OPTN

Briefing to the OPTN Board of Directors on

Data Collection to Assess Socioeconomic Status and Access to Transplant

OPTN Minority Affairs Committee

Prepared by: Kelley Poff
UNOS Policy and Community Relations Department

Contents

Data Collection to Assess Socioeconomic Status and Access to Transplant

Sponsoring Committee: *Minority Affairs*
Public Comment Period: *January 22, 2020 – March 24, 2020*
Board of Directors Date: *June 8, 2020*

Executive Summary

Currently, the Organ Procurement and Transplantation Network (OPTN) does not collect comprehensive 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 to have a more holistic understanding of how SES factors may impact transplant candidates.

The OPTN Minority Affairs Committee (MAC) developed a public comment proposal that aimed to add annual household income and household size as new fields to the OMB-approved Transplant Candidate Registration (TCR) data collection instrument.[1,2]The TCR is a data collection instrument submitted to the OPTN by transplant programs each time a patient is added to the waitlist.[3] As written, the proposal's purpose was to add these data elements 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 proposal was out for public comment during the OPTN public comment period from January 22 – March 24, 2020. The MAC intended to bring a data collection proposal to the OPTN Board of Directors (BOD) in June 2020, but the proposal did not garner strong support during the public comment period. Therefore, the MAC opted to solicit direction and feedback from the Board in regards to potential revisions and continued work on the proposal.

The purpose of this briefing paper is to document the feedback received and next steps for BOD consideration. This briefing paper is not a proposal.

Overview of Proposal that Went to Public Comment

Purpose

The Final Rule requires the OPTN to develop organ allocation policies that, among other factors, promote patient access to transplantation. The Final Rule states that the OPTN is required to develop policies that reduce inequities that result from SES.[3,4] 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.

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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] 42 C.F.R. § 121.4(a).
[4] 42 C.F.R. § 121.11.

The purpose of the proposal was to collect additional patient-level SES data. The MAC believes that the collection of annual household income and household size would have allowed the OPTN to perform better analyses on the potential impact of SES on patient access to transplantation. As written, the proposal planned to collect the data at the time of registration on the waiting list. These data were not intended for analysis of access to placement on the waiting list, but were intended to be used to measure access to transplantation from the time of listing forward.[5]

SES is defined as the social standing or class of an individual or group, often measured by a combination of education, income, and occupation.[6] 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.[7]

Questions asked of the Community

The proposal the MAC submitted for the January, 2020 OPTN Public Comment period welcomed all feedback from individuals and organizations with vested interest, but specifically asked for input on the following[8]:

- 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?

Summary of Public Comment Feedback

The MAC submitted their proposal "Data Collection to Assess Socioeconomic Status and Access to Transplant" to the Winter 2020 Public Comment period. This section address public comment sentiment by region, committee, and member type followed by discussion on emergent themes observed throughout the public comment period.

Sentiment

Region

Regions 1, 5, 9, 10, and 11 supported the proposal. Regions 2, 3, 4, 6, 7, and 8 opposed it. The OPTN conducts sentiment voting for proposals on a 5- point Likert scale. Region 8 had the lowest mean sentiment score (2.3). Regions 9 and 10 had the highest mean sentiment score (3.7) The overall regional mean sentiment score was 3.0. There is an almost even split between those members voted to strongly oppose and oppose the proposal when compared with members who voted to support and strongly

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[5] Data Collection to Assess Socioeconomic Status and Access to Transplant, OPTN Minority Affairs Committee, January 2020, https://optn.transplant.hrsa.gov/media/3542/data-collection-to-assess-socioeconomic-status-and-access-to-transplant.pdf (accessed April 21, 2020)

[6] American Psychological Association. (2019) Socioeconomic Status. Available at: https://www.apa.org/topics/socioeconomicstatus/.

[7] Id.

