

Briefing to the OPTN Board of Directors on

Strategic Plan 2024-2027

OPTN Executive Committee

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Strategic Plan 2024-2027

Sponsoring Committee: Executive
Public Comment Period: January 23, 2024 to March 19, 2024
Board of Directors Meeting: June 17-18, 2024

Executive Summary

The OPTN Board of Directors (hereinafter “the Board”) adopts a new strategic plan every three years. The current strategic plan expires in June 2024. The strategic plan aligns OPTN resources with specific, significant opportunities within the transplant community. Recognizing the dynamic nature of the field of organ donation and transplantation, the OPTN Executive Committee (hereinafter “the Committee”) acknowledges the importance of focusing efforts on key areas that hold the potential for substantial impact.

This strategic plan is not an exhaustive list of the OPTN’s work, but rather serves as a high-level framework to guide the OPTN’s strategic focus. The plan’s flexibility allows adaptation to emerging opportunities, ensuring responsiveness to the evolving landscape of organ transplantation. The Committee intentionally selected goals with greater specificity to allow for a focusing of resources on key opportunities, driving action to ultimately benefit patients.

The committee reviewed several themes of public comment feedback. These themes included a request for greater emphasis on equity within the strategic plan, a request for the refinement of metrics, support of the emphasis on data and data driven decisions, concerns regarding the prioritization of OPTN projects, support for the inclusion of education and emphasis on visibility, as well as other considerations and suggestions. These themes reflect community priorities, questions, and concerns, and were therefore key in improving the focus and content of the strategic plan.

Since public comment, the Committee has made several updates to the proposed plan including:

- An increased emphasis on equity and support of vulnerable populations has been added to the OPTN vision within the plan.
- Goals have been refined to increase the emphasis on equity, living donation, and OPTN Modernization.
- Metrics have been refined to ensure measurability and accountability within the plan.

The Committee proposes four goals for the OPTN 2024-2027 Strategic Plan:

- **Increase Opportunities for Transplants:** Improve offer acceptance for deceased donation and enhance access to living donation to increase patients’ opportunities for transplant.
- **Optimize Organ Use:** Optimize organ use for transplantation, while improving equity to benefit all patients.
- **Enhance OPTN Efficiency:** Increase the efficiency of the OPTN through improvement and innovation to serve the greatest number of patients.
- **Support OPTN Modernization Initiatives:** Collaborate to lay the foundation for the OPTN of the future.

Background

To create this plan, the Committee focused on opportunities within organ transplantation and leveraged insights and feedback from the transplant community. The Board and Committee Chairs participated in a brainstorming session at the June 2023 Board meeting and identified potential priorities for the community and system. These priorities were then shared and discussed during the summer 2023 regional meetings, engaging over 2,000 members of the organ donation and transplant community, including patients, donor families, and living donors. This transparent, participatory approach supports engagement of diverse perspectives and anticipates the challenges and opportunities facing the transplant community in the coming years.

Creation of the Plan

- Plan creation began at the June 2023 Board meeting with a goal brainstorming activity.
- Themes were shared with the Committee to prioritize and refine further.
- Themes were discussed at summer 2023 regional meetings; an opportunity for the community to provide feedback and insights on prioritization.
- The Committee chose to select more focused goals in response to the community's feedback. These specific goals allow the focusing of resources.
- The Committee selected specific objectives to guide project identification and prioritization in pursuit of the strategic goals.
- A collection of metrics was selected for this plan to measure progress towards the defined goals.
- The Committee chose not to include specific resource allocation commitments. Rather, the Committee proposes the Board consider community needs and strategic plan progress when determining the allocation of resources to achieve this plan.
- The proposed strategic plan received feedback from OPTN members and the transplant and donation community through public comment. General public comment sentiment supported the proposed plan and written comments provided feedback themes for the Committee's consideration.
- The Committee chose to revise the proposed plan's commitment to the OPTN vision, goals, objectives, and metrics in response to public comment feedback.

Components of the Strategic Plan

The proposed OPTN Strategic Plan contains the below components:

- **Introduction:** The introduction provides context to the identity of the OPTN, its members, and the commitment to serving patients.
- **Vision:** The strategic plan is grounded in the OPTN's vision in alignment with National Organ Transplant Act (NOTA), the Final Rule, and the OPTN Contract. This vision statement includes foundational commitments the OPTN remains dedicated to. The commitments of the OPTN have been updated to include equity and support of vulnerable populations in response to public comment themes.
- **Goals:** Goals are intentionally broad and ambitious. The goals listed focus on achieving high-level outcomes in pursuit of realizing the OPTN's vision. This plan contains four goals that have been refined in response to public comment themes.
- **Objectives:** Objectives add a degree of specificity to the outlined goals, breaking goals into more specific measurable outcomes. These provide direction and focus on how to achieve the overall

goal. This plan contains two to three objectives per goal. Objectives have been refined in response to public comment themes.

- **Metrics:** Metrics are included in the strategic plan to provide actionable insights. The holistic review of these metrics facilitates informed decision-making and offers perspective on how the plan is progressing. Since public comment, the metrics within this plan have been refined to provide greater insight into the achievement of the desired outcomes outlined in the plan's goals and objectives. This plan includes thirteen metrics.

