Ultrasounds; Other specify) is complete, pending or unable to complete.[29] A multi- select would allow the OPO to select the reason(s) the test could not be completed. Proposed reasons include capacity/workflow issue, proxy refusal, expertise issue, equipment issue, and other, specify.[30]

Initially, the Workgroup discussed adding the above diagnostic test status data collection to only bronchoscopy and chest CT scans. Members agreed that this feature aims to increase efficiency by reducing communication between OPOs and transplant centers outside the OPTN Donor Data and Matching System regarding test status and barriers to testing completion.[31] To ensure consistency in reporting requirements for diagnostic tests, members of the Workgroup supported adding diagnostic test status options to all diagnostic tests in the OPTN Donor Data and Matching System.[32] The Workgroup agreed upon the test status options: complete, pending (awaiting test result), and unable to complete. Required reporting of the reason(s) for incomplete donor testing ensures OPOs are accountable for meeting policy requirements, while allowing flexibility for cases in which completing a test is not possible.[33] The options to report capacity/workflow, expertise, and equipment issues would

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[23] Lung compliance is a measure of the expansion of the lung, is critical to the proper function of the respiratory system. Edwards Z, Annamaraju P. Physiology, Lung Compliance. [Updated 2023 Mar 13]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK554517/

[24] Mora Carpio AL, Mora JI. Ventilator Management. [Updated 2023 Mar 27]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK448186/ Ventilator Management

[25] See Promote Efficiency of Lung Allocation Workgroup meeting summary, August 13, available https://optn.transplant.hrsa.gov/media/krqlhko2/20240813_lungefficiencywg_ms.pdf.

[26] Ibid.

[27] See Promote Efficiency of Lung Allocation Workgroup meeting summary, August 13, available https://optn.transplant.hrsa.gov/media/krqlhko2/20240813_lungefficiencywg_ms.pdf.

[28] See Promote Efficiency of Lung Allocation Workgroup meeting summary, September 10, 2024, available https://optn.transplant.hrsa.gov/media/fy2hobmk/20240910_lungefficiencywg_ms.pdf.

[29] See Promote Efficiency of Lung Allocation Workgroup meeting summary, August 20, 2024, available https://optn.transplant.hrsa.gov/media/2ijd40r5/20240820_lungefficiencywg_ms.pdf.

[30] Ibid.

[31] See Promote Efficiency of Lung Allocation Workgroup meeting summary, August 20, 2024, available https://optn.transplant.hrsa.gov/media/2ijd40r5/20240820_lungefficiencywg_ms.pdf.

[32] Ibid.

[33] Ibid.

capture information on the extent of OPO/donor hospital resource limitations. "Proxy refusal" would apply to cases in which the donor's proxy declines testing. The preference to refrain from data fields in the "other, specify" format was acknowledged; however, members reported a need to capture less common scenarios that could not be categorized otherwise.[34] *Promote Efficiency of Lung Donor Testing* requires that OPOs document the reason(s) any of the Lung Donor Testing outlined in *OPTN Policy 2.11.D: Required Information for Deceased Lung Donors* could not be obtained.[35] This data modification to Diagnostic Testing better enables OPOs to align with this requirement.

*Remove*

> Cigarette use (>20 pack years) ever

The Committee proposes removing data collection from the OPTN Donor Data and Matching System that requires OPOs to indicate if a donor smoked greater than 20 pack years and continued smoking in the last six months.[36] As previously mentioned, the Committee proposes more granular and clinically significant Cigarette Smoking History data collection and supports that the current cigarette smoking data collection in the OPTN Donor Data and Matching System is no longer necessary and can therefore be removed.[37]

## Deceased Donor Registration (DDR)

The Committee proposes updating the Deceased Donor Registration (DDR) to mirror the proposed addition of Cigarette Smoking History data and proposed removal of Cigarette use (>20 pack years) and continued in last six months data collection. **Table 3** shows the proposed changes to the DDR.

**Table 3. Proposed changes to the Deceased Donor Registration (DDR)**

| Action | Data field | Response Option/ Data Entry Description |
|---|---|---|
| **Add** | Cigarette Smoking History | <ul><li>Current cigarette smoker</li><li>Former cigarette smoker</li><li>Never smoked cigarettes</li><li>Cigarette smoking history unknown</li></ul> If Current cigarette smoker, or if Former cigarette smoker- <br><br> Frequency of cigarette smoking: <ul><li>Packs per day</li><li>Cigarettes per day</li><li>Unknown</li></ul> How many years did the donor smoke?: |

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[34] See Promote Efficiency of Lung Allocation Workgroup meeting summary, August 20, 2024, available https://optn.transplant.hrsa.gov/media/2ijd40r5/20240820_lungefficiencywg_ms.pdf.

