

Briefing to the OPTN Board of Directors on

Guidance for Data Collection Regarding Classification of Citizenship Status

OPTN Ad Hoc International Relations Committee

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Guidance for Data Collection Regarding Classification of Citizenship Status

Sponsoring Committee: Ad Hoc International Relations

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Executive Summary

The OPTN Ad Hoc International Relations Committee (hereinafter “the Committee”), in its role as advisory to the OPTN Board of Directors, proposes a guidance document to address the classification of citizenship status in OPTN data. The citizenship status data element is collected on the Transplant Candidate Registration (TCR), Living Donor Registration (LDR), and Deceased Donor Registration (DDR) forms, which are submitted by transplant programs and organ procurement organizations (OPOs) upon the registration of all organ transplant candidates, living donors, and deceased donors. The data collected from the citizenship status field is utilized for analyzing trends to inform the development of evidence-based policies. The citizenship status data element presents unique challenges for transplant programs and OPOs to capture and report due to differing interpretations of the various citizenship status categories. Upon review of current data and literature, as well as a member request for guidance, the Committee decided that guidance on the citizenship status data element was needed to promote accurate data collection. The proposed document seeks to provide guidance in order to improve data collection by addressing accurate classification of citizenship status at registration as well as accurate, complete, and timely follow-up data collection in regards to citizenship status. Following public comment, the Committee clarified several areas of the guidance document to distinguish between living donors and deceased donors, to broaden the categorization of U.S. citizen, and to clarify, that in addition to citizenship status, the DDR collects home country. Other post-public comment changes included eliminating references to OPOs checking source documentation and verifying citizenship status, and added language to address the unique challenges that OPOs face when collecting citizenship status.

Purpose

Through feedback from the community and member questions, the Committee found the transplant community had a lack of clarity on the OPTN citizenship status data element, which is collected on the TCR, LDR, and DDR forms. The Committee decided to develop a document to provide the transplant community with guidance on the classification of citizenship status. The guidance document addresses accurate classification of citizenship status at registration, as well as the accurate, complete, and timely collection of follow-up data. The guidance document addresses how citizenship status data is utilized with the aim of creating trust and transparency between patients and providers in order to increase the accuracy of reported data.

Accurately capturing the citizenship status of transplant candidates, living donors, and deceased donors is important for the overall integrity and quality of OPTN data. Accurate capture of data allows for analyses to be performed in order to identify and review current trends, and subsequently develop evidence-based policy, if needed. The collection of the citizenship status data element aligns with the OPTN Principles of Data Collection: specifically, the data element fulfills the principle of developing transplant, donation, and allocation policies.¹

Additionally, it is critical for transplant centers to consider the obstacles of accurate, complete, and timely follow-up data submission, given a patient's citizenship status, during the evaluation process. Due consideration of follow-up data submission related obstacles allows programs to take the necessary measures to ensure accurate reporting and OPTN record maintenance as well as ensure stewardship of organs, regardless of citizenship status. Accurate collection of citizenship status allows health care professionals to appropriately plan, with the intent of improving rates of follow-up data submission. Lastly, the guidance document highlights the importance of collecting citizenship status for deceased donors on the DDR.

Background

Throughout this document the term 'citizenship status' refers to the OPTN data collection element "citizenship status". This OPTN data element collects information on citizenship, residency, and country of origin. It is not within the OPTN's function to discern legality of immigration status of patients. Therefore, statements and guidance within this document focus solely on accurately collecting citizenship status as it pertains to OPTN data collection.

The Committee is charged by the OPTN Board of Directors with reviewing issues related to non-U.S. citizens/non-U.S. resident (NCNR) transplant patients. The Committee works within this charge to address topics related to NCNR patients who enter the U.S. for transplant as well as U.S. candidates who seek transplant in other countries. In order to accurately review emerging issues as well as make informed decisions, quality data is essential for the Committee.

OPTN Policy 17.1.C: Report of Activities Related to The Transplantation of Non-US Citizens/Non-US Residents requires the Committee to "prepare and provide public access to an annual report of transplant hospital activities related to the registration and transplantation of non-US citizens/non-US

¹ "Principles of Data Collection," OPTN (June 2021). Available at <https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/>.

residents.”² The Committee has sought to bring transparency to activity related to NCNR transplant patients through review of their annual data report, as well as data collection changes.³ The Committee continues to bring transparency to NCNR patient transplant activity by proposing a document to further guide the transplant community on the OPTN citizenship status data element in order to improve accurate data collection.

The OPTN collects citizenship status on transplant candidates, living donors, and deceased donors. The citizenship status data element is the sole data element that allows the OPTN to review citizenship, residency, and country of origin of its patient and donor population, pursuant to OPTN Policy.⁴ The collection of these data elements lends to gathering demographic data on patients, and enabling health care professionals to appropriately plan, with the intent of improving follow-up data submission rates.