The proposed strategic plan does not include:

- **Specific Projects or Initiatives:** Engagement with OPTN members, committees, task force(s), and professional societies within the community will shape the formation and implementation of specific initiatives, reflecting a collaborative effort to achieve the outlined goals of this plan.
- **Project or Initiative level metrics:** As projects are developed in detail over the period covered by the strategic plan, appropriate metrics and monitoring plans are maintained for each project.
- **Resource allocations:** This plan does not define specific resource allocations per goal, but rather provides flexibility. Leveraging insights from regular strategic plan progress reviews, the Board will adjust resources as needed to the greatest benefit of the transplant community.

Proposed Strategic Plan

The proposed strategic plan seeks to attain four goals:

- **Increase Opportunities for Transplants:** Improve offer acceptance for deceased donation and enhance access to living donation to increase patients' opportunities for transplant.
- **Optimize Organ Use:** Optimize organ use for transplantation, while improving equity to benefit all patients.
- **Enhance OPTN Efficiency:** Increase the efficiency of the OPTN through improvement and innovation to serve the greatest number of patients.
- **Support OPTN Modernization Initiatives:** Collaborate to lay the foundation for the OPTN of the future.

Strategic plan elements that have been updated post public comment in response to community feedback are noted with an * and *italicized text* within the proposed plan below. Additional details on the changes can be found in the public comment section.

The OPTN Strategic Plan is not intended to be an exhaustive list of the OPTN's work or focus areas. The plan includes flexibility for the Board to add or redirect as needed to capitalize on emerging opportunities.

In addition to the goals, the OPTN vision detailed in the strategic plan maintains commitment to:

- Increase the number of successful transplants.
- Honor the selfless gift of life given by organ donors.
- Safeguard the well-being of patients and living donors.
- Continuously improve the outcomes of patients on the waiting list, living donors, and transplant recipients.
- * *Advance equity within the transplant system and support vulnerable populations¹.*

¹ A commitment of continued dedication to equity and support of vulnerable populations has been added to the strategic plan's vision statement.

**Goal 1: Increase Opportunities for Transplants: Improve offer acceptance for deceased donation and enhance access to living donation to increase patients' opportunities for transplant.²*

Objectives:

- **Develop, implement, and effectively promote educational programs for patients and transplant programs focused on understanding offer acceptance and living donation³.*
- Collaborate with stakeholders to improve offer and acceptance processes to increase consistency.
- **Collaborate with stakeholders to enhance access to living donor transplants.⁴*

Metrics:

- Increased organ offer acceptance rates, **annually.⁵*
- Decreased variability in time from first offer to organ offer acceptance.
- Decreased median number of declines prior to organ offer acceptance.
- **Increased number of living donor transplants, annually.⁶*

² This goal has been refined from "Improve Offer Acceptance Rate" to "Increase Opportunities for transplants" with the inclusion of living donation within the larger goal statement.

³ Objective has been updated to incorporate living donation.

⁴ Addition of a new objective focused on living donation. The intent of this goal and objective is enhancement of living donation while improving equity and safety for living donors.

⁵ The Committee considered historical trends and determined that annual improvement was an appropriate target.

⁶ The Committee added a metric focused on living donor transplants to ensure accountability and visibility.

***Goal 2: Optimize Organ Use:** Optimize organ use for transplantation, while improving equity to benefit all patients.⁷

Objectives:

- **Collaborate with stakeholders to identify and reduce key barriers influencing organ non-use and non-utilization, promoting best practices and effective strategies across the transplantation community.*⁸
- Explore and evaluate allocation strategies for organs at high risk of non-use.⁹
- **Advance equity within the transplant system.*¹⁰

Metrics:

- **Decrease non-utilization rate for heart and lung.*¹¹
- **Decrease non-use rate for kidney (Stratified by KDPI group).*¹²
- **Decrease non-use rate for liver (Stratified by the combination of donor age and DCD status).*¹³
- **Improve equity: Access-to-Transplant Scores (ATS).*

***Key Definitions:**¹⁴

- **Non-use rate: The proportion of deceased donor¹⁵ organs recovered for the purpose of transplant, but not transplanted.*
- **Non-utilization rate: The proportion of deceased donor organs not transplanted from all deceased donors¹⁶.*

⁷ This goal has been refined. The “maximize” language has been updated to “optimize”. The language “waitlisted patients” has been refined to “all patients” to be more inclusive. “Maintaining or improving upon past equity gains” has been refined to “improving equity” emphasizing the commitment to equity within this goal.

⁸ This objective combines two separate objectives listed in the proposal.

⁹ This objective has been refined through the removal of “alternative” describing allocation strategies.

¹⁰ This objective has been added in response to public comment themes.

¹¹ This metric has been updated to include non-utilization; a metric utilized by the OPTN. This is not a substantive change as compared to the metric listed in the proposal.

¹² This metric has been updated to include non-use, a metric utilized by the OPTN. This metric was refined include stratification by KDPI group; an inclusion to consider organs at high-risk of non-use.

¹³ This metric has been updated to include non-use, a metric utilized by the OPTN. This metric was refined include stratification by the combination of donor age and DCD status; an inclusion to consider organs at high-risk of non-use. The Committee considered historical data and determined a directional target was appropriate.

¹⁴ The Committee desired the display of key definitions of non-use rate and non-utilization rate within the strategic plan to ensure accessibility of metrics to all audiences.