[35] "Promote Efficiency of Lung Donor Testing", OPTN, Briefing Paper, Accessed November 20, 2024, https://optn.transplant.hrsa.gov/media/xu2p1qrd/lung_donor-testing_bp.pdf

[36] See Lung Transplantation Committee meeting summary, November 14, 2024, available https://optn.transplant.hrsa.gov/media/2ode2rtz/20241114_lung_summary.pdf

[37] Ibid.

| Action | Data field | Response Option/<br>Data Entry Description |
|---|---|---|
| | | • Enter years in open text field<br>• Unknown |
| **Remove** | Cigarette use (>20 pack years) ever | • Yes<br>• No<br>• Unknown<br><br>If yes- And continued in the last six months?:<br>• Yes<br>• No<br>• Unknown |

The proposed Marijuana Smoking History data changes will not be mirrored on the DDR. On September 14, 2023, the OPTN implemented data collection changes to the DDR that will capture information on deceased donor drug use history, including any history of marijuana smoking.[38] This data collection is as follows:

Ever use or take drugs, such as steroids, cocaine, heroin, amphetamines, opioids or marijuana?
• Type of drug
• How often and how long was it used?
• When was it last used?
• Route (inhaled, needles, ingested)

The proposed Vape Use History and PIP data changes will also not be mirrored on the DDR. PIP is a lung-specific data point that needs to be collected at multiple points in the donation process alongside ABGs.[39] Vaping is a novel practice and while early research suggests vaping may be harmful to the lungs, the overall impact is not yet known.[40, 41]

## OPTN Waiting List

The Committee proposes the addition of an optional feature that would allow a transplant program to screen donors based on an acceptable donor pTLC range. The Committee proposes the removal of data collection that allows a program to indicate if they would accept a donor with a cigarette use greater than 20 pack years. **Table 4** shows the proposed changes to the OPTN Waiting List.

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[38] "Modifications to the Deceased Donor Registration (DDR)", OPTN, Policy Notice, available https://optn.transplant.hrsa.gov/media/4700/ddr_june_2021_policy_notice.pdf.

[39] See Promote Efficiency of Lung Allocation Workgroup meeting summary, August 13, available https://optn.transplant.hrsa.gov/media/krqlhko2/20240813_lungefficiencywg_ms.pdf

[40] Ibid.

[41] Honeycutt L, Huerne K, Miller A, Wennberg E, Filion KB, Grad R, Gershon AS, Ells C, Gore G, Benedetti A, Thombs B, Eisenberg MJ. A systematic review of the effects of e-cigarette use on lung function. NPJ Prim Care Respir Med. 2022 Oct 22;32(1):45. doi: 10.1038/s41533-022-00311-w. PMID: 36273009; PMCID: PMC9588082.

**Table 4. Proposed changes to the OPTN Waiting List**

| Action | Data field | Response Option/Data Entry Description |
|---|---|---|
| Add | Acceptable donor predicted Total Lung Capacity (pTLC) range | Enter minimum and maximum acceptable donor pTLC range in Liters (L) |
| Remove | Accept a donor with cigarette use > 20 pack years ever? | • Yes<br>• No |

*Add*

### Acceptable donor predicted Total Lung Capacity (pTLC) range

Total Lung Capacity (TLC) is the volume of air in the lungs upon the maximum effort of inspiration.[42] TLC can be reported as actual (aTLC) or predicted (pTLC) values. The aTLC refers to the real, measured total lung capacity of an individual, obtained through pulmonary function tests, while pTLC is an estimation of total lung capacity that is calculated based on factors like height, age, and birth sex.[43] The Committee proposes the calculation and display of pTLC for the donor and updating Lung Donor Acceptance Criteria to allow for screening of donors that are outside a range of the transplant program's acceptable pTLC values. Transplant programs may use this optional feature by entering the minimum and maximum range of donor predicted total lung capacity they would accept for their patient in Liters (L).[44] Additionally, the Committee proposes that this screening could be used in addition to donor height screening or in place of donor height screening.[45]

The Committee proposes the use of the Global Lung Initiative's (GLI) formula to calculate the donor's pTLC.[46] The Committee discussed the limitations of the GLI formula, including that it was developed on an all-European cohort and that variability between donors' actual TLC and their pTLC may be greater in a more racially and ethnically diverse American donor population than in the European cohort in which the formula was originally developed.[47] The Committee recommends programs account for this potential increased variability by setting wider acceptable ranges of donor pTLC in the donor acceptance criteria. Additionally, the Committee recommends that if a donor's height or age falls outside of the GLI formula limitations (donors outside 5-80 years or 50-230 cm tall) or the GLI calculation is not available, the pTLC will not be calculated or used for screening. Before recommending the GLI formula for calculating donor pTLC, the Committee considered using the European Respiratory Society (ERS) formula. The Committee consulted with experts in the Pulmonary Function Testing (PFT) field, who recommended the GLI reference equations, as they are the current standard for reporting and

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[42] Total Lung Capacity, ScienceDirect, Accessed December 11, 2024, https://www.sciencedirect.com/topics/medicine-and-dentistry/total-lung-capacity

[43] See Promote Efficiency of Lung Allocation Workgroup meeting summary, June 11, 2024, available https://optn.transplant.hrsa.gov/media/jiifq0ws/20240611_lungefficiencywg_ms.pdf.