In 2011, the OPTN Board of Directors approved changes to the citizenship status data collection field, a data collection proposal sponsored jointly by the Committee and the OPTN Ethics Committee. The Committees were interested in quantifying the number of individuals who travel to the U.S. for transplant in order to understand the magnitude of “transplant tourism”, as outlined in the *Declaration of Istanbul on Organ Trafficking and Transplant Tourism*.⁵ The Committees’ interest in quantifying transplant tourism was to better analyze whether the U.S. was impairing its ability to provide transplants for its residents due to NCNR patients entering the U.S. to undergo organ transplantation from deceased organ donors.⁶ The proposal deleted the term “alien” and proposed the terms “resident and “non-resident”, as residency is important to understand transplant tourism within the U.S.⁷ The citizenship status data collection changes (Table 1) were implemented in UNet in 2012.⁸

The UNetSM Help Documentation definitions were updated in conjunction with the citizenship status data element change. The main distinction to note is that, prior to the data elements changes in 2011, residency was previously based on legal immigration status, whereas, post 2011 changes, it is defined as where the patient considers their primary place of residence.⁹ The following are data definitions for the citizenship status data element as they currently appear in UNet Help Documentation¹⁰.

- **U.S. Citizen:** A United States citizen by birth or naturalization.
- **Non-U.S. Citizen/U.S. Resident:** A non-citizen of the United States for whom the United States is the primary place of residence.

² OPTN Policy 17.1.C, Report of Activities Related to The Transplantation of Non-US Citizens/Non-US Residents (June, 2021).

³ 2019 Annual Report of Non-U.S. Resident Transplant Activity, OPTN Ad Hoc International Relations Committee. Available at <https://optn.transplant.hrsa.gov/>.

⁴ OPTN Policy 17.1.B: Review of Non-US Citizens/Non-US Residents, and 17.1.C: Report of Activities Related to the Transplantation of Non-US Citizens/Non-US Residents.

⁵ Steering Committee of the Istanbul Summit. Organ trafficking and transplant tourism and commercialism: The Declaration of Istanbul. *Lancet* (2008) 372: 5–6.

⁶ Report to the Board of Directors, OPTN/UNOS Ad Hoc International Relations Committee, June 28, 2011.

⁷ Glazier, A., et al. “Organ transplantation for nonresidents of the United States: A policy for transparency”, *American Journal of Transplantation* (2014): 14; 1740-1743.

⁸ 2019 Summary of Non-US Resident Transplant Activity, OPTN Ad Hoc International Relations Committee. Available at <https://optn.transplant.hrsa.gov/>.

⁹ *Proposed Revisions to and Reorganization of Policy 6.0*, OPTN Ad Hoc International Relations Committee & OPTN Ethics Committee, 2011.

¹⁰ UNetSM Help Documentation, as of June 2021.

- **Non-U.S. Citizen/Non-U.S. Resident, Traveled to U.S. for Reason Other Than Transplant:** A non-citizen of the United States for whom the United States is not the primary place of residence, and who came to the U.S. for a reason other than transplant.
- **Non-U.S. Citizen/Non-U.S. Resident, Traveled to U.S. for Transplant:** A non-citizen of the United States for whom the United States is not the primary place of residence, and who came to the U.S. for the purpose of transplant.

Table 1: Citizenship Status Data Element Changes

Prior to 2011	Current
<p>Citizenship status data field categories on the TCR & LDR forms:</p> <ul style="list-style-type: none"> • U.S. Citizen • Resident Alien • Non-Resident Alien, Year of Entry to the U.S. 	<p>Citizenship status data field categories on the TCR & LDR forms:</p> <ul style="list-style-type: none"> • U.S. Citizen • Non-U.S. Citizen/U.S. Resident • Non-U.S. Citizen/Non-U.S. Resident, Traveled to U.S. for Reason Other than Transplant • Non-U.S. Citizen/Non-U.S. Resident, Traveled to U.S. for Transplant
<p>Citizenship status data field categories on the DDR form:</p> <ul style="list-style-type: none"> • U.S. Citizen • Resident Alien • Non-Resident Alien, Specify Home Country 	<p>Citizenship status data field categories on the DDR form:</p> <ul style="list-style-type: none"> • U.S. Citizen • Non-U.S. Citizen/U.S. Resident • Non-U.S. Citizen/Non-U.S. Resident

The Committee utilizes data from the citizenship status data element for their annual report which analyzes activities related to the transplantation of non-U.S. citizen/non-U.S. residents, per *OPTN Policy 17.1.C*. Historically, the Committee also utilized this data to identify transplant programs who reported more than 5% of their deceased donor transplants recipients as non-U.S. citizens. The OPTN removed this provision from policy, often referred to as the “5% Rule”, because it was widely misunderstood as a 5% cap on a transplant program’s ability to list and transplant non-U.S. citizens. Currently, per *OPTN Policy 17.1.B: Review of Non-U.S. Citizens/Non-U.S. Resident Registrations and Transplants*, the Committee may request transplant programs to provide additional information regarding registrations or transplant of NCNR patients.¹¹

Given the Committee’s charge, the Committee sought to better understand transplant activity in the U.S. by analyzing citizenship status data. During the summer of 2020, the Committee developed and sent a Program Information Request to 75 transplant programs. The purpose of the Program Information Request was to better understand transplant programs’ policies and practices regarding acceptance of NCNR as transplant patients. The Committee sent their Program Information Request to heart, liver, and kidney programs who met both of the following conditions during any single year from 2017-2019:

¹¹ OPTN Policy 17.1.B, Review of Non-U.S. Citizens/Non-U.S. Resident Registrations and Transplants (June 2021).