¹⁵ Deceased donors are individuals from whom at least one organ is recovered for the purpose of transplantation after declaration of death. All donors were assumed to have two transplantable kidneys and two transplantable lungs.

¹⁶ Ibid.

Goal 3: Enhance OPTN Efficiency: Increase the efficiency of the OPTN through improvement and innovation to serve the greatest number of patients.

Objectives:

- Refine the policy development and implementation process to be more efficient, **equitable*,¹⁷ and strategically aligned.
- **Enhance OPTN data collection: increase availability of actionable data.*¹⁸

Metrics:

- **Establishment of Quarterly Strategic Plan reviews, inclusive of metric reviews by Fiscal Year 2025.*¹⁹
- Improved policy development **and implementation* timeliness: Stratified by project type. (ex. allocation, guidance, data collection, etc.).²⁰
- **Increased Policy Project Benefit.*²¹

**Goal 4: Support OPTN Modernization Initiatives: Collaborate to lay the foundation for the OPTN of the future.*²²

Objectives:

- **Develop and implement processes to support an OPTN and OPTN Board of Directors independent of OPTN contractors.*
- **Develop an effective partnership and ongoing collaboration with HHS and OPTN contractors.*
- **Collaborate with HHS and OPTN contractors, to improve OPTN technology systems.*

Metrics:

- **Achievement of OPTN Independence by Fiscal Year 2025.*
- **Develop and implement feedback process for metrics of successful collaboration and challenges to collaboration (OPTN, HHS, and contractors) by the end of Fiscal Year 2025.*

¹⁷ The Committee added equitable to the policy development and implementation objective emphasizing the commitment to equity within the plan.

¹⁸ This objective has been updated removing the emphasis on reducing member burden.

¹⁹ This metric was included to establish accountability and in response to the call for more data-driven decisions, the Committee committed to the establishment of a quarterly strategic plan review.

²⁰ This metric was expanded by the Committee to include the implementation of policies. The Committee sees this expanded scope as more appropriate to measure the desired efficiency improvements.

²¹ This metric was added by the Committee to ensure balance. The POC has developed a scoring rubric regarding the benefit of each project. An aggregate score will be used to balance efficiency gains with the selection of projects to the greatest benefit of the community.

²² The fourth goal has been added in response to public comment feedback themes. All objectives and metrics within this goal are new additions.

Overall Sentiment from Public Comment

The Committee requested public comment feedback, including input on the following questions.²³:

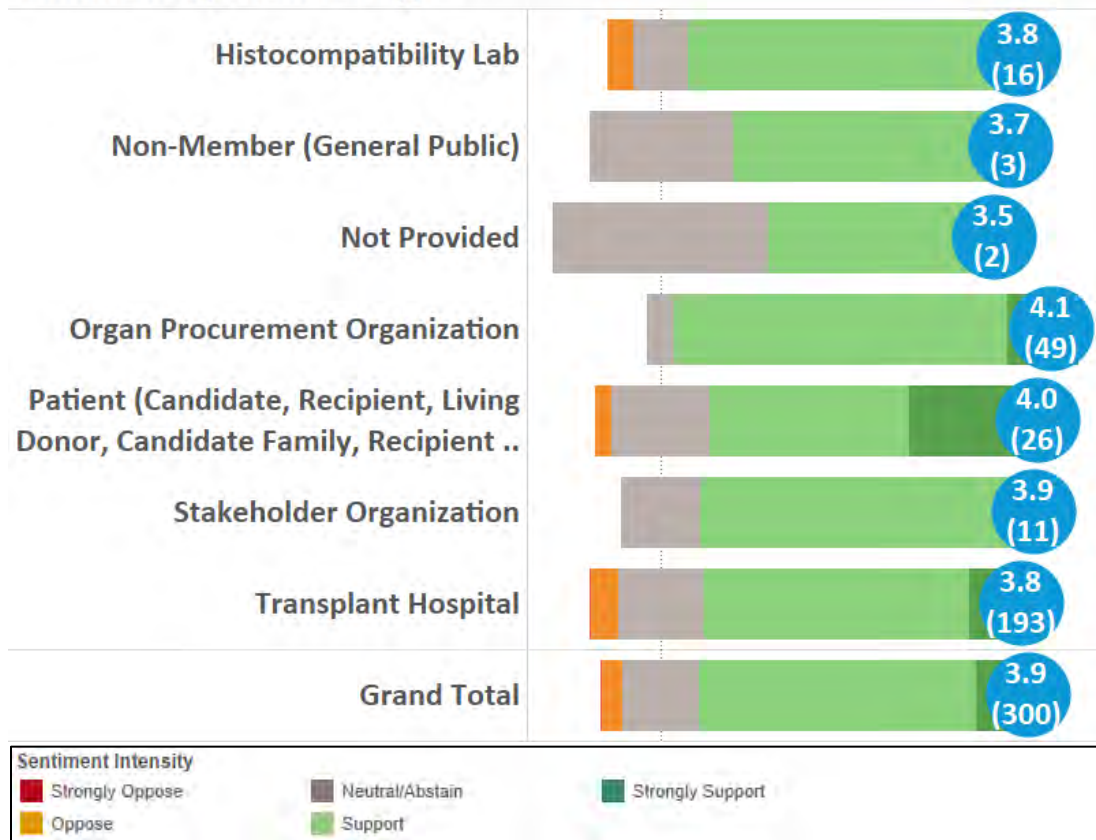
- Do you agree with the Board’s proposed areas of strategic focus for the 2024-2027 plan?
- Is a goal or objective missing from this plan that should be considered a strategic priority?
- Are there goals or objectives that should not be included in this plan? If so, should they be maintained in the OPTN’s future operations or discontinued altogether?
- Are the stated performance metrics sufficient, measurable, and specific? Are metrics missing from this plan that are needed to provide a holistic view of progress on strategic priorities?
- What organs are at the greatest risk of non-use?
 - o What characteristics or criteria describe those organs?