[44] Ibid.

[45] See Promote Efficiency of Lung Allocation Workgroup meeting summary, August 20, 2024, available https://optn.transplant.hrsa.gov/media/2ijd40r5/20240820_lungefficiencywg_ms.pdf.

[46] See Lung Transplantation Committee meeting summary, September 27, 2024, available https://optn.transplant.hrsa.gov/media/o1zjqeex/20240927_lung_summary.pdf.

[47] Hall GL, Filipow N, Ruppel G, Okitika T, Thompson B, Kirkby J, Steenbruggen I, Cooper BG, Stanojevic S; contributing GLI Network members. Official ERS technical standard: Global Lung Function Initiative reference values for static lung volumes in individuals of European ancestry. Eur Respir J. 2021 Mar 11;57(3):2000289. doi: 10.1183/13993003.00289-2020. PMID: 33707167.

*Public Comment Proposal*

interpretation of lung volume measurements.[48, 49] After thoroughly discussing the limitations expressed above, the Committee recommends proceeding with the GLI formula.[50] Given the need to increase efficiency in lung allocation and the formula's utility in size-matching, members agreed it would be justified to use this formula until and unless a calculation is validated against a more diverse cohort in the future, in which case the Committee would revisit this recommendation to make sure that it remains up to date with science and practice in the community. Members suggested displaying a disclaimer in the OPTN system to bring awareness to the limitations of the formula.[51] It is important to note that in alignment with the American Thoracic Society's Official Statement on Race, Ethnicity and Pulmonary Function Test Interpretation, the GLI formula does not include any race-based coefficients.[52] **Figure 1** shows the GLI formula.

**Figure 1. Global Lung Initiative formula [53, 54]**

| TLC | Male | $\exp(-10.5861+0.1433*\log(age)+2.3155*\log(height)+\text{Mspline})$ |
|-----|--------|-----|
|     | Female | $\exp(-10.1128+0.1062*\log(age)+2.2259*\log(height)+\text{Mspline})$ |

In January 2024, the Committee released *Promote Efficiency of Lung Allocation* to public comment.[55] This project proposed new data collection in the OPTN Donor Data and Matching System to aid evaluation of lung offers and provided an overview of planned and potential system enhancements that are intended to make it easier for lung transplant programs to say "yes" to organ offers. One of the feedback questions for the community asked, "How else might the OPTN improve the efficiency of lung allocation for both transplant programs and OPOs?". One of the most common and actionable responses to this question was the addition of pTLC to the OPTN Computer System. During discussions about ways to operationalize this feature, the Committee also considered the transplant program providing an aTLC for lung candidates in the OPTN Waiting List, or that the system would calculate the pTLC for lung candidates, based on data that is already required in the system.[56] The Committee proposes the calculation of pTLC for donors with the transplant program's ability to screen based on the

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[48] See Lung Transplantation Committee meeting summary, September 27, 2024, available https://optn.transplant.hrsa.gov/media/o1zjqeex/20240927_lung_summary.pdf.

[49] Hall GL, Filipow N, Ruppel G, Okitika T, Thompson B, Kirkby J, Steenbruggen I, Cooper BG, Stanojevic S; contributing GLI Network members. Official ERS technical standard: Global Lung Function Initiative reference values for static lung volumes in individuals of European ancestry. Eur Respir J. 2021 Mar 11;57(3):2000289. doi: 10.1183/13993003.00289-2020. PMID: 33707167.

[50] Ibid.

[51] Hall GL, Filipow N, Ruppel G, Okitika T, Thompson B, Kirkby J, Steenbruggen I, Cooper BG, Stanojevic S; contributing GLI Network members. Official ERS technical standard: Global Lung Function Initiative reference values for static lung volumes in individuals of European ancestry. Eur Respir J. 2021 Mar 11;57(3):2000289. doi: 10.1183/13993003.00289-2020. PMID: 33707167.

[52] "ATS Publishes Official Statement on Race, Ethnicity and Pulmonary Function Test Interpretation", American Thoracic Society, Accessed November 20, 2024, https://site.thoracic.org/about-us/news/ats-publishes-official-statement-on-race-ethnicity-and-pulmonary-function-test-interpretation.

[53] Hall GL, Filipow N, Ruppel G, Okitika T, Thompson B, Kirkby J, Steenbruggen I, Cooper BG, Stanojevic S; contributing GLI Network members. Official ERS technical standard: Global Lung Function Initiative reference values for static lung volumes in individuals of European ancestry. Eur Respir J. 2021 Mar 11;57(3):2000289. doi: 10.1183/13993003.00289-2020. PMID: 33707167.

[54] Age represents the donor's age in years and height represents the donor's height in cm. Mspline is an age-and-sex-varying coefficient that is provided by the GLI for use with this equation.

[55] " Promote Efficiency of Lung Allocation", OPTN, Public Comment proposal, available https://optn.transplant.hrsa.gov/media/3ftfa23x/lung_allocation-efficiency_pcjan24.pdf.