- Greater than 5% NCNR candidate registrations or deceased donor transplants to NCNR recipients for a specific organ
- Greater than 5 NCNR candidate registrations or deceased donor transplants to NCNR recipients for a specific organ

The Program Information Request had a 44% response rate. 48% of programs that responded indicated their program does not have a formal process for accepting NCNR candidates. 32 of the 33 programs indicated that their program evaluates the resources available to support NCNR candidates. Programs also provided responses on the documents or processes utilized to establish a NCNR candidate. 20 programs cited the patient (i.e. self-reporting) as the process used to establish a NCNR candidate, while other responses were evenly spread across utilization of passports, referring physicians, family, or government issued evidence.

While 66% of responding programs reported having processes to ensure pre-transplant and post-transplant follow-up care, for NCNR patients, literature reported a 10-20 % lower rate of follow-up data submission for living donor NCNR liver and kidney recipients compared to U.S. citizen living donor liver and kidney recipients starting at one-year follow-up reporting.¹² Additional literature reported similar trends for follow-up data submission of deceased donor NCNR liver and heart recipients.¹³ Additionally, the Program Information Request results indicated the majority of programs did not know whether their NCNR candidates' country of origin had a transplant program for the organ needed, and did not know whether their NCNR candidates had sought transplant services in their country of origin.

The Committee also reviewed literature related to NCNR living donors who donate organs within the U.S. One peer-reviewed article, which analyzed a cohort of living kidney donors from 2000-2016, showed follow-up rates for NCNR living kidney donors were lower compared to U.S. citizen living kidney donors. U.S. citizen living kidney donor follow-up rates varied between about 65% – 75% for six-month, 12-month, and 24-month follow-up. In contrast, NCNR living kidney donor follow-up rates varied between about 30% – 45% for six-month, twelve-month, and twenty-four-month follow-up.¹⁴

In addition to the results from the Program Information Request, as well as review of current literature and data, the Committee reviewed member questions. A few transplant programs requested clarification on how to accurately enter citizenship status. One specific member question that the Committee reviewed stated that they had been inaccurately capturing citizenship status and requested guidance on categorizing patients as NCNR in order to submit better quality data.¹⁵

The Committee discussed the possibility of a data collection project; however, it was decided that the citizenship status data element, as well as data definitions were acceptable. The Committee moved forward with developing a guidance document by outlining the following goals for the guidance document:

- Awareness of citizenship status data element
- Accurate data collection
- Adherence to data collection

¹² OPTN data from January 1, 2016 – December 31, 2019.

¹³ OPTN data as of January 22, 2021.

¹⁴ Ammary, F., et al. "The landscape of international living kidney donation in the United States", *American Journal of Transplant*, (2019) 19(7): 2009-2019.

¹⁵ September 8, 2020 meeting summary, OPTN Ad Hoc International Relations Committee. Available at <https://optn.transplant.hrsa.gov/>.

- Share best practices for accurate, complete, and timely data collection

During the development of the guidance document, the Committee sought feedback from the OPTN Data Advisory, Minority Affairs, and Transplant Administrators Committees. The Committee received positive support from OPTN collaborating committees. Feedback reinforced the Committee's decision to address how the citizenship status data element is utilized in order to gain patient trust, as well as address the importance of collecting citizenship status data on deceased donors.

Recommendations

The proposed document offers guidance on accurately capturing the citizenship status data element. Per *OPTN Policy 18.1: Data Submission Requirements*, members must report accurate data to the OPTN.¹⁶ The guidance document addresses the purpose of collecting the citizenship status of transplant candidates, living donors, and deceased donors as well as how this data is utilized. The document provides guidance on how to accurately categorize individuals as U.S. citizen, non-U.S. citizen/U.S. resident (NCR), NCNR traveling to U.S. for transplant, and NCNR traveling to U.S. for reason other than transplant, on the OPTN data collection forms. The document provides guidance for how health care professionals can appropriately plan for accurate, complete, and timely follow-up data submission of the Transplant Recipient Follow-up (TRF) and Living Donor Follow-up (LDF) forms, given a patient's citizenship status.

Transplant Candidate Registration & Living Donor Registration Forms

Data collected from the citizenship status field is neither used for punitive measures against programs nor for determining patient access to transplant. *OPTN Policy 5.4.A: Nondiscrimination in Organ Allocation* states "a candidate's citizenship or residency status in the United States must not be considered when allocating deceased donor organs to candidates for transplantation."¹⁷ It is important to establish trust and transparency between patients and providers to improve the ability to collect accurate data. It is emphasized that citizenship status data collection lends to fulfilling the OPTN's function to collect quality data in order to produce evidence-based policy solutions. The guidance document clarifies citizenship status data definitions, and addresses measures that healthcare professionals can use to confirm patient citizenship status and enter accurate related data.