The Committee presented the proposal to all 11 OPTN regions and twenty-one committees for feedback and posted a video presentation describing the proposal to the OPTN website. The proposal received 300 comments, including 59 substantive, written comments. Public comment sentiment has been supportive of the proposed strategic plan, with some pockets of concern. Sentiment by member type and region are shown below in **Figures 1** and **2**.

²³ OPTN Public Comment, OPTN Strategic Plan 2024-2027, https://optn.transplant.hrsa.gov/media/nwrksrgl/exec_2024-2027-strategic-plan_pcjan24.pdf

Figure 1 shows sentiment received from all respondents (regional meeting, online, and email) by their stated member type. The “Not provided” category represents those commenters who did not provide their state/region or relationship to transplant. There was overall support for the concept, demonstrated by a sentiment score of 3.9. Although there was some opposition seen among patients, histocompatibility labs, and transplant hospitals, their overall sentiment was in support of the proposal.

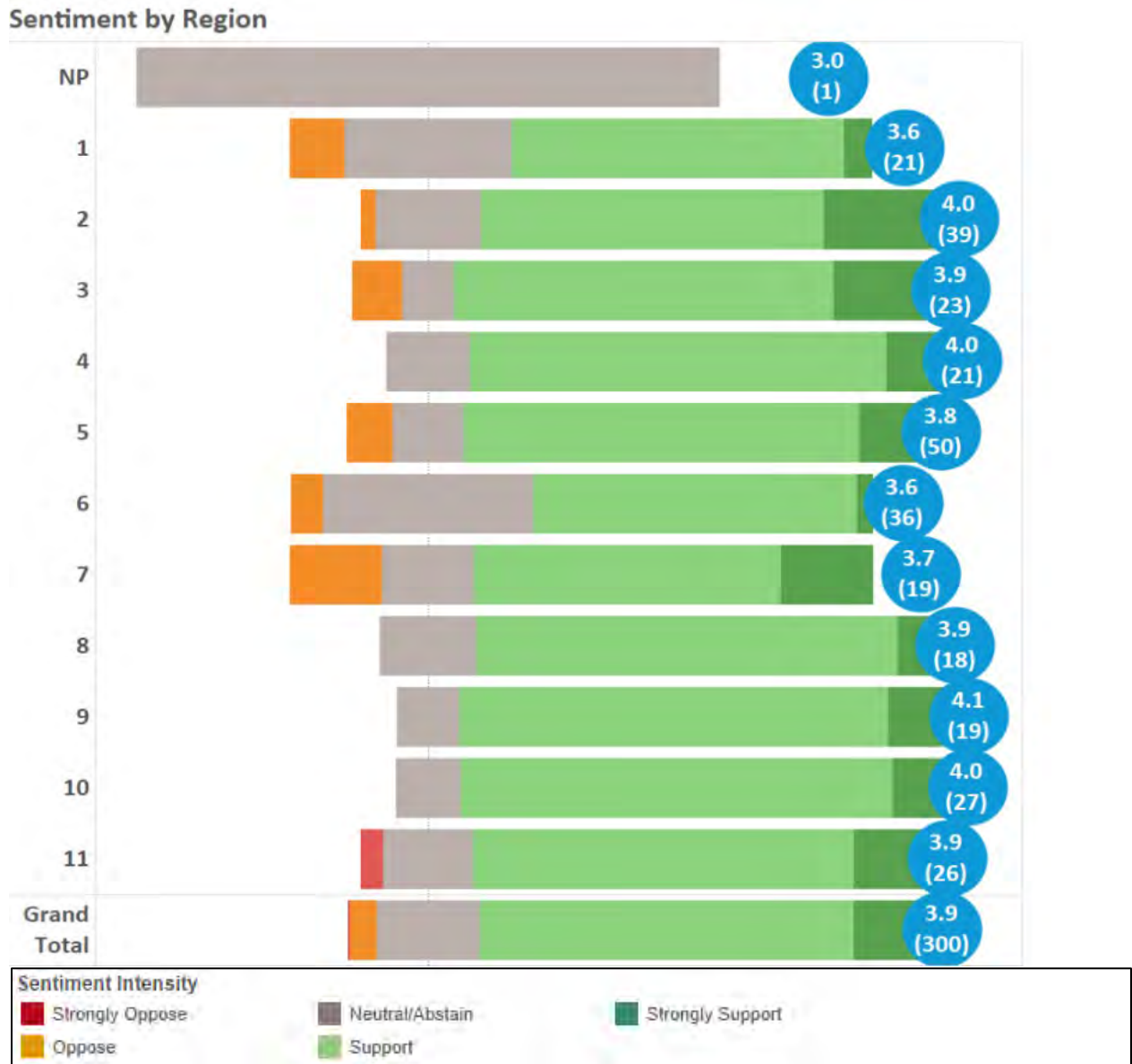
Figure 1. Sentiment by Member Type, OPTN Strategic Plan 2024-2027²⁴
Sentiment by Member Type



²⁴ The circles after each bar indicate the average sentiment score and the number of participants in is in the parentheses.