[56] See Lung Transplantation Committee meeting summary, June 11, 2024, available https://optn.transplant.hrsa.gov/media/jiifq0ws/20240611_lungefficiencywg_ms.pdf.

*Public Comment Proposal*

calculated pTLC. Members discussed the variation in size-matching practices and that the use of pTLC is a surgeon-driven decision. The Committee proposes this feature as optional and therefore, it may improve efficiency for some programs but not all.[57]

*Remove*

### Accept a donor with cigarette use > 20 pack years ever?

The Committee proposes the removal of data collection from the OPTN Waiting List that allows a program to indicate if they would accept a donor with a cigarette use greater than 20 pack years.[58] This proposed change removes the capability to set candidate-level screening on donor smoking history, as oftentimes programs have a standard cutoff of pack years they will accept for all their candidates, as opposed to candidate- specific pack year preferences.[59] The following section describes an addition to Lung Offer Filters, which improves upon the current data collection. Once implemented, the "accept a donor with a cigarette use greater than 20 pack years" field will no longer be necessary.

## Lung Offer Filters

Organ offer filters allow transplant programs to apply custom-designed, program-specific, multi-factorial filters to bypass donor offers that they do not want to receive. The purpose of offer filters is to get to organ offer acceptance faster by reducing the number of unwanted organ offers that OPOs need to make and transplant programs need to review, thereby decreasing allocation time and increasing organ acceptance. **Table 5** shows the proposed changes to the Lung Offer Filters.

**Table 5: Proposed changes to lung Offer Filters**

| Action | Data field | Response Option/Data Entry Description |
|--------|-----------|----------------------------------------|
| Add | Donor cigarette use exceeds | Enter number of pack years an acceptable donor must not exceed |

*Add*

### Donor cigarette use exceeds

The Committee proposes the addition of a lung offer filter which allows programs to filter out lung offers that exceed a cigarette pack year quantity of their choosing.[60] For example, if a program indicated they did not want to see any lung offers from donors that have more than 30 cigarette pack years, the program would only receive lung offers with donors that have 30 cigarette pack years or less. This proposed addition to Lung Offer Filters could be used in combination with the existing lung offer filters

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[57] Ibid.

[58] See Lung Transplantation Committee meeting summary, November 14, 2024, available https://optn.transplant.hrsa.gov/media/2ode2rtz/20241114_lung_summary.pdf

[59] See Lung Transplantation Committee meeting summary, June 11, 2024, available https://optn.transplant.hrsa.gov/media/jiifq0ws/20240611_lungefficiencywg_ms.pdf

[60] See Promote Efficiency of Lung Allocation Workgroup meeting summary, August 20, 2024, available https://optn.transplant.hrsa.gov/media/2ijd40r5/20240820_lungefficiencywg_ms.pdf

implemented in January 2024.[61, 62] Programs will still be able to exclude certain candidates from this filter if they want those candidates to receive offers from donors with any cigarette smoking history.[63]

# Compliance Analysis

## NOTA and OPTN Final Rule

The Committee submits this proposal under the authority of the National Organ Transplant Act (NOTA), which states the OPTN shall "collect, analyze, and publish data concerning organ donation and transplants,"[64] as well as the OPTN Final Rule, which states that the OPTN shall "maintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors."[65] This proposal would manage information about transplant candidates by providing tools for screening and filtering donors through new features to the OPTN Waiting List and Lung Offer Filters.

# Implementation Considerations

This proposal is expected to affect the operations of organ procurement organizations, transplant hospitals, and OPTN, but is not expected to affect the operations of histocompatibility laboratories.

## Member and OPTN Operations

### *Operations affecting Organ Procurement Organizations*

OPOs would be required to provide additional data on deceased lung donors in the OPTN Donor Data and Matching System. Reporting this additional lung donor data may require staff training, adjustments to existing workflows, and increased staff time spent on each lung donor offer. OPOs should also be aware of the changes to the DDR.

### *Operations affecting Transplant Hospitals*

While this proposal does not require any action from lung transplant programs, these programs will need to ensure staff are educated on the new features in OPTN Waiting List and Lung Offer Filters and consider modifying how offers are screened at the candidate-level (via donor acceptance criteria) and bypassed at the program-level (via offer filters). Programs should also be aware of changes to changes to the OPTN Donor Data and Matching System.

### *Operations affecting Histocompatibility Laboratories*

This proposal is not anticipated to affect the operations of histocompatibility laboratories.

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[61] "Offer Filters now available for lung allocation," https://unos.org/news/offer-filters-now-available-for-lung-allocation/.
[62] Lung Offer Filters include donor type, distance in nautical miles, donor age is less than, donor age is more than.
[63] See Lung Transplantation Committee meeting summary, November 14, 2024, available https://optn.transplant.hrsa.gov/media/2ode2rtz/20241114_lung_summary.pdf
[64] 42 USC §274(b)(2)(I).
[65] 42 CFR §121.11(a)(1)(i).

