At a glance

Title: Data Collection to Assess Socioeconomic Status and Access to Transplant
Sponsoring Committee: Minority Affairs

What is current policy and why change it?

The OPTN currently collects limited information that pertains to a transplant candidate's socioeconomic status (SES). Collecting detailed socioeconomic related data will inform the OPTN and the public. (e.g. assessment of the potential impact candidates' SES could have on access to organ transplantation).

What's the proposal?

- Transplant hospital staff would be responsible for asking candidates at the time of registration on the waitlist their **annual household income** and **household size**.
- These two data points would be entered on the patient's **Transplant Candidate Registration (TCR)** form.
    - At the time of listing, every transplant candidate has a TCR form entered into UNet℠, the OPTN computer system.
- This data will inform OPTN Committees and the community on the impact of a candidate's socio-economic status.

What's the anticipated impact of this change?

- **What it's expected to do**
    - Transplant hospitals would develop a process for collecting annual household income and household size from candidates and enter the data in the TCR form.

    - This data will inform OPTN Committees and the community on the impact of a candidate's socio-economic status.
- **What it won't do**
    - Candidates access to transplant will not be impacted by providing this information.
        - The two data points are for informational purposes in future analyses by OPTN Committees and the community.

    - Provide any data on patients who were not referred to the waiting list.

Themes to consider

- Best types of data to measure SES
- Barriers to collecting data
- Timeline to implement required collection of data

Terms you need to know

- **Annual household income:** total income (in US dollars) for all persons living within the transplant candidate's home.
- **Household size:** the total number of people living in the same household as the transplant candidate who are dependent on the household income.
- **Transplant Candidate Registration (TCR) data collection instrument:** The data collection instrument completed and submitted by the transplant hospital when a patient is added to the waiting list or when living donor feedback is completed for patients who are not listed. The form contains information on candidate demographics, previous transplants, payment, clinical information at time of listing and organ specific medical factors.
- Click here to search the OPTN glossary

Public Comment Proposal

Data Collection to Assess Socioeconomic Status and Access to Transplant

OPTN Minority Affairs Committee

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OPTN

Data Collection to Assess Socioeconomic Status and Access to Transplant

Sponsoring Committee: *OPTN Minority Affairs Committee*
Public Comment Period: *January 22, 2020 – April 24, 2020*

Executive Summary

Currently, the Organ Procurement and Transplantation Network (OPTN) does not collect certain data on socioeconomic status (SES) factors that could be used to explore the potential association between patient SES and patient access to organ transplantation. The collection of better patient-level data would provide the OPTN the opportunity have a more holistic understanding of how SES factors may impact transplant candidates. In this public comment document, the OPTN Minority Affairs Committee (MAC) proposes adding annual household income and household size as new fields to the OMB-approved Transplant Candidate Registration (TCR) data collection instrument[1, 2.] The proposed data elements would be added to the existing SES indicators collected on the TCR. The SES indicators currently collected by the OPTN are patients' primary source of payment, highest level of education, and whether they are working for income. The TCR is a data collection instrument submitted to the OPTN by transplant programs each time a patient is added to the waitlist[3]. These data are not intended for analysis of access to placement on the waiting list, but will be used to measure access to transplantation from the time of listing forward. The proposal aligns with the Final Rule, as it proposes gathering SES information that could inform the OPTN on methods to promote patient access to transplant.[4] Collection of these data could be used to inform new policy that aims to reduce inequities resulting from SES.

The MAC welcomes all feedback from individuals and organizations with vested interest, but specifically asks for input on the following:

- Are annual household income and household size the best data elements to collect to measure SES?
- What barriers might there be to collecting and reporting these data?
- Are there other data related to SES the OPTN should collect?

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[1] Transplant Candidate Registration TIEDI Data Collection Instrument for all organs can be accessed here https://unos.org/data/data-collection/.

[2] September 23rd 2019, Minority Affairs Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/.

[3] OPTN Policy 18: Data Submission Requirements, Table 18-1: Data Submission Requirements.

[4] 42 C.F.R. § 121.8(a).