Figure 2 shows sentiment received from all respondents (regional meeting, online, and email) by their geographical region. The “Not provided” category represents those commenters who did not provide their state/region or relationship to transplant. Sentiment is collected from participants who submit an individual public comment and from regional meeting participants. Overall sentiment was supportive, as indicated by a total sentiment score of 3.9. Opposition was raised in regions 1, 2, 3, 5, 6, and 7 and strong opposition raised in region 11 mostly under the theme of equity and metrics.

Figure 2. Sentiment by Region, OPTN Strategic Plan 2024-2027²⁵



²⁵ The circles after each bar indicate the average sentiment score and the number of participants in is in the parentheses.

Themes in Public Comment

Respondents submitted 59 substantive, written public comments.²⁶ Responses were submitted by members of the public at large, OPTN members, patients, stakeholder organizations as well as on behalf of regions and committees. Commenters covered many different topics, including the following themes:

- Requesting a greater emphasis on Equity
- Request for refinement of metrics
- Support of the emphasis on data and data driven decisions
- Concerns regarding the prioritization of OPTN projects (note: this includes comments regarding OPTN Modernization Initiatives)
- Support for inclusion of education and emphasis on visibility
- Other suggestions/considerations

Requesting a greater emphasis on Equity

Many comments advocated for a more explicit emphasis on equity in the strategic plan goals, including equity for vulnerable populations and living donors/donation. Commentors expressed that while gains have been made in equity, it has not been fully realized and there was a desire for a more explicit commitment to increasing equity in the strategic plan.

The committee considered this feedback and agreed that placing greater emphasis on equity was appropriate given the OPTN's commitment to protect vulnerable populations and the highlighted opportunities in the realization of equity across patient populations. The strategic plan was modified to increase the emphasis on equity through:

- Equity and commitment to supporting vulnerable populations were added as a commitment of the OPTN.
- Additionally, the equity incorporation in goal two was strengthened; updating language to improve equity and adding an additional equity focused objective.
- The committee chose to incorporate living donation in several places:
 - Enhancing opportunities for living donor transplants has been incorporated into the overall goal statement of goal one and as an objective within that goal.
 - Goal one has been updated to include a metric focused on living donation transplants.
 - The language in goal two has been updated from “waitlisted patients” to “all patients” to be more inclusive.

Request for refinement of metrics

Commenters advocated for refined metrics. Specifically, commenters sought metrics that provided insight to the progress of the strategic plan. This included comments seeking the addition of specific targets to include percentage improvement and milestone dates. Some commentors recommended metrics focused on specific initiatives or projects that could or are being pursued to achieve the desired outcomes of the goals. Other commentors recommended specific stratification of metrics, these comments were balanced by feedback on the burden placed on members through additional tracking of

²⁶ OPTN Public Comment, OPTN Strategic Plan 2024-2027, https://optn.transplant.hrsa.gov/media/nwrksrgl/exec_2024-2027-strategic-plan_pcjan24.pdf

data or the variability across the nation. Other comments emphasized the importance of metric reviews in the spirit of improvement and not disciplinary action. Commentors also expressed a desire for accountability and visibility to metrics and to understand the strategic plan metric review process. There were also comments expressing concern for the monitoring of outcomes and consequences not explicitly outlined within the strategic plan metrics.

The Committee considered the feedback on metrics and determined considerable review and refinement was appropriate. Appreciating the balanced feedback on granular metrics related to initiatives or projects, options for segmentation and stratification of metrics, the variation in metrics that can be present across the nation, and the importance of utilizing currently available and actionable data, the Committee chose to target a succinct group of metrics that would prompt insightful discussion of the OPTN's progress towards the desired outcomes of the strategic plan.

To approach metrics refinement, the Committee considered the refined goals and objectives post-public comment and aligned on the desired outcomes that would be achieved through the goals and objectives. The metrics discussion then focused on how achievement of those outcomes could be measured. The committee considered available historical data and trends and determined that directional targets were appropriate, with a commitment to annual improvements in some cases. The Committee seeks to leverage the metric review as a dynamic process where targets may be added at the Board's discretion as the plan progresses. Given the approach of focusing on outcomes, most milestones were removed from the plan with the exception of:

- Establishment of Quarterly Strategic Plan reviews, inclusive of metric reviews by Fiscal Year 2025.
- Achievement of OPTN Independence by Fiscal Year 2025.
- Develop and implement feedback process for metrics of successful collaboration and challenges to collaboration (OPTN, HHS, and contractors) by the end of Fiscal Year 2025.

These milestones remain given the foundational and future focused nature of the fourth goal and the public comment feedback advocating for accountability and visibility of metrics and the metric review process.