*Operations affecting the OPTN*

This proposal requires the submission of official OPTN data that are not presently collected by the OPTN. The OPTN Contractor has agreed that data collected pursuant to the OPTN's regulatory requirements in §121.11 of the OPTN Final Rule will be collected through OMB approved data collection forms. Therefore, after OPTN Board approval, the forms will be submitted for OMB approval under the Paperwork Reduction Act of 1995. This will require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

To implement this proposal, the OPTN would add new data fields in the OPTN Computer System and communicate the changes to the transplant community. The OPTN would provide help documentation for the new data fields to provide additional instruction for submitting these data.

## Potential Impact on Select Patient Populations

This proposal considers changes to OPTN data collection. These changes intend to improve the efficiency of the organ offer and acceptance processes for lung transplant programs and OPOs so that donor lungs can more quickly be placed with the appropriate lung transplant candidate. This proposal is not expected to have a disproportionate impact on any select populations of lung transplant candidates.

## Projected Fiscal Impact

The Fiscal Impact Group (FIG), comprised of representatives from histocompatibility laboratories, organ procurement organizations, and transplant hospitals, reviewed this proposal and completed a survey to estimate anticipated costs. They rated this project as low, medium, or high based on the estimated staffing and/or training, overtime, equipment, or IT support needed in the implementation of this proposal.

*Overall Projected Fiscal Impact*

The proposal was determined to have a low overall fiscal impact on organ procurement organizations. No significant fiscal impacts were recorded for histocompatibility labs or transplant hospitals.

*Projected Fiscal Impact on the OPTN*

It is estimated that $89,755 is needed for the development of this proposal. Development includes committee preparation and facilitation, proposal development, research and analysis, presentations, compliance evaluation, and data collection requirements. It is estimated that $546,007 would be needed to implement this proposal. Implementation would involve implementation communications and educational materials, updates to OPTN documents, templates, and processes, software engineering, IT project management, analysis, and quality assurance. It is estimated that $63,344 will be needed for ongoing support. Ongoing support will include member support, monitoring, and post-implementation evaluation. The total for development, implementation, and ongoing support is estimated to be $699,106.[66]

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[66] Resource estimates are calculated by the current contractor for that contractor to perform the work. Estimates are subject to change depending on a number of factors, including which OPTN contractor(s) will be performing the work, if the project is ultimately approved.

*Projected Fiscal Impact on Organ Procurement Organizations*

This proposal is expected to have low fiscal impact on OPOs. Extra time will be needed to review additional data points added by the proposal.

*Projected Fiscal Impact on Transplant Hospitals*

There were no significant fiscal impacts indicated with this proposal.

*Projected Fiscal Impact on Histocompatibility Laboratories*

There were no significant fiscal impacts indicated with this proposal.

# Post-implementation Monitoring

## Member Compliance

The Final Rule requires that allocation policies "include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program."[67] This proposal will not change the current routine monitoring of OPTN members. Any data entered in the OPTN Computer System may be reviewed, and members are required to provide documentation as requested.

## Policy Evaluation

The Final Rule requires that allocation policies "be reviewed periodically and revised as appropriate." The impact of changes to donor testing requirements will be monitored six months post-implementation and then annually for two years, as the Committee sees fit. Each report will evaluate the following metrics, using pre and post comparisons when appropriate:

- Sequence number of the final acceptor
- Number of programs notified before the final acceptor
- Number of programs notified for the first time after the final acceptor
- Allocation time (time from first electronic notification to offer acceptance)
- Utilization rate by donor type
- Non-use rate by donor type

Each report will also summarize the reasons that select diagnostic tests were unable to be completed. Additional summaries of new data collection fields will be provided at the request of the Committee.

# Conclusion

The Committee seeks to promote efficiency of lung allocation by considering changes to OPTN data collection to make it easier for lung programs to respond to lung offers. These efforts also aim to streamline communication and information sharing between OPOs and lung transplant programs as lung transplant programs consider offers. The Committee proposes the addition of new data collection to

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[67] 42 CFR §121.8(a)(7)

include History of Smoking (Cigarette Smoking History, Vape Use History, Marijuana Smoking History), Peak Inspiratory Pressure (PIP), and Acceptable donor Predicted total Lung Capacity (pTLC) range. The Committee proposes modifying Diagnostic Testing data by adding Diagnostic Test Status data collection. Additionally, the Committee proposes an addition to Lung Offer Filters, which allows programs to bypass offers with donors that exceed a cigarette pack year threshold of their choosing. Lastly, the Committee proposes removing the data fields that indicate if a donor smoked greater than 20 pack years and if the program would accept a donor with greater than 20 pack years smoking history.

## Considerations for the Community

The Committee is requesting public comment feedback, including input on the following questions:

- Will this new and updated data collection provide transplant programs with useful, granular information for making decisions about potential lung donors?
- Do OPOs foresee challenges or burden related to this data collection?
- Could the data fields, response options, or data definition be clearer?
- Does the community support use of the Global Lung Function Initiative (GLI) calculation to predict Total Lung Capacity?
- Will lung transplant programs use the proposed addition to lung offer filters?
- Do OPOs and transplant programs think the proposed Diagnostic Test Status data collection will increase efficiency and decrease back and forth regarding the availability of lung donor testing?
- Do patients and donor family members support proposed data collection changes to streamline communications between transplant programs and OPOs to place organs more efficiently?