Purpose of the Proposal

The purpose of this proposal is to collect additional patient-level SES data. These new data will allow the OPTN to perform better analyses on the potential impact of SES on patient access to transplantation. This data collection would take place one time at the time of registration on the waiting list. This data is not intended for analysis of access to placement on the waiting list, but will be used to measure access to transplantation from the time of listing forward. This goal is consistent with the Final Rule requirement that the OPTN reform allocation policies based on their cumulative effect on socioeconomic inequalities. [5] Official OPTN data are defined as all data collected by the OPTN pursuant to regulatory requirements.[6]

SES is defined as the social standing or class of an individual or group, often measured by a combination of education, income, and occupation.[7] Examination of SES can show disparities in access to resources. Individuals and households are grouped based on these metrics into high, medium, or low SES. SES is known to be a key determinant of health outcomes.[8]

Background

In the fall of 2018, the MAC submitted a data request aimed to investigate disparities in access to kidney transplant based on SES[9]. The MAC stratified candidates by SES status and examined waitlist outcomes to determine if an inequity existed. Upon the presentation of these data, the MAC observed a disparity in access to living organ donation. It was also noted that low SES patients had higher waitlist mortality when compared to higher SES patients.[10] The MAC expressed their need to identify data elements that better describe current challenges low SES candidates face in access to transplant, and to provide data that may assist in future OPTN policymaking including efforts to improve equity in access to transplantation as required by the Final Rule.[11,12]

Currently, the OPTN collects very little data on the SES of patients. Some measures of SES data are collected by the OPTN on Transplant Information Electronic Data Interchange (TIEDI) data collection instruments.[13] The table below displays the SES data collected by each data collection instrument.

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[5] 42 C.F.R. § 121.4(a).

[6] 42 C.F.R. § 121.11.

[7] American Psychological Association. (2019) Socioeconomic Status. Available at: https://www.apa.org/topics/socioeconomic-status/.

[8] Winters- Miner, L A., Bolding, P. S., Hilbe, J. M., Goldstein, Hill. T., Nisbet, R., Walton, N., & Miner, G. D. (2015). Personalized medicine. In L. A. Winters-Miner et al. (Eds.), Practical predicative analytics and decisioning systems for medicine (176-204). Cambridge, Massachusetts: Academic Press.

[9] OPTN Descriptive Data Request. ”Disparities in Access to Kidney Transplant by Socioeconomic Status.” Prepared for Minority Affairs Committee In-Person Meeting, March 29, 2019.

[10] Id.

[11] May 6th 2019, Minority Affairs Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/.

[12] 42 C.F.R. § 121.4(a).

[13] TIEDI Data Collection Instruments can be accessed here https://unos.org/data/data-collection/.

Table 1: SES Data Collected by TIEDI Data Collection Instruments

SES Data on TIEDI Forms	Transplant Candidate Registration	Transplant Recipient Registration	Transplant Recipient Follow- up	Living Donor Registration	Living Donor Follow-up
Primary Source of Payment	x	x	x		
Highest level of Education	x			x	
Working for Income	x	x	x		x

The Committee feels that the data currently collected by the OPTN is not adequate to fully understand factors that define the SES of transplant candidates. Collection of additional patient- level data would allow the OPTN and its committees to better assess the impact of patient SES on access to transplant.[14]

The MAC selected the type of proposal they would develop. The Committee compared the benefit of providing a guidance document to the community or collecting additional data. Additional data collection was assessed to be more appropriate than a guidance document.[15] A guidance document serves as a reference for OPTN members. It provides recommendations on best practices and protocols. Guidance documents usually have a specific audience they are aiming to reach, but do not require change from this audience. Data collection is comprehensive and captures consistent and usable information. The MAC determined that data collection was the more appropriate mechanism as the OPTN collects limited SES data. The SES data currently collected by TIEDI instruments can be seen above in **Table 1.** The Committee does not think the OPTN has enough data to fully assess equity in access to transplant based on SES factors.[16] With this data collection, the OPTN has the opportunity to observe the difference in access to transplant impacted by SES. This first step would establish data collection and investigate the level of disparity that exists in the current system.

The Committee collaborated with the Transplant Administrators Committee (TAC), Transplant Coordinators Committee (TCC), and the Data Advisory Committee (DAC) in developing this proposal.