Transplant Recipient Follow-up & Living Donor Follow-up Forms

The TRF and LDF forms are data collection tools which are utilized to collect post-transplant and post-donation data on recipients and living donors. *OPTN Policy 18.1: Data Submission Requirements*, requires transplant programs to submit organ specific TRF forms 30 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure.^{18, 19} However, even with a policy requirement, data shows that deceased donor liver NCNR transplant recipients have lower rates of follow-up compared to deceased donor liver U.S. citizen transplant recipients.²⁰ Additionally, *OPTN*

¹⁶ OPTN Policy 18.1, *Data Submission Requirements* (June 2021).

¹⁷ OPTN Policy 5.4.A, *Nondiscrimination in Organ Allocation* (June 2021).

¹⁸ OPTN Policy 18.1

¹⁹ *Modify Data Submission Policies*, change this requirement to 90 days following implementation of policy changes.

²⁰ OPTN data as of January 22, 2021.

Policy 18.1: Data Submission Requirements states that recovery hospitals must submit LDF forms 60 days after the six-month, one-year, and two-year anniversary of the donation date.^{21, 22} While required follow-up for living donors is a significantly shorter timeframe, the rates of follow-up between U.S. citizens and NCNR patients show similar trends as deceased donor transplant recipients.²³ The guidance document is a tool for programs with NCNR and NCR transplant recipients as well as NCNR and NCR living donors, to inform themselves on the importance of accurate, complete, and timely patient follow-up data submission planning given a patient’s citizenship status. Some obstacles that health care professionals should consider for NCNR patients are similar to those faced by U.S. citizens, such as the recipient’s access to health insurance and financial resources. Others may differ from the obstacles faced by U.S. citizens, including the following: (1) availability of clinical transplant expertise in the NCNR recipient’s country of origin or, (2) geographic distance, especially if the recipient returns to their country of origin to receive care.

Deceased Donor Registration Form

It is equally important to capture citizenship status for transplant candidates, living donors, and deceased donors. Data collected on deceased donors lends to the ability to contextualize, relevant to the overall population of organ donors and overall population of transplant recipients, the transplantation of NCNR and NCR candidates in the U.S. Additionally, individuals who may be categorized as NCNR or NCR and are in the U.S. at the time of their death, do contribute to the deceased donor organ pool.

Overall Sentiment from Public Comment

The Committee’s proposed guidance document was issued for public comment from August 3, 2021 to September 30, 2021. There was support from OPTN regions, with some suggested modifications. The OPTN Minority Affairs Committee & Ethics Committee as well as the Society for Transplant Social Workers, NATCO, and American Nephrology Nurses Association expressed support for the proposed guidance document and offered feedback.

The American Society of Transplant Surgeons (ASTS) supported the concept of the document, but did not support the use of terminology which has intrinsic “legal” connotations (i.e. residency). Since the term “resident” is used in citizenship status data collection element, it is unable to be removed from the guidance document. The guidance document specifies that “U.S. resident” is used to capture those who live in the U.S., regardless of their immigration status. The Committee recognizes the importance of accurate data collection elements, and will utilize this feedback during future review of the OPTN citizenship status data element. The Association of Organ Procurement Organizations (AOPO) expressed support for the proposed guidance document and offered modifications based on the inherent differences of collecting citizenship status for deceased donors compared to transplant candidates and living donors. The Committee addressed clarifications within the guidance document based on AOPO’s public comment, which are further detailed below. The American Society of Transplantation (AST) offered support of the proposal in concept and suggested a few modifications, such as additional context on the citizenship status data element. The guidance document addresses background

²¹ OPTN Policy 18.1

²² *Modify Data Submission Policies*, change this requirement to 90 days following implementation of policy changes.

²³ Ammary, F., et al. “The landscape of international living kidney donation in the United States”, *American Journal of Transplant*, (2019) 19(7): 2009-2019.

information on the citizenship status data element, as well as highlights *OPTN Policy 5.4.A: Nondiscrimination in Organ Allocation* which states that a candidate's citizenship or residency status in the United States must not be considered when allocating deceased donor organs to candidates for transplantation. The purpose of the guidance document is to improve accuracy of data collected and clarify the categorization of citizenship status within OPTN data collection, as such the Committee appreciates AST's feedback and has addressed clarifications regarding the categorization of U.S. citizen and deceased donation.

Feedback of support in public comment noted the importance of clarification of citizenship status data element definitions and improvement of transparency. Feedback also noted that it is critical to understand a patient's background in order to better serve and understand the transplant population. Some opposition noted that the guidance document was unnecessary, however a majority of the opposition was related to the collection of citizenship status on OPTN data collection forms, which is outside of the scope of the Committee's current project.

Minor Clarifications

Public comment feedback expressed that the guidance document needed to better clarify the term "donor" throughout. The Committee supported this feedback and, throughout the guidance document, the use of the term donor has been clarified to specify either living donors, deceased donors, or both. Additional modifications to the guidance document were made to clarify that, in addition to citizenship status, the TCR and LDR forms capture county of permanent residence and year of entry to the U.S., while the DDR form captures home country.

Additionally, community feedback requested for a more complete clarification for the categorization of U.S. Citizen. Public comment feedback highlighted that the clarification in the guidance document was incomplete as it did not address certain pathways to obtaining U.S. citizenship, such as adoption. The Committee agreed with this feedback and concluded to modify the U.S. citizenship categorization clarification with language that is broadly encompassing in order to not leave out any particular pathway to U.S. citizenship.

