Proposed Strategic Plan for Public Comment OPTN Strategic Plan 2024-2027

OPTN Executive Committee

Contents

Overview	2
Background	3
NOTA and Final Rule Analysis	4
Implementation Considerations	6
Considerations for the Community	6
Proposed Strategic Plan	7

Strategic Plan 2024-2027

Sponsoring Committee: Public Comment Period:

Executive January 23-March 19, 2024

Overview

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. This plan contains goals, objectives, and metrics, but does not detail each needed initiative or project. Engagement with OPTN members, committees, task force(s), and professional societies within the community will shape the formation and implementation of specific initiatives; a collaborative effort to achieve the outlined goals of this plan.

The Committee intentionally selected goals with greater specificity to allow for a focusing of resources on key opportunities, driving action to ultimately benefit patients:

- Improve Offer Acceptance Rate: Increase opportunities for transplants for patients in need by enhancing offer acceptance.
- Optimize Organ Use: Maximize the use of organs for transplantation for waitlisted patients, while maintaining or improving upon past equity gains.
- Enhance OPTN Efficiency: Increase the efficiency of the OPTN through improvement and innovation to serve the greatest number of patients.

The plan proposes trackable metrics for each of the key goals. The metrics should be impacted by progress towards the strategic plan objectives. One objective or project may impact multiple metrics. Metrics within this plan are intended to be reviewed holistically to assess progress. As projects are developed in detail over the period covered by the strategic plan, appropriate metrics and monitoring plans are maintained for each project. 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.

Background

To create this plan, the Committee focused on opportunities within organ transplantation to leverage insights and feedback from the transplant community. The Board and committee chairs participated in a brainstorming session in 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.

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.
- 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 three goals.
- 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.
- Metrics: Metrics are included in the strategic plan to provide actionable insights. The review of these metrics facilitates informed decision-making and offers perspective on how the plan is progressing. Within the plan are metrics to provide insight to the progress of overall goals, and metrics linked more closely to individual objectives. This plan includes nineteen metrics.

Alternatives Considered

The Committee considered alternative goals, including goals from the 2021-2024 Strategic Plan. Increase the number of transplants aligned with a theme from the June 2023 brainstorming session. The Committee and the community prioritized this theme, while also providing feedback to refine the theme and make the scope more focused. The Committee noted that increasing the number of transplants is a result of the achievement of the vision of the OPTN, more than a specific goal.

Past equity gains have been incorporated into the proposed plan's strategic goal "Optimize Organ Use: Maximize the use of organs for transplantation for waitlisted patients, while maintaining or improving upon past equity gains;" recognizing that as advances in efficiency occur, equity must be maintained or improved.

The Committee considered a goal focused on patient education and engagement. However, as they considered the prioritization of goals, they recognized that all goals focus on benefiting patients and the importance of patient education and engagement in pursuit of all goals. The Committee intentionally wrote each goal to emphasize its impact on patients.

While not specific goals within this plan, the Committee added statements highlighting the OPTN's continued commitment to its vision and continued dedication to core activities in alignment with NOTA, the Final Rule, the OPTN Contract, and the OPTN Vision:

- 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.

Preparation for the Strategic Plan

Recognizing the need to prioritize and manage work differently, a Board work group will be launched to refine the project prioritization and approval processes. This process will be used to operationalize this strategic plan and work outside of this plan deemed necessary by the Board or Executive Committee on behalf of the Board. Leveraging this process, projects identified in pursuit of the 2021-2024 strategic plan applicable to support the 2024-2027 plan will be considered. The Board and the Executive Committee will be responsible for prioritizing projects.

NOTA and Final Rule Analysis

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,"¹ which also "address[es] requirements for OPTN performance identified in NOTA and the OPTN Final Rule."²

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 Offer

² Id.

¹ OPTN PWS HHSH250201900001C.

Acceptance" is supported by the authority of NOTA, 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...,"³ 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."⁴ 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;"⁵ 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"⁶ and requires transplant programs to "document...to the OPO and to the OPTN the reasons for refusal"⁷ which can provide helpful data as to why organ offers are not being accepted, leading to change in organ offer acceptance practices which in turn could improve the offer acceptance rate.

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"⁸ as well as the Final Rule, which requires the OPTN to develop allocation policies that..."shall be designed to avoid wasting organs."⁹ 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."¹⁰

The proposed goal of "Enhance OPTN Efficiency" is supported by the authority of NOTA, which requires 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"¹¹ and "collect, analyze, and publish data concerning organ donation and transplants."¹² 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"¹³ and "maintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors...."¹⁴

³ 42 USC §274(b)(2)(A)(ii).
 ⁴ 42 CFR §121.7(a)(3).
 ⁵ 42 CFR §121.8(a)(5).
 ⁶ 42 CFR §121.11(b)(1)(iv).
 ⁷ 42 CFR §121.12(b)(4)(4).