[8] Data Collection to Assess Socioeconomic Status and Access to Transplant, OPTN Minority Affairs Committee, January 2020, https://optn.transplant.hrsa.gov/media/3542/data-collection-to-assess-socioeconomic-status-and-access-to-transplant.pdf (accessed April 21, 2020)

support the proposal. About 14% of members who voted at regional meetings remained neutral/abstained. [9]

Figure 1: Regional Meeting Sentiment[10]
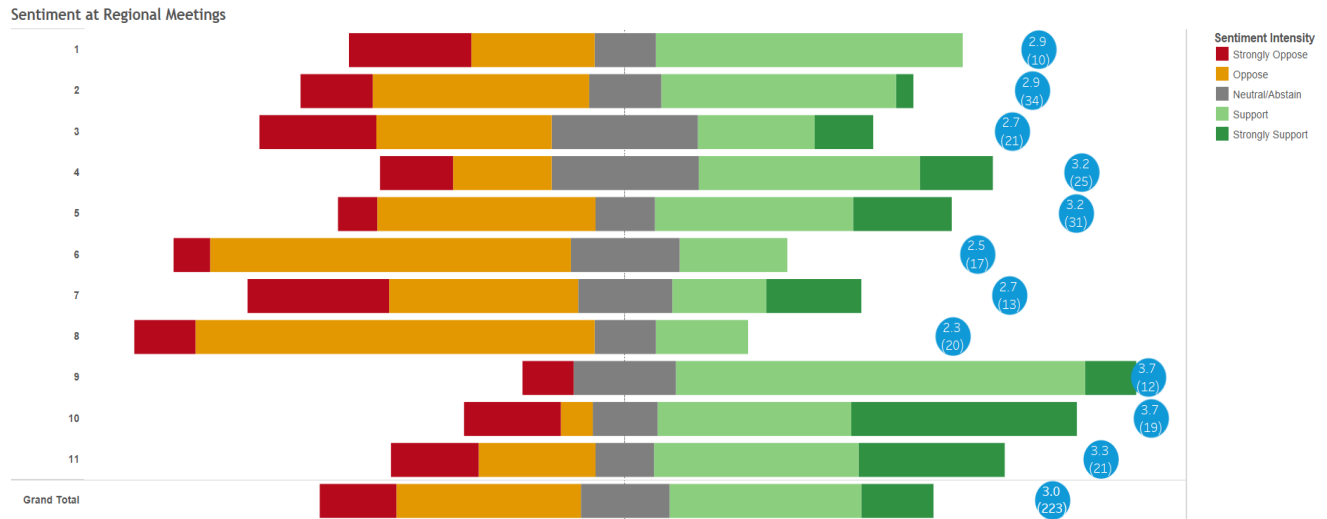

Member Type

The proposal received 202 responses from transplant hospitals, 40 responses from organ procurement organizations (OPO), 21 responses from patients, 16 responses from histocompatibility labs, 5 responses from stakeholder organizations, and 4 responses from the general public. 6 respondents did not identify their member type. Respondents who identified themselves as OPOs and histocompatibility labs supported the proposal. Respondents who identified themselves as transplant hospitals, patients, stakeholder organizations, and the general public opposed the proposal. 5 of the 7 member types had a mean sentiment score of 2.8 or below. The general public had the lowest mean sentiment score (2.0) and OPOs had the highest mean sentiment score (3.0) The overall member type mean sentiment score was 2.8. 34% of transplant hospitals opposed the proposal and 19% strongly opposed the proposal. Over 50% of patients who responded opposed or strongly opposed the proposal.[11]

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[9] OPTN Public Comment, https://optn.transplant.hrsa.gov/governance/public-comment/ (accessed April 21, 2020).

[10] This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for regional meetings only includes attendees at that regional meeting. Region 6 uses the average score for each institution. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses

[11] OPTN Public Comment, https://optn.transplant.hrsa.gov/governance/public-comment/ (accessed April 21, 2020).

Figure 2: Sentiment by Member Type[12]
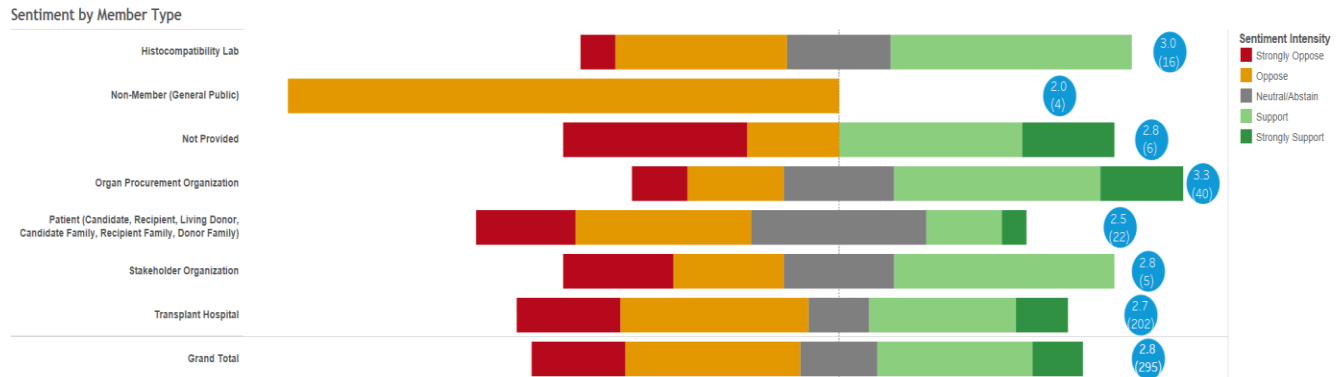
Committees