MAC brainstormed the following data elements and considered which would be a better measure for patient SES:

- Annual household income & household Size
- Expanded "Working for Income" Options like Living Donor Registry (LDR)
- Access to Transportation
- Individual Patient Income

The MAC discussed each element to determine which would be the best measure of SES to include in a data collection proposal. The paragraphs below summarize their conclusions and recommendations.[17]

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[14] September 23rd 2019, OPTN Minority Affairs Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/

[15] July 15th 2019, OPTN Minority Affairs Committee Meeting Summary, Available at https://optn.transplant.hrsa.gov/

[16] September 23rd 2019, OPTN Minority Affairs Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/

[17] November 18th 2019, OPTN Minority Affairs Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/

Annual Household Income & Household Size

When collected together annual household income and household size can be compared to the Federal Poverty Guideline (FPG), a widely used standard for measuring income.[18] The U.S. Federal government uses this measure to determine who is eligible for certain financial services and participation in assistance programs. The comparison of household income and size to these federal benchmarks is a common method of determining whether households have access to adequate resources or might be expected to have poor health outcomes.[19]

Expanded "Working for Income"

The LDR is a data collection instrument that is submitted to the OPTN by transplant programs each time a living donor is registered.[20] This form requires additional data under the "working for income" field that are not included in the TCR. Yes or no responses branch out and seek more detail.[21] The table below displays the additional data that is required in the LDR:

If No, Not Working Due To: (check one)	If Yes:
Disability	Working Full Time
Insurance Conflict	Working Part Time due to Disability
Inability to Find Work	Working Part Time due to Insurance Conflict
Donor Choice- Homemaker	Working Part Time due to Inability to Find Full Time Work
Donor Choice- Student Full Time/Part Time	Working Part Time due to Donor Choice
Donor Choice - Retired	Working Part Time Reason Unknown
Donor Choice- Other	Working, Part Time vs. Full Time Unknown
Unknown	

After considering this potential data element the Committee decided not to recommend expanding the "Working for Income" data collection on the TCR. They concluded annual household income and household size to be more descriptive measures of SES.[22] Therefore, working for income data collection with simple "yes," "no," or "unknown" responses will continue to be collected on the TCR.[23]

Access to Transportation

The Committee discussed adding transportation to the TCR to measure SES, but ultimately eliminated this potential data element from consideration because it had potential for various interpretations and no standard definition. This potential data element lacked the clarity necessary for consistent entry.[24]

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[18] U.S. Department of Health and Human Services. Office of the Assistant Secretary for Planning and Evaluation. (2019). Poverty Guidelines. Retrieved from https://aspe.hhs.gov/poverty-guidelines.

[19] Id.

[20] OPTN Policy 18: Data Submission Requirements.

[21] Living Donor Registration TIEDI Data Collection Instrument can be accessed here https://unos.org/wp-content/uploads/unos/LDR-1.pdf.

[22] September 23rd 2019, OPTN Minority Affairs Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/.

[23] Transplant Candidate Registration TIEDI Data Collection Instrument for all organs can be accessed here https://unos.org/data/data-collection/.

[24] September 23rd 2019, OPTN Minority Affairs Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/.

Individual Income

MAC felt annual household income would be more informative of SES than individual income, as all people residing in one household will often share finances and be of similar SES.[25] The Committee also felt annual household income would be a better method of capturing economic status in the instances where a candidate is too sick to work, but is monetarily supported by another member of the household.

In summary, MAC decided to propose to adding annual household income and household size to the TCR.[26] The MAC determined that the TCR is the most appropriate form for these data because it captures information on every candidate registered to the waitlist and will allow the OPTN to conduct access and outcome analyses. The LDR and Living Donor Follow-up (LDF) data collection instruments were not chosen because they only collect data on living donors.[27,28] In order to measure inequity, the OPTN must capture data from all waitlist candidates. The TRF and TRF were also eliminated as they gather information on recipients post-transplant.[29] The TCR is also the only TIEDI form that collects all three SES elements currently required by the OPTN.[30]

Literature Review

The Committee reviewed relevant literature, including studies that examined the association between primary healthcare payer, education level, income level, and other SES factors to transplant access and outcomes. The OPTN already collects education level and primary source of payment. The literature supports the continued collection of these SES factors that educate the OPTN on SES's relationship to transplant.

More data are needed to investigate the extent of the issue. This review of the literature confirms that gaps exist in the analysis of SES, access, and outcomes. The OPTN can collect patient-level data to explore the extent of the problem and then adequately address SES's impact on transplant.