# Proposed Changes to Data Definitions

Proposed new language is underlined (example) and language that is proposed for removal is struck through (example). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

1 **History of Smoking:** Select yes if the donor has any history of smoking cigarettes, marijuana, or vapes.
2 Select No if the donor has no history of smoking cigarettes, marijuana, or vapes. Select unknown if
3 donor historian or donor medical records are not available or it is not clear or known if the donor had a
4 history of smoking cigarettes, marijuana, or vapes. Required field.

5 If **yes** is selected, use the dropdowns to indicate cigarette smoking, marijuana smoking, and vaping
6 history
7 - **Cigarette smoking history:** Cigarette smoking refers to the inhalation of smoke from a burning
8   cigarette into the lungs.[68] Field required if History of Smoking is yes.
9     o **Current cigarette smoker**: Select if donor smoked cigarettes up until time of death.
10    o **Former cigarette smoker**: Select if donor had smoked cigarettes in the past, but quit
11      before time of death.
12    o **Never smoked cigarettes:** Select if the donor never smoked cigarettes.
13    o **Cigarette history unknown:** Select if the donor historian and donor medical records are
14      not available or it is not clear or known if the donor had a history of smoking cigarettes.

15    If donor is a **Current cigarette smoker** or **a Former cigarette smoker:**
16      ▪ **Frequency of cigarette smoking:** Enter on average, how many packs per day **or**
17        cigarettes per day in respective field. Field required if Cigarette Smoking History
18        is either current cigarette smoker or former cigarette smoker.
19          - Packs per day: enter the average number of cigarette packs smoked
20            each day. This can be entered as a whole number (1 pack, 2 packs) or
21            decimals (0.25 pack, 0.5 pack). Absolute range- minimum: 0.1 packs,
22            maximum: 5 packs.
23          - Cigarettes per day: enter the average number of cigarettes smoked each
24            day. This can be entered as whole numbers (1 cigarette, 2 cigarettes) or
25            decimals (0.1 cigarette, 0.5 cigarettes).For example, if a donors smoked
26            3 cigarettes a week (3 cigarettes per 7 days), enter .4 cigarettes.
27            Absolute range- minimum: 0.1 cigarette, maximum: 20 cigarettes. There
28            are 20 cigarettes in each pack.
29          - Unknown: Select if the donor historian and donor medical records are
30            not available or it is not clear or known how many packs per day or
31            cigarettes per day the donor smoked. If unknown is entered, cigarette
32            pack years will not be calculated.
33      ▪ **How many years did the donor smoke?:** The number of years as a cigarette
34        smoker. Enter years in open text field. Used to calculate donor cigarette pack
35        years. If the donor has smoked less than a year, enter as decimal. Field required

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[68] Clevland Clinic, Smoking, https://my.clevelandclinic.org/health/articles/17488-smoking. Accessed October 23, 2024.

36          if Cigarette Smoking History is either **Current cigarette smoker** or **Former**

37          **cigarette smoker.** Absolute range: minimum- 0, maximum- donor's age.

38              • Unknown: Select if the donor historian and donor medical records are not

39                available or it is not clear or known how many years the donor smoked. If

40                unknown is entered, cigarette pack years will not be calculated.

41    • **Vape Use History** [69]**:** Vape use refers to the inhalation of vapor through the mouth from a

42      usually battery-operated electronic device (such as an electronic cigarette) that heats up and

43      vaporizes a liquid or solid. Report if donor has a history of vaping because lung transplant

44      programs may rule out donors with this history in combination with other factors. Field required

45      if History of Smoking is yes. If a donor vaped marijuana or THC, it should be entered under Vape

46      Use History.

47         o **Current vape user**: Select if donor vaped up until time of death.

48         o **Former vape user**: Select if donor had vaped in the past, but quit before time of death.

49         o **Never vaped:** Select if the donor never vaped.

50         o **Vape history unknown:** Select if the donor historian and donor medical records are not

51           available or it is not clear or known if the donor had a history of vaping.

52      If donor is a **Current vape user** or **a Former vape user**-

53            ▪ **Frequency of vaping:** Indicate, on average, how often the donor vapes/vaped.

54              Field required if Vape Use History is either current vape user or former vape

55              user.

56                • Every day: Select if the donor vaped every day.

57                • Every week: Select if the donor vaped once a week or more but less

58                  than once a day.

59                • Less than weekly: Select if the donor vaped less than once a week.

60                • Unknown: Select if the donor historian and donor medical records are

61                  not available or it is not clear or known how often the donor vaped.

62            ▪ **How many years did the donor vape?:** Indicate the number of years as a vape

63              user. Enter years in open text field. If the donor has smoked less than a year,

64              enter as decimal. Field required if Vape Use History is either current vape user

65              or former vape user. Absolute range: minimum- 0, maximum- donor's age.