While the number of metrics in the plan has been limited, additional data may support and aid in insightful discussions when the Board reviews the strategic plan. Additionally, the strategic plan metrics are not the sole monitoring approach of the OPTN. Critical monitoring such as patient safety, policy implementation, etc. will continue despite not being named metrics within the strategic plan. The thirteen metrics included in the proposed plan are listed above. Metrics that were refined are noted with *italic font and an **.

Support of the emphasis on data and data driven decisions

Several commenters supported the use of data and data driven decisions in pursuit of the achievement of strategic plan goals. Within the comments, there were endorsements of continuous improvement, benchmarking, and the use of data in understanding barriers and root causes impeding desired results. Several commentors included ideas for improvement to OPTN data and processes.

The committee appreciated this feedback and agreed with the importance of data-driven discussions, data driven decisions, and emphasis on utilization of OPTN data. In response to the call for more data-driven decisions, the committee committed to the establishment of a quarterly strategic plan review. This process, which should be in place by 2025, will allow accountability in strategic plan execution. The routine reviewing of initiatives in pursuit of the desired outcomes and associated metrics will facilitate data driven discussions on progress and decisions.

Concerns regarding the prioritization of OPTN projects

There were comments voicing concern for the current OPTN projects (i.e., continuous distribution, multi-organ transplantation focused efforts, living donor data collection efforts) and how they may be deprioritized or no longer in alignment with the new strategic goals proposed. Additionally, commentors recommended specific initiatives to be included in the plan. Finally, there was concern raised on the OPTN Modernization Initiative and how this may align with the strategic plan and future projects.

The Committee discussed prioritization of OPTN projects and the focused nature of the proposed strategic plan goals. The Committee remains committed to focused goals, providing a structure to gain traction on key opportunities to benefit patients. They also stressed that this is a flexible plan allowing for increased collaboration and agility as the needs of the transplant community evolve over the next three years. The goals included in this plan do not holistically encompass the work of the OPTN and the Committee recognizes and supports the need to allocate OPTN resources to projects that may not align with the strictest interpretation of the outlined goals. The Committee advocates for consideration of the plan goals by the OPTN when selecting priority projects but supports the prioritization of projects to the greatest benefit of the transplant community. Recommended initiatives shared in public comment should be considered by committees and prioritized.

OPTN Modernization Initiatives have been added as a fourth goal within the proposed plan. This goal has been added recognizing the amount of change currently occurring within the OPTN. The Committee desires the achievement of an increase in collaboration between the OPTN Board, HHS and HRSA, and contractors. This goal is focused on establishing the foundation of the OPTN of the future and includes milestones such as the implementation of a feedback process for successful collaboration or challenges to collaboration. As an example of this foundational collaboration, the Committee desires to discuss and possibly add to this goal's metrics upon completion of HRSA's RFP process.

Support for inclusion of education and emphasis on visibility

Commenters stressed the importance of education and transparency for patients, the transplant community, and the public. Comments were overall supportive of the inclusion of education and the emphasis on transparency, communications, and visibility. There was a comment challenging the OPTN to consider the outcomes of education. The comment shared that while the desire to inform is admirable, the Committee was challenged to consider if education efforts were achieving the desired impact and outcome on the overall goal.

The Committee discussed this feedback and agreed that increased education and communication is a critical approach to achievement of the strategic plan goals. Additionally, the Committee chose to remove the education process-oriented metrics and focus on utilizing education as a key objective to

achieve the overall outcome-based metrics. The committee has committed to strategic plan reviews and increased transparency and visibility of the strategic plan.

Other suggestions/considerations

There were comments that provided suggestions related to innovations, considerations related to the infrastructure of the transplant system, and future outlooks. These comments include several references to the consideration of the potential applications of artificial intelligence.

As a result of this feedback, the Committee chose to emphasize improvement of OPTN technology systems within the OPTN Modernization goal by the inclusion of a specific objective on technology.

Compliance Analysis

NOTA and OPTN Final Rule

The Committee submits this proposed strategic plan in alignment with the requirement in the OPTN Contract for the OPTN Contractor to work with the Board to create a strategic plan to “develop long-term goals to target OPTN resource planning,”²⁷ which also “address[es] requirements for OPTN performance identified in NOTA and the OPTN Final Rule.”²⁸

Additionally, as the Committee considered strategic goals, each was analyzed for alignment to NOTA, the Final Rule, the OPTN Contract, and the OPTN Bylaws. The proposed goal of “Increase Opportunities for Transplants” is supported by the authority of NOTA, which requires that the OPTN “work actively to increase the supply of donated organs,”²⁹ which requires the OPTN to operate a matching system “through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list...,”³⁰ as acceptance is a necessary part of matching organs and individuals on the waiting list. This goal is also authorized by the Final Rule, which permits screening activities by requiring that “when a donor or donor organ does not meet a transplant program’s donor acceptance criteria...transplant candidates of that program shall not be ranked among potential recipients of that organ and shall not appear on a roster of potential recipients of that organ.”³¹ This supports a goal of increasing the rate of organ offer acceptance because organ offers that would not be acceptable to a program are offered only to programs with candidates who may actually accept those organs, resulting in a higher acceptance rate. The Final Rule requires the OPTN to develop allocation policies that in part, “shall be designed to avoid wasting organs...to promote patient access to transplantation, and to promote the efficient management of organ placement;”³² which all may be achieved by improving organ offer acceptance practices and therein increasing the organ offer acceptance rate. The Final Rule requires the OPTN and SRTR to report on “transplant program-specific information on...refusal of organ offers”³³ and requires transplant programs to “document...to the OPO and to the OPTN the reasons for refusal”³⁴ which can provide helpful data as to why organ offers are not being accepted, leading to

²⁷ OPTN PWS HSH250201900001C.