Modifications to Address Deceased Donor Data Collection

Feedback from AOPO, as well as other public comments, cited the inherent differences of collecting citizenship status for deceased donors compared to living donors and transplant candidates. Specifically, AOPO requested that references to OPOs checking source documentation and verifying citizenship status be eliminated from the guidance document. The Committee reviewed AOPOs feedback and modified the guidance document to eliminate these references. Additionally, the Committee discussed the inherent challenges with acquiring data collection on deceased donors compared to living donors and transplant candidates, and determined that they do not wish for information in the guidance document to interfere with current OPO practices. Due to this, the Committee added additional language to acknowledge the unique challenges OPOs face. The Committee recognizes that citizenship status data may not be consistent but feels it is important for OPOs to ascertain when able as to have a complete understanding of citizenship status among candidates, living donors, and deceased donors, and acknowledges the OPO's ability to enter citizenship status as "unknown" when needed.

Citizenship Status Data Collection

Additional feedback from the community questioned the need to collect citizenship status data. Highlighted concerns surrounding the collection of citizenship status on OPTN data collection forms included there to be no medical benefit of collecting this data, the potential to defer non-citizens from seeking transplant, and unnecessary burden on transplant centers. Feedback also highlighted potential changes to the current data collection, such as removing legal terminology, which the Committee has documented for future review. Addressing data collection modifications is outside the scope of the Committee's current guidance document proposal. However, the Committee recognizes the importance of the community's feedback and stays committed to reviewing data collection measures to ensure relevancy.

Additional Comments

There was feedback that highlighted concern regarding data security and citizenship status data. While data security is an important consideration, it is not the purpose of the guidance document to address it. The Committee recognizes that the OPTN and HRSA have developed ample security infrastructure and work continually to ensure patient data remains protected. Additionally, there was broad recognition from the community that citizenship status data may not be accurate or reliable. The Committee emphasizes that the purpose of the guidance is to increase accuracy of citizenship status data entry by providing guidance and clarity to the transplant community on current classification of citizenship status. Other public comments suggested that there should be explanation of how citizenship status data is used. The Committee appreciates broader feedback on the topic of citizenship status data and intends to further discuss this topic as a Committee.

Compliance Analysis

NOTA and OPTN Final Rule

The Committee submits the following proposal under the authority of the National Organ Transplant Act (NOTA), which states the OPTN shall "provide information to physicians and other health professionals regarding organ donation"²⁴, as well as the OPTN Final Rule, which states "An organ procurement organization or transplant hospital shall...submit to the OPTN...information regarding transplant candidates, transplant recipients, [and] donors of organs..."²⁵ and that the OPTN shall:

- (i) Maintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors, including a computerized list of individuals waiting for transplants;
- (ii) Maintain records of all transplant candidates, all organ donors and all transplant recipients;
- (iii) Operate, maintain, receive, publish, and transmit such records and information electronically, to the extent feasible, except when hard copy is requested; and

²⁴ 42 U.S.C. §274(b)(2)(H).

²⁵ 42 CFR §121.11(b)(2).

(iv) In making information available, provide manuals, forms, flow charts, operating instructions, or other explanatory materials as necessary to understand, interpret, and use the information accurately and efficiently.²⁶

The Committee's citizenship status guidance document aims to improve quality of data collection of the existing citizenship status field on the TCR, LDR, and DDR forms by providing information to transplant hospital professionals and OPO professionals about how to appropriately report citizenship status for donors and candidates. The guidance document aims to promote an increase in reported follow-up among NCR and NCR recipients and donors, given their citizenship status, for OPTN records.

OPTN Strategic Plan

The Committee's proposal aligns with the strategic plan by promoting living donor and transplant recipient safety. Improving data collection allows for transplant professionals to appropriately plan for accurate, timely, and complete data collection and pre- and post-transplant patient care.

Conclusion

The proposed document provides guidance on the classification of citizenship status as an OPTN data element, and provide information on how the citizenship status data element is utilized. The guidance document addresses accurate collection of citizenship status at registration, and accurate, complete, and timely follow-up data collection given a patient's citizenship status. Accurate collection of citizenship status assists the ability to (1) perform quality data analyses; (2) develop evidence based policies; (3) monitor patient safety and welfare; and (4) ensure stewardship of donated organs. While the transplant community was broadly supportive of the proposed guidance document, they also offered feedback for suggested modifications. The Committee reviewed and discussed these public comments, and concluded to incorporate some suggested modifications. The Committee edited the guidance document to provide further clarification on the use of "donors", and the categorization of U.S. citizen. Additionally, the Committee clarified, that in addition to citizenship status, the TCR and LDR collect country of permanent residence and year of entry in the U.S., and the DDR collects home country. Other post-public comment changes included eliminating references to OPOs checking source documentation and verifying citizenship status, and added language to address the unique challenges that OPOs face when collecting citizenship status. The modifications that the Committee incorporated do not impact the intent or meaning of the guidance document, but add additional clarity to reinforce the goal of promoting accurate data collection and usability of the guidance document by the community.