66                • Unknown: Select if the donor historian and donor medical records are

67                  not available or it is not clear or known how many years the donor

68                  vaped.

69    • **Marijuana Smoking History** [70]**:** Marijuana smoking refers to the inhalation of smoke or vapor

70      released by heating the flowers, leaves, or extracts of cannabis and releasing the main

71      psychoactive chemical, THC, which is absorbed in the bloodstream via the lungs. Report if donor

72      has a history of marijuana smoking. If a donor vaped marijuana or THC, enter that information

73      under Vape Use History. Field required if History of Smoking is yes.

74         o **Current marijuana smoker**: Select if donor smoked marijuana up until time of death.

[69] American Cancer Society, What Do We Know About E-cigarettes?, https://www.cancer.org/cancer/risk-prevention/tobacco/e-cigarettes-vaping/what-do-we-know-about-e-cigarettes.html. Accessed October 23, 2024.

[70] National Institute on Drug Abuse, Cannabis, https://nida.nih.gov/research-topics/cannabis#use-cannabis. Accessed October 23, 2024.

75       o  **Former marijuana smoker**: Select if donor had smoked marijuana in the past, but quit
76            before time of death.
77       o  **Never smoked marijuana:** Select if the donor never smoked marijuana.
78       o  **Marijuana smoking history unknown:** Select if the donor historian and donor medical
79            records are not available or it is not clear or known if the donor had a history of smoking
80            marijuana.

81       If donor is a **Current marijuana smoker** or a **Former marijuana smoker**-

82             ▪  **Frequency of marijuana smoking:** Indicate, on average, how often the donor
83                smoked marijuana. Field required if Marijuana Smoking History is either current
84                marijuana smoker or former marijuana smoker.
85                  •  Every day: Select if the donor smoked marijuana every day.
86                  •  Every week: Select if the donor smoked marijuana once a week or more but
87                    less than once a day.
88                  •  Less than weekly: Select if the donor smoked marijuana less than once a
89                    week.
90                  •  Unknown: Select if the donor historian and donor medical records are not
91                    available or it is not clear or known how often the donor smoked marijuana.
92             ▪  **How many years did the donor smoke?:** Indicate the number of years as a
93                marijuana smoker. Enter years in open text field. If the donor has smoked less than
94                a year, enter as decimal Field required if Marijuana Smoking History is either current
95                marijuana smoker or former marijuana smoker. Absolute range: minimum- 0,
96                maximum- donor's age.
97                  •  Unknown: Select if the donor historian and donor medical records are not
98                    available or it is not clear or known how many years the donor smoked
99                    marijuana.

100  **Peak Inspiratory Pressure (PIP)** [71]**:** The highest pressure delivered by the ventilator at any instant during
101  a single ventilatory cycle. Enter the donor PIP in centimeters of water pressure (cm $H_2O$). PIP values are
102  reported with the ventilator settings alongside Arterial Blood Gases (ABGs). Absolute range- minimum:
103  10, maximum: 50.

104  **Acceptable donor predicted Total Lung Capacity (pTLC) range:** This field allows for screening lung
105  donors based on the donor's predicted total lung capacity. Enter the minimum and maximum range of
106  donor predicted total lung capacity the program would accept for their patient in Liters (L). Absolute
107  range- minimum: 0.10, maximum: 14.00.

108  The system calculates the donor's pTLC based on the Global Lung Initiative's (GLI) formulas.[72] These
109  formulas were developed on an all-European cohort. Variability between donors' actual TLC and their
110  pTLC may be greater in a racially diverse American donor population than in the European cohort in
111  which the formula was originally developed. It is recommended to account for this potential increased

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[71] Science Direct, Peak Inspiratory Pressure, https://www.sciencedirect.com/topics/nursing-and-health-professions/peak-inspiratory
pressure#:~:text=Peak%20Inspiratory%20Pressure%20is%20the,airway%20resistance%20and%20lung%20compliance. Accessed October 23,
2024.
[72] Hall GL, Filipow N, Ruppel G, et al. Official ERS technical standard: Global Lung Function Initiative reference values for static lung volumes in
individuals of European ancestry. Eur Respir J2021; 57: 2000289 [https://doi.org/10.1183/13993003.00289-2020].

112 variability when setting donor acceptance criteria. If donor age or height are outside of GLI formula
113 limitations (donors outside 5-80 years or 50-230 cm tall) or the GLI calculation is not available, the pTLC
114 will not be calculated or used for screening.

115 **Diagnostic testing**
116 - **Diagnostic test status:** Report if diagnostic testing is Complete, Pending, or Unable to be
117 completed. Field is required for all selected diagnostic testing.
118   o **Complete**: Select if test is complete and results are available.
119   o **Pending:** Select if awaiting test results.
120   o **Unable to be completed:** Select if test is unable to be completed for any reason.

