

# 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 recipients<sup>1</sup>, 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.<sup>2</sup>

In 2018, non-U.S. citizens/non-U.S. residents comprised 1.3% of transplant candidate registrations, and 1.4% of organ recipients.<sup>3</sup> *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.”<sup>4</sup>

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.”<sup>5</sup> 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.”<sup>6</sup>

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

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<sup>1</sup> 42 C.F.R. §121.11(a)(1)(i)-(iv); 42 C.F.R. §121.11 (b)(2).

<sup>2</sup> 42 U.S.C. §274(b)(2)(H).

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

<sup>4</sup> OPTN Policy 5.4.A, *Nondiscrimination in Organ Allocation* (June 2021).

<sup>5</sup> OPTN Policy 1.2, *Definitions* (June 2021).

<sup>6</sup> OPTN Policy 1.2

There are many direct and indirect benefits to ascertaining the citizenship status of both living organ donors, deceased organ donors, and organ recipients. For instance, accurate tracking of citizenship status helps determine the non-U.S. citizens/non-U.S. resident's deceased organ donor to organ recipient ratio. As organ transplantation is a cost-efficient way of managing end-stage organ failure, ascertaining the citizenship status can help shed some light on the net healthcare cost of the non-U.S. citizens/non-U.S. residents' and non-U.S. citizens/U.S. residents' beneficiaries. Additionally, 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.

The concern for ascertaining the citizenship status among living organ donors and organ recipients has been explored in the past. In 2012, the terminology of citizenship status reporting was changed to replace "resident alien" and "non-resident alien", with "non-U.S. citizen/U.S. resident", "non-U.S. citizen/non-U.S. resident who traveled to the U.S. for transplant", and "non-U.S. citizen/non-U.S. resident who traveled to the U.S. for reason other than transplant".<sup>7</sup> The basis for this change was to properly analyze transplant tourism, as outlined in the *Declaration of Istanbul*, within the U.S.<sup>8</sup>

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

## Registration Data Collection

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

### 1. Clarity on citizenship status definitions of donors and recipients

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

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

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<sup>7</sup> *Proposed Revisions to and Reorganization of Policy 6.0*, OPTN Ad Hoc International Relations Committee & OPTN Ethics Committee, 2011.

<sup>8</sup> Steering Committee of the Istanbul Summit. Organ trafficking and transplant tourism and commercialism: The Declaration of Istanbul. *Lancet* (2008) 372: 5–6.

The first data element for the citizenship status data collection, U.S. citizen, is defined in the UNet Help Documentation<sup>9</sup> as, “a United States citizen by birth or naturalization.” Any transplant candidate, living organ donor, or deceased organ donor who was born in the United States, or has completed any type of United States naturalization process, is to be categorized as U.S. citizen.

Non-U.S. citizen/U.S. resident is defined in the UNet Help Documentation<sup>10</sup> as, “a non-citizen of the United States for whom the United States is the primary place of residence.” To categorize a transplant candidate, living organ donor, or deceased organ donor as non-U.S. citizen/U.S. resident, the patient must be living in the U.S. Whether or not the patient has documentation or authorization to be a resident of the U.S. is not a factor.

Non-U.S. citizen/non-U.S. resident, who traveled to U.S. for reason other than transplant, is different than the previously mentioned data element, because categorization requires the transplant candidate or living organ donor to be traveling in the U.S., not residing. This data element is defined in the UNet Help Documentation<sup>11</sup> as “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.” A common reason for traveling to the U.S. for a reason other than transplant are vacation, visiting relatives/friends, business, and temporary student.

A transplant candidate or living organ donor whose sole purpose of being in the United States is organ transplantation is to be categorized as non-U.S. citizen/non-U.S. resident, who traveled to U.S. for transplant. This data element is defined in UNet Help Documentation<sup>12</sup> as, “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”.

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

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

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

Use of data from non-validated sources may lead to incorrect data reporting on living donors and recipients in UNet at the time of listing transplant candidates and living organ donors. Transplant

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<sup>9</sup> UNet<sup>SM</sup> Help Documentation, as of June 2021.

<sup>10</sup> UNet Help Documentation, as of June 2021.

<sup>11</sup> UNet Help Documentation, as of June 2021.

<sup>12</sup> UNet Help Documentation, as of June 2021.

program staff may not be formally educated on verification of residency status.<sup>13</sup> Transplant programs should consider, and implement, a set standard for the types of source documentation utilized when reporting citizenship status.

### **3. Challenges to the language barriers and legal status**

Non-U.S. citizen/non-U.S. resident and non-U.S. citizen/U.S. resident patients may come from non-English speaking countries, or English is their second language.<sup>14</sup> Low English proficiency puts patients at the greatest challenges in communicating with transplant staff, which may result in inaccurate data collection.

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

Transplant programs should provide medical or credentialed interpreters skilled at acquiring the information needed and alleviating the fears of the patient and the family consenting for donation. Transplant program staff should explain that the transplant system does not exclude patients on the basis of citizenship, residency, or immigration status. Per *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."<sup>15</sup> Transplant program staff should explain to patients that citizenship status data is utilized for transparency and the ability to perform quality data analyses in order to create evidence based policy which ensures patient safety and welfare. Addressing language barriers and informing patients on how OPTN citizenship status data is utilized aims to create trust between patients and providers, thus improving the accuracy of reported citizenship status for data collection.

### **4. Processes for ensuring accurate citizenship status data collection**

*OPTN Policy 18.1: Data Submission Requirements* states that members must report accurate data to the OPTN<sup>16</sup>. Transplant programs and OPOs would more consistently and accurately meet these requirements with established, documented approaches to data collection in place.

## **Follow-up Data Collection**

OPTN policy requires transplant programs to submit Transplant Recipient Follow-up (TRF) and Living Donor Follow-up (LDF) forms. The follow-up data collection rates for non-U.S. citizen/non-U.S. residents and non-U.S. citizen/U.S. residents are significantly lower than follow-up data collection rates for U.S. citizens.<sup>17</sup> Non-U.S. citizen/non-U.S. resident and non-U.S. citizen/U.S. resident recipient and living donor loss to follow up and non-adherence may due to the following reasons:

1. Recipient/living donor is uninsured or is afraid of financial burden

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<sup>13</sup> Delmonico FL, et al. Deceased Donor Organ Transplantation Performed in the United States for Noncitizens and Nonresidents. *Transplantation*. 2018;102(7):1124-1131.

<sup>14</sup> 2019 Annual Report of Non-U.S. Resident Transplant Activity, OPTN Ad Hoc International Relations Committee.

<sup>15</sup> OPTN Policy 5.4.A

<sup>16</sup> OPTN Policy 18.1, *Data Submission Requirements* (June 2021).

<sup>17</sup> Ammary, F., et al. "The landscape of international living kidney donation in the United States", *American Journal of Transplant*, (2019) 19(7): 2009-2019.

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

Before a transplant program engages in transplant activity with non-U.S. citizens/non-U.S. residents and non-U.S. citizens/U.S. residents, it is critical for the transplant program to consider its ability to collect follow-up data on patients. Development of recipient and living donor follow up protocols may ensure the long-term health of living donors, ensure stewardship of organs, and improve the quality of follow-up data submissions.<sup>18</sup> The following are suggestions for improving rates of follow-up data submission for non-U.S. citizen/non-U.S. resident and non-U.S. citizen/U.S. resident recipients and living donors:

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

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

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<sup>18</sup> Lentine, K., et al. Care of International Living Kidney Donor Candidates in the United States. *The Journal of Clinical and Translational Research*.