²⁶ 42 CFR §121.11(a)(1)(i)-(iv).

Guidance Document

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.

Guidance for Data Collection Regarding Classification of Citizenship Status

Introduction

Throughout this document the term ‘citizenship status’ refers to the OPTN data collection element “citizenship status”. This OPTN data element collects information on citizenship, residency, and country of origin. It is not within the OPTN’s function to discern legality of immigration status of patients. Therefore, statements and guidance within this document focus solely on accurately collecting citizenship status as it pertains to OPTN data collection.

This guidance document may be used as a resource for transplant programs and organ procurement organizations (OPOs) to reference to ensure accurate collection of the OPTN citizenship status data element. The OPTN collects quality data on transplant candidates, living organ donors, deceased organ donors, and transplant recipients²⁷, which are used for various purposes, including developing evidence-based policies and ensuring that the OPTN can provide information to physicians and other health professionals regarding organ donation.²⁸

In 2018, non-U.S. citizens/non-U.S. residents comprised 1.3% of transplant candidate registrations, and 1.4% of organ recipients.²⁹ *OPTN Policy 5.4.A: Nondiscrimination in Organ Allocation states, “a candidate’s citizenship or residency status in the United States must not be considered when allocating deceased donor organs to candidates for transplantation. Allocation of deceased donor organs must not be influenced positively or negatively by political influence, national origin, ethnicity, sex, religion, or financial status.”*³⁰

OPTN data designates non-U.S. citizens into two distinct categories:

- Non-U.S. citizen/non-U.S. resident
- Non-U.S. citizen/U.S. resident

OPTN Policy defines non-U.S. citizen/non-U.S. residents as, “a non-citizen of the United States for whom the United States is not the primary place of residence.”³¹ A non-U.S. citizen/U.S. resident is defined in OPTN Policy as “a non-citizen of the United States for whom the United States is the primary place of residence.”³²

²⁷ 42 C.F.R. §121.11(a)(1)(i)-(iv); 42 C.F.R §121.11 (b)(2).

²⁸ 42 U.S.C. §274(b)(2)(H).

²⁹ 2019 Annual Report of Non-U.S. Resident Transplant Activity, OPTN Ad Hoc International Relations Committee. Available at <https://optn.transplant.hrsa.gov/>.

³⁰ OPTN Policy 5.4.A, *Nondiscrimination in Organ Allocation* (June 2021).

³¹ OPTN Policy 1.2, *Definitions* (June 2021).

³² OPTN Policy 1.2

33 OPTN data collection for citizenship status does not address the legal status of an individual’s place of
 34 residency. Primary place of residency is solely intended to capture where an individual lives, regardless
 35 of their legal status. It is not within the scope of the OPTN’s function to discern transplant candidates,
 36 living donors, and deceased donors’ legal citizenship status, therefore, it is not a factor when collecting
 37 citizenship status data.

38
 39 There are many direct and indirect benefits to ascertaining the citizenship status of both living organ
 40 donors, deceased organ donors, and organ recipients. For instance, accurate tracking of citizenship
 41 status helps determine the non-U.S. citizens/non-U.S. resident’s deceased organ donor to organ
 42 recipient ratio. As organ transplantation is a cost-efficient way of managing end-stage organ failure,
 43 ascertaining the citizenship status can help shed some light on the net healthcare cost of the non-U.S.
 44 citizens/non-U.S. residents’ and non-U.S. citizens/U.S. residents’ beneficiaries. Additionally, the
 45 citizenship status data element is the sole data element that allows the OPTN to review citizenship,
 46 residency, and country of origin of its patient and donor population.

47
 48 The concern for ascertaining the citizenship status among living organ donors and organ recipients has
 49 been explored in the past. In 2012, the terminology of citizenship status reporting was changed to
 50 replace “resident alien” and “non-resident alien”, with “non-U.S. citizen/U.S. resident”, “non-U.S.
 51 citizen/non-U.S. resident who traveled to the U.S. for transplant”, and “non-U.S. citizen/non-U.S.
 52 resident who traveled to the U.S. for reason other than transplant”.³³ The basis for this change was to
 53 properly analyze transplant tourism, as outlined in the *Declaration of Istanbul*, within the U.S.³⁴

54
 55 Ascertaining citizenship status can be a complex task. Some of the complexities may be related to the
 56 inexperience of the transplant professional asking the questions, language barriers, or fear of
 57 immigration-related punitive consequences, especially in regions of the U.S. that do not routinely
 58 accommodate undocumented immigrants. Finally, the lack of policies to guide transplant programs and
 59 OPOs reporting the documentation status further complicate the matter.

60 **Registration Data Collection**

61
 62 The current categorization scheme of the citizenship status data element on the Transplant Candidate
 63 Registration (TCR), Living Donor Registration (LDR), Deceased Donor Registration (DDR) forms allow the
 64 OPTN to better capture all activities pertaining to transplantation of non-U.S. citizen/U.S. resident and
 65 non-U.S. citizen/non-U.S. resident. Citizenship status information is provided by the transplant program
 66 and OPO staff filling out the data collection forms in UNetSM at the time of listing transplant candidates,
 67 living donors, and deceased donors. U.S. transplant programs and OPOs should ensure accurate
 68 information is provided by the transplant candidate, living organ donor, or their care giver. There are
 69 several factors that contribute to inaccurate collection of citizenship status at registration. Four main
 70 factors are outlined below, as well as guidance on how to improve accurate collection of the citizenship
 71 status data element.