121   **If Unable to be completed is selected, select all reasons that apply-**

122   - **Capacity/workflow issue:** Select if unable to complete test due to
123     staffing/personnel resource limitations.
124   - **Proxy refusal:** Select if unable to complete test due to donor family timeframe or
125     authorization challenges.
126   - **Expertise issue:** Select if unable to complete test due to lack of available trained
127     staff.
128   - **Equipment issue:** Select if unable to complete test due to lack of equipment.
129   - **Other, specify - free text:** Enter other reason test is unable to be completed.

130 **Donor cigarette use exceeds:** Enter the number of pack years of cigarette use an acceptable donor must
131 not exceed. Absolute range- minimum: 0, maximum: 100.
132 - Pack-year equation: Number of packs of cigarettes smoked per day X Number of years the person
133 smoked.

# Proposed Changes to Data Collection

**Proposed changes to OPTN Donor Data and Matching System**

| Action | Data field | Child Field | Response Option/ Data Entry Description |
|---|---|---|---|
| **Add** | History of Smoking | | • Yes<br>• No<br>• Unknown<br><br>If Yes-<br>  • Cigarette Smoking History<br>  • Vape Use History<br>  • Marijuana Smoking History |
| **Add** | | Cigarette Smoking History | • Current cigarette smoker<br>• Former cigarette smoker<br>• Never smoked cigarettes<br>• Cigarette smoking history unknown<br><br>If Current cigarette smoker, or if Former cigarette smoker-<br><br>Frequency of cigarette smoking<br>  • Packs per day<br>  • Cigarettes per day<br>  • Unknown<br><br>How many years did the donor smoke?:<br>  • Enter years in open text field<br>  • Unknown<br><br>Cigarette pack years calculated and displayed. |
| **Add** | | Vape Use History | • Current vape user<br>• Former vape user<br>• Never vaped<br>• Vape history unknown<br><br>If Current vape user or Former vape user-<br><br>Frequency of vape use<br>  • Every day<br>  • Every week<br>  • Less than weekly<br>  • Unknown<br><br>How many years did the donor vape?:<br>  • Enter years in open text field<br>  • Unknown |
| **Add** | | Marijuana Smoking History | • Current marijuana smoker |

| Action | Data field | Child Field | Response Option/ Data Entry Description |
|---|---|---|---|
| | | | • Former marijuana smoker<br>• Never smoked marijuana<br>• Marijuana smoking history unknown<br><br>If Current marijuana smoker or Former marijuana smoker-<br><br>Frequency of marijuana smoking<br>• Every day<br>• Every week<br>• Less than weekly<br>• Unknown<br><br>How many years did the donor smoke?:<br>• Enter years in open text field<br>• Unknown |
| Add | Peak Inspiratory Pressure (PIP) | | Enter PIP in open text field in centimeters of water pressure (cm $H_2O$). |
| Modify | Diagnostic Test Status [73] | | Select test status<br>• Complete<br>• Pending (awaiting result)<br>• Unable to complete<br><br>If status is Unable to complete, select all reasons that apply<br>• Capacity/workflow issue<br>• Proxy refusal<br>• Expertise issue<br>• Equipment issue<br>• Other, specify - free text |
| Remove | ~~Cigarette use (>20 pack years) ever~~ | | • ~~Yes~~<br>• ~~No~~<br>• ~~Unknown~~<br><br>~~If yes- And continued in the last six months?:~~<br>• ~~Yes~~<br>• ~~No~~<br>• ~~Unknown~~ |

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[73] Diagnostic tests include Angiography; Bronchoscopy; Cardiac catheterization; Chest x-ray; CT/MRI; Echocardiograms; EKGs; Ultrasounds; Other specify.

135

## Proposed changes to the Deceased Donor Registration (DDR)

| Action | Data field | Response Option/ Data Entry Description |
|---|---|---|
| **Add** | Cigarette Smoking History | • Current cigarette smoker<br>• Former cigarette smoker<br>• Never smoked cigarettes<br>• Cigarette smoking history unknown<br><br>If Current cigarette smoker, or if Former cigarette smoker-<br><br>Frequency of cigarette smoking<br>  • Packs per day<br>  • Cigarettes per day<br>  • Unknown<br><br>How many years did the donor smoke?:<br>  • Enter years in open text field<br>  • Unknown |
| **Remove** | ~~Cigarette use (>20 pack years) ever~~ | • ~~Yes~~<br>• ~~No~~<br>• ~~Unknown~~<br><br>~~If yes- And continued in the last six months?:~~<br>  • ~~Yes~~<br>  • ~~No~~<br>  • ~~Unknown~~ |

136

## Proposed changes to the OPTN Waiting List

| Action | Data field | Response Option/Data Entry Description |
|---|---|---|
| Add | Acceptable donor predicted Total Lung Capacity (pTLC) range | Enter minimum and maximum acceptable donor pTLC range in Liters (L) |
| Remove | ~~Accept a donor with cigarette use > 20 pack years ever?~~ | • ~~Yes~~<br>• ~~No~~ |

137

## Proposed changes to lung Offer Filters

| Action | Data field | Response Option/Data Entry Description |
|---|---|---|
| Add | Donor cigarette use exceeds | Enter number of pack years an acceptable donor must not exceed |

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