The Patient Affairs (PAC), Transplant Administrators (TAC), and Transplant Coordinators (TCC) Committees opposed the proposal. One member of PAC expressed support while the majority provided sentiment scores that were opposed or strongly opposed (n=10). The main concerns expressed by this group were patient discomfort in sharing the data, potential misuse of the data, and eroding trust by asking these types of questions. One member asked if there were other questions that were less intrusive that could be used to get at the same information. No members of the TCC voted in support of the proposal. They echoed some of the same concerns raised by PAC yet they did comment that "there is need to better determine how socioeconomic status impacts transplantation, and that the data that is currently collected by the OPTN is insufficient to do so". TAC was the most supportive although still ultimately opposed the proposal. Members voiced concerns that patients may think transplant centers will prefer candidates based on their income and that this will discourage these patients from seeking transplants. TAC was also concerned about the risk of losing patient trust and questioned if "data is going to be rich enough to give enough gain to compensate for this potential risk". TCC had the lowest mean sentiment score (1.8) and TAC had the highest mean sentiment score (2.1) The overall committee mean sentiment score was 2.1. In total 38% of committee members opposed and 35% strongly opposed the proposal. Only 15% of committee members supported or strongly supported the proposal.[13]

As an operating committee, the Data Advisory Committee (DAC) is charged with overseeing the collection of official OPTN data that are pertinent to the operation of the OPTN and necessary for the development of evidence-based OPTN policies.[14] The DAC was introduced to the project idea in Fall 2019 and continually consulted throughout the proposal's development. The DAC commented on potential challenges the MAC may face in regards to data sensitivity and inability to verify candidate income, but gave the project their endorsement and agreed it was on the correct path.[15] The DAC also

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[12] This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment by member type includes all comments regardless of source (regional meeting, committee meeting, online, fax, etc.) The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

[13] OPTN Public Comment, https://optn.transplant.hrsa.gov/governance/public-comment/ (accessed April 21, 2020).

[14] OPTN Data Advisory Committee, https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/ (accessed April 30, 2020)

[15] October 10, 2019, Data Advisory Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/.

recommended the annual household income and household size be required fields on the TCR in order to capture as much data as possible.[16] When the DAC heard an update on the project during the Winter 2020 public comment period, they agreed with many of the concerns expressed by the community regarding loss of patient trust and expressed that, "questions asking about household income and household size might make patients and programs uncomfortable". The DAC also expressed that the MAC should be more explicit about what would be done with the data after collection.[17]

Figure 3: Committee Sentiment[18]
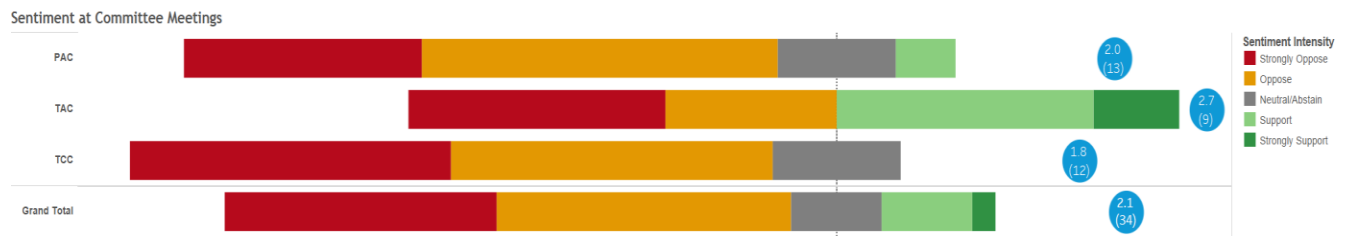
Stakeholder Organizations