Education Level

The literature suggests that there is an association between education level and access to transplant. Patients who have graduated college are three times more likely to be placed on the waiting list and receive a kidney transplant than patients with less than 12 years of education.[31] Patients with more extensive education may have more means to seek organ transplantation as an option.[32] Patients with

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[25] September 23rd 2019, OPTN Minority Affairs Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/.

[26] August 5th 2019, OPTN Minority Affairs Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/.

[27] Living Donor Registration TIEDI Data Collection Instrument can be accessed here https://unos.org/wp-content/uploads/unos/LDR-1.pdf .

[28] Living Donor Follow- up TIEDI Data Collection Instrument can be accessed here https://unos.org/wp-content/uploads/unos/LDR-1.pdf.

[29] Transplant Recipient Registration and Transplant Recipient Follow- up TIEDI Data Collection Instrument for all organs can be accessed here https://unos.org/data/data-collection/.

[30] Transplant Candidate Registration TIEDI Data Collection Instrument for all organs can be accessed here https://unos.org/data/data-collection/.

[31] Gold-Rumyantzev et al. (2006) Role of socioeconomic status in kidney transplant outcome. *American Society of Nephrology,* 1(2), 313-322. https://doi.org/10.2215/CJN.00630805.

[32] Hod, T. & Gold-Rumyantzev, A. S. (2014). The role of disparities and socioeconomic factors in access to kidney transplantation

higher education levels have better health literacy, post- transplant compliance, and medication adherence, factors known to influence graft and patient survival. Outcomes improve incrementally as the amount of education patients receive increases.[33]

Primary Source of Payment (Health Insurance)

Primary source of payment impacts a candidate's access to organs and post-transplant outcomes. Primary healthcare payer may reflect a candidate's underlying SES, as candidates with higher incomes or educational levels might be expected to have private insurance at higher rates than lower SES candidates. Liver candidates in the highest socioeconomic quartile are four times as likely to receive a transplant as those patients in the lowest quartile without private insurance.[34] Patients without prescription drug coverage are more likely to be of lower SES background than patients with prescription drug coverage.[35] These patients are more likely to forgo taking required immunosuppressant drugs due to the high cost of these medications. This impacts medication adherence and post operation outcomes for those of low SES.[36]

Median Household Income by ZIP Code

Median household income by ZIP Code as used as a proxy for patient income in much of the reviewed literature. Patients living in ZIP Codes with lower median incomes are shown to have less opportunity to be waitlisted and more likely to have poor transplant outcomes.[37] These patients are shown to be less likely to be found medically appropriate for transplant and do not complete pre- transplant evaluations as often as those living in higher median income ZIP Codes[38]. Patients living in lower income ZIP Codes also have an increased risk for negative post- operation incidents such as hospitalization, rejection, and infection.[39] A lack of financial means can prevent patients who would otherwise be suitable transplant candidates from being placed on the national waitlist.[40] Those who make it onto the list, but cannot afford the required medication regimens post-transplant, have a higher risk of experiencing organ failure. Some of these patients will return to the waiting list, where the cycle will repeat itself.[41] This association of waitlist and transplant outcomes with ZIP Code median household income data suggests that a stronger association may be found if measured at a patient-specific level.[42]

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and its outcome, *Renal Failure, 36*(8), 1193-1199. https://doi.org/10.3109/0886022X.2014.934179.

[33] Hod, T. & Gold-Rumyantzev, A. S. (2014). The role of disparities and socioeconomic factors in access to kidneys transplantation and its outcome, *Renal Failure, 36*(8), 1193-1199. https://doi.org/10.3109/0886022X.2014.934179.

[34] Wong, L. L., Hernandez, B. Y., & Albright, C. L. (2012). Socioeconomic factors affect disparities in access to liver transplant for hepatocellular cancer. *Journal of Transplantation, 2012*(2012), 1-6. https://dio.org/10.1155/2012/870659.

[35] Gold-Rumyantzev et al. (2006) Role of socioeconomic status in kidney transplant outcome. *American Society of Nephrology,* 1(2), 313-322. https://doi.org/10.2215/CJN.00630805.

[36] Id.

[37] Hod, T. & Gold-Rumyantzev, A. S. (2014). The role of disparities and socioeconomic factors in access to kidney transplantation and its outcome, *Renal Failure, 36*(8), 1193-1199. https://doi.org/10.3109/0886022X.2014.934179.