²⁸ Id.

²⁹ 42 USC §274(b)(2)(K).

³⁰ 42 USC §274(b)(2)(A)(ii).

³¹ 42 CFR §121.7(a)(3).

³² 42 CFR §121.8(a)(5).

³³ 42 CFR §121.11(b)(1)(iv).

³⁴ 42 CFR §121.7(b)(4).

change in organ offer acceptance practices which in turn could improve the offer acceptance rate. In addition, HRSA requires the OPTN to “develop policies regarding living organ donors and living organ donor recipients, including policies for the equitable allocation of living donor organs.”³⁵ The proposed goal of “Increase Opportunities for Transplants” is now inclusive of increasing access to living donation while maintaining equity and safety for all living donors.

The proposed goal of “Optimize Organ Use” is supported by the authority of NOTA, which requires the OPTN to “work actively to increase the supply of donated organs”³⁶ as well as the Final Rule, which requires the OPTN to develop allocation policies that...“shall be designed to avoid wasting organs.”³⁷ Optimizing organ use will be driven by aims to reduce the instances where organs are not recovered and could have been or were not transplanted following recovery when could have been, which will increase the supply of donated organs. The Final Rule further establishes the priority of optimizing organ use by specifying that “[n]othing in this section shall prohibit a transplant program from transplanting an organ into any medically suitable candidate if to do otherwise would result in the organ not being used for transplantation.”³⁸ The Final Rule also identifies that the OPTN develops “Policies for the equitable allocation of cadaveric organs” and “Policies that reduce inequities resulting from socioeconomic status.”³⁹ The proposed goal of “Optimize Organ Use” includes a focus on increasing or maintaining equity in accordance with these provisions of the Final Rule.

The proposed goal of “Enhance OPTN Efficiency” is supported by the authority of NOTA, which contains requirements for the OPTN policy development process, such as requiring the OPTN to “establish membership criteria and medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria”⁴⁰ and “collect, analyze, and publish data concerning organ donation and transplants.”⁴¹ The Final Rule requires the OPTN Board of Directors to “provide opportunity for the OPTN membership and other interested parties to comment on proposed policies and shall take into account the comments received in developing and adopting policies for implementation by the OPTN”⁴² and “maintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors....”⁴³ Improvements and innovations in the areas of policy development and data collection aim to create a more efficient process for executing the responsibilities of the OPTN.

The proposed goal of “Support OPTN Modernization Initiatives” to develop and implement an OPTN and OPTN Board of Directors independent of the OPTN contractor(s). NOTA supports the partnership and collaboration with HHS and OPTN contractors, requiring that the OPTN “shall be operated through awards to public or private entities made by the Secretary (of HHS) that are distinct from the awards made to support the organization tasked with supporting the board of directors”⁴⁴. NOTA emphasizes that the awards made by HHS for the operational support to the OPTN must be separate from awards

³⁵ Response to Solicitation on Organ Procurement and Transplantation Network (OPTN) Living Donor Guidelines, 71 FR 34946 (June 16, 2006).

³⁶ 42 USC §274(b)(2)(K).

³⁷ 42 CFR §121.8(a)(5).

³⁸ 42 CFR §121.7(f).

³⁹ 71 FR 34946.

⁴⁰ 42 USC §274(b)(2)(B).

⁴¹ 42 USC §274(b)(2)(I).

⁴² 42 CFR §121.4(b)(1).

⁴³ 42 CFR §121.11(a)(1)(i).

⁴⁴ 42 CFR §274(b)(1)(A)

made to the board support contractor. This section in NOTA allows for multiple contractors for the OPTN and collaboration between these contractors.

Collaborating with HHS and OPTN contractors to improve OPTN technology systems is supported by the Final Rule provision requiring that the OPTN shall “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”⁴⁵. This section of the Final Rule requires the OPTN to ensure record maintenance within the OPTN Computer System.

Implementation Considerations

OPTN

Operational Considerations

- Pending approval from the Board, this strategic plan would take effect July 1, 2024, and expire on September 30, 2027. This plan extends to three and a quarter year to align the strategic plan cycle with the fiscal year.
- This plan will be managed by the Board through review of strategic plan metric results, review of OPTN resource allocation, and discussion of transplant community needs.
- This plan is intentionally structured to provide flexibility and latitude to the Board to be responsive to the needs of the community. Initiatives or projects are not included in the plan, but rather will be selected and approved by the Board and Executive Committee.

Fiscal Impact

It is estimated that 255 hours would be needed to implement this proposal. This will involve updates and creation of communication and educational content, as well as other general support as the updated plan starts to be implemented. It is also estimated that 170 hours would be needed for ongoing support. Ongoing support will include supporting work for the monitoring report.