72 **1. Clarity on citizenship status definitions of donors and recipients**

73
 74 Various interpretations of the citizenship status data elements have resulted in misclassification of
 75 citizenship status for patients. The following categories of citizenship status are the current data
 76 element choices collected on the TCR and LDR forms:

³³ *Proposed Revisions to and Reorganization of Policy 6.0*, OPTN Ad Hoc International Relations Committee & OPTN Ethics Committee, 2011.

³⁴ Steering Committee of the Istanbul Summit. Organ trafficking and transplant tourism and commercialism: The Declaration of Istanbul. *Lancet* (2008) 372: 5–6.

- 77 I. U.S. citizen
- 78 II. Non-U.S. citizen/U.S. resident
- 79 III. Non-U.S. citizen/Non-U.S. resident, who traveled to U.S. for reason other than transplant
- 80 IV. Non-U.S. citizen/Non-U.S. resident, who traveled to U.S. for transplant.

81

82 The first data element for the citizenship status data collection, U.S. citizen, is defined in the UNet Help
 83 Documentation³⁵ as, “a United States citizen by birth or naturalization.” Any transplant candidate, living
 84 organ donor, or deceased organ donor who was born in the United States, or has completed any type of
 85 United States naturalization process, is to be categorized as U.S. citizen.

86

87 Non-U.S. citizen/U.S. resident is defined in the UNet Help Documentation³⁶ as, “a non-citizen of the
 88 United States for whom the United States is the primary place of residence.” To categorize a transplant
 89 candidate, living organ donor, or deceased organ donor as non-U.S. citizen/U.S. resident, the patient
 90 must be living in the U.S. Whether or not the patient has documentation or authorization to be a
 91 resident of the U.S. is not a factor.

92

93 Non-U.S. citizen/non-U.S. resident, who traveled to U.S. for reason other than transplant, is different
 94 than the previously mentioned data element, because categorization requires the transplant candidate
 95 or living organ donor to be traveling in the U.S., not residing. This data element is defined in the UNet
 96 Help Documentation³⁷ as “a non-citizen of the United States for whom the United States is not the
 97 primary place of residence, and who came to the U.S. for a reason other than transplant.” A common
 98 reason for traveling to the U.S. for a reason other than transplant are vacation, visiting relatives/friends,
 99 business, and temporary student.

100

101 A transplant candidate or living organ donor whose sole purpose of being in the United States is organ
 102 transplantation is to be categorized as non-U.S. citizen/non-U.S. resident, who traveled to U.S. for
 103 transplant. This data element is defined in UNet Help Documentation³⁸ as, “a non-citizen of the United
 104 States for whom the United States is not the primary place of residence, and who came to the U.S. for
 105 the purpose of transplant”.

106

107 For any transplant candidate or living donor who is not a U.S. citizen and is not a resident in the U.S., a
 108 transplant program should obtain the country of permanent residence and year of entry into the U.S. on
 109 the TCR and LDR. For any deceased donor who is not a U.S. citizen, an OPO should obtain the home
 110 country for complete citizenship status collection on the DDR.

111

112 **2. Various data sources used by transplant programs**

113 Transplant programs are using inconsistent processes and/or documents to determine the citizenship
 114 status of candidates and living organ donors. Since most residency and citizenship statuses are self-
 115 reported by patients, family, and referring physicians, information regarding citizenship, primary place
 116 of residency, country of origin, and year of entry into U.S. most likely cannot be validated. The additional
 117 determination of traveling to the U.S. for reasons other than transplant versus traveling for transplant is

³⁵ UNetSM Help Documentation, as of June 2021.

³⁶ UNet Help Documentation, as of June 2021.

³⁷ UNet Help Documentation, as of June 2021.

³⁸ UNet Help Documentation, as of June 2021.

118 also determined by transplant programs, who may have different interpretations for these various
 119 classifications.

120
 121 Use of data from non-validated sources may lead to incorrect data reporting on living donors and
 122 recipients in UNet at the time of listing transplant candidates and living organ donors. Transplant
 123 program staff may not be formally educated on verification of residency status.³⁹ Transplant programs
 124 should consider, and implement, a set standard for the types of source documentation utilized when
 125 reporting citizenship status.

126
 127 **3. Challenges to the language barriers and legal status**
 128 Non-U.S. citizen/non-U.S. resident and non-U.S. citizen/U.S. resident patients may come from non-
 129 English speaking countries, or English is their second language.⁴⁰ Low English proficiency puts patients at
 130 the greatest challenges in communicating with transplant staff, which may result in inaccurate data
 131 collection.