[38] Id.

[39] Wayda et al. (2018). Socioeconomic disparities in adherence and outcomes after heart transplant. *Circ Heart Failure, 11*(3), 1-11. https://doi.org/ 10.1161/CIRCHEARTFAILURE.117.004173.

[40] Simmerling, M. (2007). Beyond scarcity; poverty as a contraindication for organ transplant. *Virtual Mentor American Medical Association Journal of Ethics, 9*(6), 441-445. https://doi.org/ 10.1001/virtualmentor.2007.9.6.pfor1-0706.

[41] Id.

[42] Schold et al. (2012). The association of community health indicators with outcomes for kidney transplant recipients in the United States. *National Institute of Health, 147*(6), 520-526. https://doi.org/10.1001/archsurg.2011.2220.

Annual Household Income and Household Size

The examined literature repeatedly calls for the collection of patient- level income data that is more granular than an estimate based on summary reporting of income or poverty status for a ZIP Code, patient education level, or primary healthcare payer.[43] The use of ZIP Code level income data to measure an individual's poverty status or income is an incomplete measure of SES status, due to the variation of incomes within any given ZIP Code.[44] Therefore, the median income in a ZIP Code may not be representative of a patient's SES level. [45] This limitation could weaken a potential connection between SES levels and access to transplant and transplant outcomes.[46] The literature suggests that differences in transplant access and outcomes between low and high socioeconomic backgrounds exist even with the use of data that is not considered patient level (i.e. data at the ZIP Code level). This association may be stronger or reveal more specific patient-level findings if more granular data on patient household income were collected.[47] Including collection of household size when household income is collected would allow for the calculation of patient-level household poverty status, an additional measure that could be used to standardize examinations of income and associated outcomes across multiple disparate groups by accounting for differences in household size, better reflecting patients' access to financial means.[48]

Stakeholder Feedback

Upon proposing these potential new data fields, MAC solicited feedback from TAC, TCC, DAC and the Society of Transplant Social Workers (STSW)[49]. The groups expressed some concerns.

The first concern was that the OPTN may not be able to collect this data, due to patient reluctance to provide this potentially sensitive information.[50] The Committee confirmed that these particular data points are already collected as routine practice when patients are evaluated for transplantation by medical social workers or finance specialists. Stakeholders agreed that these patient data likely already exists within a hospital's Electronic Health Record (EHR) because routine financial evaluations are completed before adding a patient to the waitlist. This information would need to be transferred onto the TCR form.[51]

These groups gave feedback that candidates may report their annual household income inaccurately and inflate their earnings for fear of not being given high quality treatment if they reveal that they are of low SES background.[52] However, a literature review of the public health surveys conducted by paper, telephone, and through in-person interviews by the Centers for Disease Control and Prevention and

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[43] Wayda et al. (2018). Socioeconomic disparities in adherence and outcomes after heart transplant. Circ Heart Failure, 11(3), 1-11. https://doi.org/ 10.1161/CIRCHEARTFAILURE.117.004173.

[44] Id.

[45] Id.

[46] Schold et al. (2012). The association of community health indicators with outcomes for kidney transplant recipients in the United States. *National Institute of Health, 147*(6), 520-526. https://doi.org/10.1001/archsurg.2011.2220.

[47] Id.

[48] U.S. Department of Health and Human Services. Office of the Assistant Secretary for Planning and Evaluation. (2019). Poverty Guidelines. Retrieved from https://aspe.hhs.gov/poverty-guidelines.

[49] November 18th 2019, OPTN Minority Affairs Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/.

[50] Id.

[51] Id.

[52] Id.

state and local health departments (including the Medical Monitoring Project, National Health Interview Survey, National Health and Nutrition Examination Survey, Behavioral Risk Factor Surveillance System, and Pregnancy Risk Assessment Monitoring System), collect self-reported income and household size for the purposes of analyzing health outcomes and health disparities in the United States.[53] These data are considered reliable enough that federal, state and local public health entities and public health researchers use them to study population-level health outcomes.

The STSW suggested the development of an educational training for transplant staff that will be collecting these data fields. They recommended including in the training explanations of why the OPTN is collecting these data.[54]

The Committee considered and responded to all stakeholder feedback. Some of this feedback, such as comments about data burden, are standard for any proposal that aims to add more fields to forms and collect more data. Other concerns, such as those about the accuracy of sensitive information, are more specific to this proposal and will need specialized consideration. The Committee welcomes all feedback during the public comment period.