Conclusion

The Committee proposes a refined strategic plan with increased emphasis on equity, vulnerable populations, living donation, and OPTN modernization initiatives. The refined metrics focused on outcomes of the strategic plan will aid in providing structure to support data driven decisions and resource allocation discussions. The Committee remains committed to a flexible and focused plan that allows for prioritization of projects most beneficial to the transplant community. The Committee reviewed and discussed the results of public comment and concluded the public sentiment supported sending the proposal to the Board of Directors with refinements.

⁴⁵ 42 CFR §121.11(a)(1)(i)

OPTN Strategic Plan 2024-2027

The Organ Procurement and Transplantation Network (OPTN) leads the network of transplant hospitals, organ procurement organizations, and thousands of volunteers dedicated to honoring the gifts of life entrusted to us and to making lifesaving transplants possible for patients in need. Over 100,000 people are waiting for a transplant and rely on the organ donation and transplant community to strengthen the system to provide equitable access to lifesaving organs to patients.

The OPTN's Strategic Plan encompasses a comprehensive understanding of the most important factors that currently impact the transplant community and a focus on building trust through action on opportunities most impactful to the community and ultimately, the patients we serve. The OPTN achieves these goals through partnership, convening the transplant community to pursue innovation and improvement while maintaining patient safety. These goals include:

- **Increase Opportunities for Transplants:** Improve offer acceptance for deceased donation and enhance access to living donation to increase patients' opportunities for transplant.
- **Optimize Organ Use:** Optimize organ use for transplantation, while improving equity to benefit all patients.
- **Enhance OPTN Efficiency:** Increase the efficiency of the OPTN through improvement and innovation to serve the greatest number of patients.
- **Support OPTN Modernization Initiatives:** Collaborate to lay the foundation for the OPTN of the future.

The OPTN Strategic Plan is not intended to be an exhaustive list of the OPTN's work or focus areas. The plan includes flexibility for the Board to add or redirect as needed to capitalize on emerging opportunities.

OPTN Vision

The OPTN promotes long, healthy, and productive lives for persons with organ failure by promoting maximized organ supply, effective and safe care, and equitable organ allocation and access to transplantation; and doing so by balancing competing goals in ways that are transparent, inclusive, and enhance public trust in the national organ donation system.

We commit our resources to achieve the goals outlined in our Strategic Plan while continuing our dedication to:

- Increase the number of successful transplants.
- Honor the selfless gift of life given by organ donors.
- Safeguard the well-being of patients and living donors.
- Continuously improve the outcomes of patients on the waiting list, living donors, and transplant recipients.
- Advancing equity within the transplant system and supporting vulnerable populations.

Goal 1: Increase Opportunities for Transplants: Improve offer acceptance for deceased donation and enhance access to living donation to increase patients' opportunities for transplant.

Objectives:

- Develop, implement, and effectively promote educational programs for patients and transplant programs focused on understanding offer acceptance and living donation.
- Collaborate with stakeholders to improve offer and acceptance processes to increase consistency.
- Collaborate with stakeholders to enhance access to living donor transplants.

Metrics:

- Increased organ offer acceptance rates, annually.
- Decreased variability in time from first offer to organ offer acceptance.
- Decreased median number of declines prior to organ offer acceptance.
- Increased number of living donor transplants, annually.

Goal 2: Optimize Organ Use: Optimize organ use for transplantation, while improving equity to benefit all patients.

Objectives:

- Collaborate with stakeholders to identify and reduce key barriers influencing organ non-use and non-utilization, promoting best practices and effective strategies across the transplantation community.
- Explore and evaluate allocation strategies for organs at high risk of non-use.
- Advance equity within the transplant system.

Metrics:

- Decrease non-utilization rate for heart and lung.
- Decrease non-use rate for kidney (Stratified by KDPI group).
- Decrease non-use rate for liver (Stratified by the combination of donor age and DCD status).
- Improve equity: Access-to-Transplant Scores (ATS).

Key Definitions:

- Non-use rate: The proportion of deceased donor⁴⁶ organs recovered for the purpose of transplant, but not transplanted.
- Non-utilization rate: The proportion of deceased donor organs not transplanted from all deceased donors⁴⁷.

⁴⁶ Deceased donors are individuals from whom at least one organ is recovered for the purpose of transplantation after declaration of death. All donors were assumed to have two transplantable kidneys and two transplantable lungs.

⁴⁷ Ibid.

Goal 3: Enhance OPTN Efficiency: Increase the efficiency of the OPTN through improvement and innovation to serve the greatest number of patients.

Objectives:

- Refine the policy development and implementation process to be more efficient, equitable, and strategically aligned.
- Enhance OPTN data collection: increase availability of actionable data.

Metrics:

- Establishment of Quarterly Strategic Plan reviews, inclusive of metric reviews by Fiscal Year 2025.
- Improved policy development and implementation timeliness: Stratified by project type. (ex. allocation, guidance, data collection, etc.).
- Increased Policy Project Benefit.

Goal 4: Support OPTN Modernization Initiatives: Collaborate to lay the foundation for the OPTN of the future.

Objectives:

- Develop and implement processes to effectively support the OPTN and OPTN Board of Directors.
- Develop an effective partnership and ongoing collaboration with HHS and OPTN contractors.
- Collaborate with HHS and OPTN contractors, to improve OPTN technology systems.

Metrics:

- Develop and implement feedback process for metrics of successful collaboration and challenges to collaboration (OPTN, HHS, and contractors) by the end of Fiscal Year 2025.

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