Several stakeholder organizations provided feedback on the proposal. 4 out of the 5 organizations did not support the addition of annual household income and household size to the TCR. The main concerns expressed by these groups related to the potential impact this proposal could have on patients. The Organization for Transplant Professionals (NATCO) commented that they "strongly believe that such a question will impact the perception that a candidate's income will be a determining factor in their ability to receive a timely transplant, or to receive one at all." The American Nephrology Nurses Association (ANNA) did not support the proposal and expressed that asking about income could contribute to patient suspicion or mistrust in the organ allocation system. The Society of Transplant Social Workers (STSW) did not support the proposal and indicated that the data already collected are adequate to track SES. STSW expressed concern about unintended consequences, such as the addition of extra barriers to candidacy for low income patients. The American Society of Transplantation (AST) also did not support the proposal as written. Instead AST suggested that "providing patients with a range of categorical options for household income may be better than asking for a precise income amount." The American Society of Transplant Surgeons (ASTS) supported the proposal. Their narrative comments indicated the organization's understanding of SES as an issue in transplant that should be addressed. The ASTS

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[16]November 18, 2019, Data Advisory Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/.

[17]March 9, 2020, Data Advisory Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/.

[18] This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for committees only includes attendees at that committee meeting. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

highlighted that identification of the low SES patient population "could help transplant teams better understand and allocate resources to candidates at risk."[19]

Themes

The proposal received significant concerns during the OPTN public comment period.[20] These public comments can be categorized into four themes:

- Data entry burden
- Impact on patients
- Data quality
- Use of data

Data Entry Burden

Data entry burden was a recurring feedback theme throughout public comment. Members believed that the addition of annual household income and household size to the TCR would place unnecessary data burden on transplant administrators and coordinators.[21] Some members responded to a portion of the public comment document that read:

> Stakeholders agreed that these patient data likely already exist 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.[22]

The American Society of Transplantation reported that there is no standard practice or requirements for collecting annual household income in medical records. Some programs ensure candidates have adequate insurance or document other psychosocial factors to assess SES, but do not necessarily record a candidate's annual household income. Responses from transplant programs emphasize the lack of uniformity in the collection of SES data at various transplant programs. For some programs the addition of these data fields would create far more burden then the MAC originally anticipated.[23]

Members also expressed concern that the amount of data burden this proposal would place on transplant administrators would outweigh the benefit of the data collected. Some transplant administrators reported that the SES data their hospitals currently collects is adequate, while others do not believe additional data is necessary as the relationship between SES, access to medical care, and impact on outcomes is already known. Some members believe that the SES data currently collected by the OPTN is insufficient, but had concerns about the proposal's method of addressing inequality.[24]

Impact on Patients

The potential impact this proposal could have on patients was discussed at length. Public comment feedback expressed concern about unintended consequences of the proposed data collection. The PAC reported that asking candidates to reveal their annual household income would be seen as intrusive. Members added that, "considering the public's general lack of trust in the organ allocation system,

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[19] OPTN Public Comment, https://optn.transplant.hrsa.gov/governance/public-comment/ (accessed April 21, 2020).

[20] Id.

[21] Id.

[22] Data Collection to Assess Socioeconomic Status and Access to Transplant, OPTN Minority Affairs Committee, January 2020, https://optn.transplant.hrsa.gov/media/3542/data-collection-to-assess-socioeconomic-status-and-access-to-transplant.pdf (accessed April 21, 2020)

[23] OPTN Public Comment, https://optn.transplant.hrsa.gov/governance/public-comment/ (accessed April 21, 2020).

[24] Id.

asking questions about income and who lives in their house would do further damage to that trust".[25] Some transplant administrators indicated they would not feel comfortable asking transplant patients about private financial matters.[26] These administrators believed that inquiring about such a sensitive issue would break down the trust between the patient and transplant program. This question has the potential to make patients feel alienated or that they must respond with the correct annual household income in order to be considered for transplant. This mistrust could place patients who are already anxious under even more stress and discourage them from seeking transplant services, ultimately decreasing the number of low SES patients that are listed for transplant. A PAC member asked if there was a less intrusive method for the collection of SES data.[27]

Data Quality

Members questioned the quality of the data this proposal would collect. The PAC voiced concern that "patients wouldn't feel comfortable sharing this type of information or might lie about their answers".[28] As mentioned above, patients may feel as though they have to respond with the correct annual household income in order to be listed for transplant. Patients might inflate their income and report inaccurately on purpose. Other patients may fear losing certain government benefits and report a number that is lower than their annual household income. If patients report their income inaccurately, the data will be of poor quality and limited in its usefulness.[29]