Collection of additional SES data would be an effective method to examine the extent of the association between SES and access to transplant. MAC feels confident that annual household income and household size, together, were the best measure of SES to add to the TCR in order to understand potential disparities in access.[55] When collected together, these data elements produce estimates that can be compared to the FPG, a measure used by health researchers to determine household poverty status and access to resources.[56] The federal government also uses these measures to determine which households qualify for income-based assistance programs. Collection of annual household income and household size will allow the OPTN to measure a patient's information against a well- known standard to determine their SES. The presented evidence shows that annual household income and household size are valuable data that should be collected by the OPTN. MAC voted to send their data collection proposal to Spring 2020 public comment.[57]

Proposal

The proposal is to add two data fields to the TCR data collection instrument: Annual Household Income and Household Size.[58] A table containing more details on the data proposed elements, including rationale and organ-specific TCR elements that would be added to can be found in *Appendix 1: Proposed Additions to TCR Data Collection.* This proposal does not remove any currently collected data elements from the TCR. Together, the proposed elements can produce a measure to be compared to the Federal Poverty Guideline (FPG). The FPG aims to measure the degree of poverty a household is experiencing.[59]

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[53] Center for Disease Control and Prevention. (2019) Behavioral Risk Factor Surveillance System. Retrieved from https://www.cdc.gov/brfss/questionnaires/index.htm.

[54] November 18th 2019, OPTN Minority Affairs Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/.

[55] Id.

[56] U.S. Department of Health and Human Services. Office of the Assistant Secretary for Planning and Evaluation. (2019). Poverty Guidelines. Retrieved from https://aspe.hhs.gov/poverty-guidelines.

[57] November 18th 2019, OPTN Minority Affairs Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/.

[58] Id.

[59] U.S. Department of Health and Human Services. Office of the Assistant Secretary for Planning and Evaluation. (2019). Poverty Guidelines. Retrieved from https://aspe.hhs.gov/poverty-guidelines.

This proposal will allow the OPTN to determine if disparities in access to transplant based on SES exist by utilizing patient-level household income and poverty data.

Data Elements

New data collection must align with one of the OPTN Data Collection Principles as passed by the Board of Directors in 2006 collection of additional data by vetting new elements through aligning with a data collection principle and providing clear data definitions.

OPTN Data Collection Principles

This proposal aligns with the OPTN Data Collection Principles to develop transplant, donation, and allocation policies.[60] If the collection of annual household income and household size data suggest that disparities in access based on SES exist, these findings could inform potential future policy changes aimed to decrease inequities.

Proposed Data Definitions

Public health surveys such as the Behavioral Risk Factor Surveillance System (BRFSS) were used as a reference during the development of these definitions.[61] The Committee seeks feedback on their proposed data definitions for annual household income and household size fields.

<u>Annual household income:</u>

The purpose of this field is to monitor policy impacts on disadvantaged populations and address inequity in outcomes; annual household income impacts access to healthcare services and health outcomes.

- Explicit documentation of income from the patient is not necessary, but can be used with developing an estimate.
- The timeframe for this response is a 12-month estimate. It includes all individuals who are living in the household and financially supporting the patient.
- This field is a text box that only accepts numeric responses in whole numbers.

<u>Household size:</u>

The purpose of this field is to clarify how many individuals in the household depend on the household income reported in the previous item. Together, these fields allow for the calculation of household poverty which aims to monitor policy impacts on disadvantaged populations and better address inequity outcomes.

- A household is defined as all persons who live with the patient in a household unit.
- The timeframe for this response is the current time period, when the patient is assessed and the TCR is completed.
- This field is a text box that only accepts positive, numeric responses in whole numbers.

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[60] OPTN, "Principles for Data Collection," Board approved language, December 13, 2006.

[61] Center for Disease Control and Prevention. (2019) Behavioral Risk Factor Surveillance System. Retrieved from https://www.cdc.gov/brfss/questionnaires/index.htm.