132
 133 Additionally, undocumented patients may have fears about being rejected from being able to receive an
 134 organ transplant or their families may fear potential repercussions of immigration enforcement if they
 135 consent to donate a patient’s organs and identify as non-U.S. citizens/non-U.S. residents, or non-U.S.
 136 citizen/U.S. resident. OPOs face unique challenges due to the inherent nature of having to collect
 137 citizenship status through deceased organ donor families. OPOs are encouraged to ascertain citizenship
 138 status if able and if it is reliable.

139
 140 Transplant programs should provide medical or credentialed interpreters skilled at acquiring the
 141 information needed and alleviating the fears of the patient and the family consenting for donation.
 142 Transplant program staff should explain that the transplant system does not exclude patients on the
 143 basis of citizenship, residency, or immigration status. Per *OPTN Policy 5.4.A: Nondiscrimination in Organ*
 144 *Allocation* states “a candidate’s citizenship or residency status in the United States must not be
 145 considered when allocating deceased donor organs to candidates for transplantation.”⁴¹ Transplant
 146 program staff should explain to patients that citizenship status data is utilized for transparency and the
 147 ability to perform quality data analyses in order to create evidence based policy which ensures patient
 148 safety and welfare. Addressing language barriers and informing patients on how OPTN citizenship status
 149 data is utilized aims to create trust between patients and providers, thus improving the accuracy of
 150 reported citizenship status for data collection.

151
 152 **4. Processes for ensuring accurate citizenship status data collection**
 153 *OPTN Policy 18.1: Data Submission Requirements* states that members must report accurate data to the
 154 OPTN⁴². Transplant programs and OPOs would more consistently and accurately meet these
 155 requirements with established, documented approaches to data collection in place.

156

³⁹ Delmonico FL, et al. Deceased Donor Organ Transplantation Performed in the United States for Noncitizens and Nonresidents. *Transplantation*. 2018;102(7):1124-1131.

⁴⁰ 2019 Annual Report of Non-U.S. Resident Transplant Activity, OPTN Ad Hoc International Relations Committee.

⁴¹ OPTN Policy 5.4.A

⁴² OPTN Policy 18.1, *Data Submission Requirements* (June 2021).

157 Follow-up Data Collection

158 OPTN policy requires transplant programs to submit Transplant Recipient Follow-up (TRF) and Living
 159 Donor Follow-up (LDF) forms. The follow-up data collection rates for non-U.S. citizen/non-U.S. residents
 160 and non-U.S. citizen/U.S. residents are significantly lower than follow-up data collection rates for U.S.
 161 citizens.⁴³ Non-U.S. citizen/non-U.S. resident and non-U.S. citizen/U.S. resident recipient and living
 162 donor loss to follow up and non-adherence may due to the following reasons:

- 163 1. Recipient/living donor is uninsured or is afraid of financial burden
- 164 2. Undocumented immigration status that prevents recipient/living donor from getting a non-
 165 emergency health insurance
- 166 3. Costs for travel, in the event there is no follow-up in the country of origin, especially seen in
 167 the international and out of state long distance recipient/living donors
- 168 4. Lack of support and resources
- 169 5. Lack of job security or is unable to take time off for the clinic visit
- 170 6. Recipient/living donor's demographic such as age, gender, ethnicity
- 171 7. Physically feeling well and no clear substantial medical reasons for follow up

172
 173 Before a transplant program engages in transplant activity with non-U.S. citizens/non-U.S. residents and
 174 non-U.S. citizens/U.S. residents, it is critical for the transplant program to consider its ability to collect
 175 follow-up data on patients. Development of recipient and living donor follow up protocols may ensure
 176 the long-term health of living donors, ensure stewardship of organs, and improve the quality of follow-
 177 up data submissions.⁴⁴ The following are suggestions for improving rates of follow-up data submission
 178 for non-U.S. citizen/U.S resident and non-U.S. citizen/U.S. resident recipients and living donors:

- 179 1. Inform recipient/living donors from the very first contact that follow-up is critical
- 180 2. Inform recipients/living donors during clinic so information can be collected for TRF/LDF
 181 data collection
- 182 3. Develop strong staff commitment to ensure there is adherence to recipient/living donor
 183 follow-up
- 184 4. Relationship building by using a dedicated living donor coordinator or social worker
- 185 5. Schedule living donor and recipient follow up at the same clinic visit
- 186 6. Inform recipient/living donors from the very first contact that follow-up is critical
- 187 7. Increase recipient/living donors' own commitment to a healthy lifestyle post-donation
- 188 8. Ask recipients/living donors to establish a relationship with a primary care physician close to
 189 their home of residence
- 190 9. If recipient/living donor will be visiting the primary care physician rather than the transplant
 191 center for LDF data collection, send a letter for primary care physician
- 192 10. Develop a systematic approach to follow-up with quality assurance

193
 194 This guidance is provided to the OPTN Board of Directors in order to assist the transplant community in
 195 accurately capturing citizenship status at time of registration, and address accurate, complete, and
 196 timely submission of follow-up data.

197 #

⁴³Ammary, F., et al. "The landscape of international living kidney donation in the United States", *American Journal of Transplant*, (2019) 19(7): 2009-2019.

⁴⁴ Lentine, K., et al. Care of International Living Kidney Donor Candidates in the United States. *The Journal of Clinical and Translational Research*.