Public comment feedback also indicated concern over data quality due to changes in patient income. Comments expressed that annual household income could change as patients become sicker and are unable to work. Households with ill transplant candidates might also need a member to switch to part-time work or quit their jobs altogether in order to fill a caregiver role. The amount of income a patient and their family earns has the potential to change based upon varying circumstances.[30]

Data Use

Members reported that a plan for the use of the data after collection was not fully described in the public comment document. While the proposal did suggest that the analysis of the collected data may lead to future policy development, it did not present specific examples of how the data may be used after this analysis. AST felt that the proposal to collect SES data read more like a research project than a method of influencing policy. Some members supported the use of this data to better understand and allocate resources to candidates at risk.[31]

While the data collected from this proposal would not be intended or permitted to be used for listing, the community raised concerns surrounding this scenario. Members have reported apprehension related to potential unethical use of this data by transplant programs. Patients of higher SES are known to have better post-operation medication adherence and overall transplant outcomes. Hospitals can be penalized if they do not meet specific measures for success. Comments reported that the collection of SES data could enable programs to list higher SES patients over low SES patients, decreasing the number of low SES patients that are served. Public comment asked what would be done to ensure patient data would remain private, secure, and only used for the intended purposes.[32]

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[25] OPTN Public Comment, https://optn.transplant.hrsa.gov/governance/public-comment/ (accessed April 21, 2020).
[26] Id.
[27] Id.
[28] Id.
[29] Id.
[30] Id.
[31] Id.
[32] OPTN Public Comment, https://optn.transplant.hrsa.gov/governance/public-comment/ (accessed April 21, 2020).

Next Steps

The MAC examined the overall sentiment on the SES proposal at the conclusion of the January to March 2020 public comment period. The Committee determined that the proposal did not garner enough support to be presented as a proposal to the Board of Directors in June, 2020. Overall, public comment feedback acknowledged the Final Rule requirement that reducing inequities in SES should be considered during policy development, and that more comprehensive SES data collection would be useful. However, the public indicated that the proposed data elements should be reconsidered.

Potential Revisions

The MAC is reviewing the public comment feedback and considering potential revisions to the proposal that could be more widely supported. The MAC is considering the following revisions:

- Annual household income range
- Household size

Annual Household Income Range

During public comment, annual household income range was suggested a less intrusive alternative field. Annual household income range was supported by ASTS, AST, region 10, and region 11. Utilization of an annual household income range could help candidates maintain privacy while still allowing the OPTN to collect useful data. This compromise would aim to increase candidate comfortability and trust, but leave the OPTN unable to measure household poverty with the Federal Poverty Guideline. The annual household income ranges proposed by the MAC are displayed in **Figure 4,** below:

Figure 4: Proposed Annual Household Income Ranges

$150, 000 & Up
$100,000 - $149,999
$90,000 - $99,999
$80,000 - $89,999
$70,000 - $79,999
$60,000 - $69,999
$50,000 - $59,999
$40,000- $49,999
$30,000- $39,999
$20,000 -$29,999
$10,000- $19,999
$1- $9,999
$0

The MAC is still discussing if these fields should be required or non-required.

Feedback on Potential Revisions

The MAC has been proactive in soliciting feedback from the DAC and plans to solicit feedback from the Board of Directors on potential revisions in June 2020.

Data Advisory Committee

As a crucial stakeholder, the MAC felt it necessary to solicit feedback from the DAC on these potential revisions to the proposal. The DAC was split on their recommendation to make the field required or non-required. The DAC also suggested collaboration with patients in order to address the trust concerns that were expressed during public comment. The DAC expressed that the MAC needs to show patients the

value of SES data and how its collection would benefit this population. Overall, the DAC saw value in the revision and resubmission of an alternative SES proposal.

Board of Directors

The MAC plans to solicit feedback from the Board on these revisions to the proposal during the Board of Directors meeting on June 8, 2020. This will not be a voting or action item. Feedback questions to the Board include:

- Does the Board see value in the OPTN collecting SES data?
- Does the Board believe MAC should work to revise the SES proposal and submit to a future public comment cycle?
- Does the Board have additional ideas for revisions?

Feedback from the Board will help to determine if the MAC should continue work on the proposal and resubmit to a future public comment cycle. The MAC values the opinions of the OPTN Board of Directors and appreciates the opportunity to solicit feedback. If given the opportunity to revise and submit an alternative proposal, the MAC plans to initiate collaboration with the PAC, DAC, ASTS, and AST in addition to other individuals and stakeholder organizations.