Alignment with the Final Rule

This proposal's purpose aligns with the Final Rule. The collection of these data aims to better understand and assess the potential relationship between SES and access to transplant. Section 121.11 (b) (2) of the Final Rule gives the OPTN authority to collect data from OPTN members on transplant candidates.[62]

The Final Rule requires the OPTN, to develop organ allocation policies that, among other factors, promote patient access to transplantation.[63] The Final Rule states that the OPTN is required to develop policies that reduce inequities that result from SES.[64] In order to reduce any existing disparities that have resulted due to SES, the OPTN must understand the extent of the impact SES has on transplant access and outcomes. The collection of additional SES data will allow the OPTN to examine this potential problem more efficiently than it can currently and determine if policies that aim to decrease disparities based on SES are necessary, as required in the Final Rule.[65]

Potential Impact on Select Patient Populations

This proposal would impact all transplant candidates. Each transplant candidate would be asked to provide these new data as a requirement by transplant program staff for the completion of the TCR.[66] This proposal has the potential to impact low SES candidates in the long term. If access and outcome inequities based on SES are found through analysis of these new data, policy could be developed or reformed in an effort to reduce disparities and promote access more equitably across all SES levels in the patient population.

Alternate Proposals Considered

The Committee considered several alternatives. A suggestion MAC heard repeatedly was to use ZIP Code level median income data from the United States Census.[67] The benefit to this alternative is that these data are easily accessible online from the United States Census Bureau. The Committee would be able to omit the field "annual household income" as a proposed data element. This alternative also relieves transplant centers from extra data burden that comes with any additional data collection. However, ZIP Code level median income data is far less patient- specific than annual household income data. ZIP Codes can cover large geographic areas with a wide range of household incomes. For this reason, the median ZIP Code income statistic could misrepresent a candidates financial standing, to the extent that those candidates have lower or higher household incomes than the ZIP Code median. ZIP Code data also becomes inaccurate as patients move and due to this factor is likely to become useless over time. The Committee believes the weaknesses of this considered alternative outweigh the strengths, as the risk for misrepresentation of patient income challenges the accuracy of the data.

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[62] 42 C.F.R. § 121.11(b) (2) https://www.ecfr.gov/cgi-bin/text-idx?SID=bb60e0a7222f4086a88c31211cac77d1&mc=true&node=pt42.1.121&rgn=div5#se42.1.121_111. Accessed January 19, 2020.

[63] 42 C.F.R. § 121.8(a).
[64] 42 C.F.R. § 121.4(a).
[65] Id.
[66] Transplant Candidate Registration TIEDI Data Collection Instrument for all organs can be accessed here https://unos.org/data/data-collection/
[67] November 18th 2019, OPTN Minority Affairs Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/

ZIP Code median income data were used for MAC's initial SES data request in October of 2018. Results from this request were detailed in the OPTN report "Disparities in Access to Kidney Transplant by Socioeconomic Status." [68] The MAC does not see value in duplication of this potentially misrepresentative method when the Committee could collect and use patient-level data that more accurately represents transplant candidates.

Stakeholders suggested the Committee consider using a patient's address to better estimate their annual household income by allowing linkage with Census tract level data on median income and poverty status. [69] The benefit to this alternative is that census tracts cover smaller geographic areas and are not as vast as ZIP Codes, yielding less potential misclassification of patient income or poverty status. Patients' street addresses along with their social security numbers may require the OPTN to assume a higher level of risk. Together, these two pieces of information meet the definition of "Sensitive Personally Identifiable Information" from the Department Homeland Security.[70] When this definition is met, additional justifications for the collection of the data along with additional safeguards are required. Much like the ZIP Code median income alternative, the OPTN would have to assume that the patient's income or poverty status was the same as the summary measure for that Census tract. This alternative was not selected due to its high risk and low accuracy.

Implementation and Operational Considerations

OPTN Actions

This proposal will require the submission of official OPTN data that are not presently collected by the OPTN. The collection of official OPTN data is subject to the Paperwork Reduction Act of 1995, which requires approval from the federal Office of Management and Budget (OMB).[71] The OMB approval process may impact the implementation timeline. If finalized, the data collected would be protected consistent with the Privacy Act of 1974, as amended[72].

Once approved by the OMB, UNOS Information Technology (IT) would program the new data fields onto the TCR in TIEDI.

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[68] OPTN Descriptive Data Request. "Disparities in Access to Kidney Transplant by Socioeconomic Status." Prepared for Minority Affairs Committee In-Person Meeting, March 29, 2019.

[69] November 18th 2019, OPTN Minority Affairs Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/.

[70] U.S Department of Homeland Security. DHS Privacy Office. (2017) Handbook for Safeguarding Sensitive PII retrieved from https://www.dhs.gov/sites/default/files/publications/dhs%20policy%20directive%20047-01-007%20handbook%20for%20safeguarding%20sensitive%20PII%2012-4-2017.pdf

[71] Office of Management and Budget (1995). Paperwork Reduction Act. Retrieved from https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/index.

[72] Privacy Act of 1974, as amended, 5 USC § 522a. https://www.govinfo.gov/content/pkg/USCODE-2018-title5/pdf/USCODE-2018-title5-partI-chap5-subchapII-sec552a.pdf.

Professional Education will monitor the proposal and determine educational needs as it approaches approval and implementation. If it is found necessary, the OPTN will prepare the community for new data submission requirements.

Member Actions

Transplant Programs

This proposal would impact all transplant programs who register candidates to the waiting list. The proposal adds data fields to each organ-specific TCR, meaning this proposal would impact data collection across all organ systems. Transplant centers are required to complete and submit the TCR each time they refer a patient to the transplant waiting list.[73] Transplant programs would be required to collect each transplant candidate's annual household income and household size as part of the TCR submission and completion process. This proposal may increase data burden for transplant programs, but stakeholders reported that these data have often already been collected during the routine financial analysis every potential transplant candidate must complete.[74]

Post-implementation Monitoring

Member Compliance

The proposed language will not change the current routine monitoring of OPTN members. Any data entered in UNet may be reviewed by the OPTN, and members are required to provide documentation as requested.[75]

Policy Evaluation

The OPTN will monitor responses entered in the new fields and produce summary reports of the number and percent of missing/refused responses out of the total number of forms, as well as summary statistics of complete responses to the two fields (household income and household size). The OPTN will examine if non-responses are disproportionately represented in specific demographic groups, waitlist organ types, or geographic areas. Additionally, the OPTN will stratify summaries of responses and non-responses by the two other available fields on the Transplant Candidate Registration Form that ask about other socioeconomic factors: 1) educational attainment, and 2) primary payer.

Conclusion

Collecting annual household income and household size will inform OPTN policymaking and will allow the OPTN to develop a greater understanding of the impact candidate SES has on inequities in the national transplant system. With these new data, the OPTN will be able to investigate the potential relationship between patient SES and access to transplant. These data will eventually inform the development of policy aimed to reduce disparities and monitor policies for equity in access. The proposal aligns with the Final Rule requiring the development and reform of policies that reduce

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[73] OPTN Policy 18: Data Submission Requirements, Table 18-1: Data Submission Requirements.

[74] November 18th 2019, OPTN Minority Affairs Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/.

[75] OPTN. About Data. Retrieved from https://optn.transplant.hrsa.gov/data/about-data/.

inequalities resulting from SES and the OPTN Principles of Data Collection in that the purpose is to develop transplant, donation, and allocation policies.[76,77]

The MAC welcomes all feedback from individuals and organizations with vested interest, but specifically asks for input on the following:

- Are annual household income and household size the best data elements to collect to measure SES?
- What barriers might there be to collecting and reporting these data?
- Are there other data related to SES the OPTN should collect?

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[76] 42 C.F.R. § 121.4(a)

[77] OPTN, “Principles for Data Collection,” Board approved language, December 13, 2006.

Appendix 1: Proposed Additions to TCR Data Collection

Add Following Data Elements:	Add Listed Data Elements to Following Organ-Specific TCRs:	Rationale:
Annual Household Income	Adult and Pediatric: Kidney, Pancreas, Kidney/Pancreas, Intestine, Liver, Heart, Lung, and Heart/Lung.	*This data element would inform the Committee about policy impacts on disadvantaged populations and assess inequity in outcomes; annual household income impacts access to healthcare services and health outcomes.*
Household Size	Adult and Pediatric: Kidney, Pancreas, Kidney/Pancreas, Intestine, Liver, Heart, Lung, and Heart/Lung.	*This data element would inform the Committee about how many individuals in the household depend on the household income reported in the previous item. Together, these fields allow for the calculation of household poverty which aims to monitor policy impacts on disadvantaged populations and better address inequity.*