- ⁷ 42 CFR §121.7(b)(4).
- ⁸ 42 USC §274(b)(2)(K).
- ⁹ 42 CFR §121.8(a)(5). ¹⁰ 42 CFR §121.7(f).
- ¹¹ 42 USC §274(b)(2)(B).
- ¹² 42 USC §274(b)(2)(I).
- ¹³ 42 CFR §121.4(b)(1).
- 14 42 CFR §121.11(a)(1)(i).

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.

Implementation Considerations

OPTN Operations

- 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 years 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.

Considerations for the Community

The Committee seeks public comment on whether this set of goals and their associated objectives and metrics are appropriate. Specifically, the Committee requests the following feedback:

- 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?

Proposed Strategic Plan

- 1 The Organ Procurement and Transplantation Network (OPTN) leads the network of transplant hospitals,
- 2 organ procurement organizations, and thousands of volunteers dedicated to honoring the gifts of life
- 3 entrusted to us and to making lifesaving transplants possible for patients in need. Over 100,000 people
- 4 are waiting for a transplant and rely on the organ donation and transplant community to strengthen the
- 5 system to provide equitable access to lifesaving organs to patients.
- 6 Our Strategic Plan encompasses a comprehensive understanding of the most important factors that
- 7 currently impact the transplant community and a focus on building trust through action on
- 8 opportunities most impactful to the community and ultimately, the patients we serve. We achieve these
- 9 goals through partnership, convening the transplant community to pursue innovation and improvement
- 10 while maintaining patient safety. These goals include:
- Improve Offer Acceptance Rate: Increase opportunities for transplants for patients in need by enhancing offer acceptance.
 Optimize Organ Use: Maximize the use of organs for transplantation for waitlisted patients, while maintaining or improving upon past equity gains.
 Enhance OPTN Efficiency: Increase the efficiency of the OPTN through improvement and innovation to serve the greatest number of patients.
- 17 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 emergingopportunities.

20 OPTN Vision

- 21 The OPTN promotes long, healthy, and productive lives for persons with organ failure by promoting
- 22 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
- 24 enhance public trust in the national organ donation system.
- We commit our resources to achieve the goals outlined in our Strategic Plan while continuing ourdedication 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.

- 32 Goal 1 Improve Offer Acceptance Rate: Increase opportunities for
- transplants for patients in need by enhancing offer acceptance.

Objectives	Metrics
Develop, implement, and effectively promote educational programs for patients and transplant programs focused on understanding offer acceptance.	 Launched learnings versus completed learnings. (<i>Target: % learnings completed</i>) % of programs utilizing education offerings (<i>Target: % programs utilizing offerings</i>)
Collaborate with stakeholders to improve offer and acceptance processes to increase consistency.	 Time from first time offer to organ offer acceptance. (<i>Target: time reduction</i>); Segmented by organ. Time from first time offer to organ offer acceptance. (<i>Target: decrease in variability</i>); Segmented by organ. Median number of declines prior to organ offer acceptance. (<i>Target: decreased count of declines</i>); Segmented by organ.
Overall Metrics:	 Organ Offer Acceptance Rates (Target: Organ Offer Acceptance Rate Increase); Segmented by organ.

- 34 Goal 2 Optimize Organ Use: Maximize the use of organs for
- ³⁵ transplantation for waitlisted patients, while maintaining or improving

³⁶ upon past equity gains.

Objectives	Metrics
Collaborate with stakeholders to identify and reduce key barriers influencing organ non- use.	 Milestone: Collaborate with stakeholders, including donor hospitals, patients, and transplant hospitals to identify the top three barriers contributing to organ non-use. Consider these barriers by organ type, stakeholder group, and geographical region to understand specific challenges. (<i>Target: Milestone Achievement by XX DATE</i>) Milestone: Once the key barriers are identified, create specific metrics that target improvements to these barriers. (<i>Target: Milestone Achievement by XX DATE</i>)
Disseminate and promote best practices and effective strategies for reducing organ non-use across the transplantation community.	 Variation of risk adjusted non-use rate by OPOs (Organ Procurement Organizations) (Target: reduction in variation); Segmented by organ.
Explore and evaluate alternative allocation strategies for organs at high risk of non-use.	 High risk organ non-use rate High risk organs need to be defined.
Overall Metrics:	 % of organs recovered for transplant and not transplanted (kidney and liver) (<i>Target: decrease in non-use % based upon recovered organs</i> <i>for transplant; Target is not 0%; recognizing focus on avoidable</i> <i>non-use);</i> Segmented by organ. % of organs not recovered for transplant from deceased organ donors (heart and lung) (<i>Target: decrease in non-use % based</i> <i>upon total deceased organ donors; Target is not 0%;</i> <i>recognizing focus on avoidable non-use);</i> Segmented by organ. Equity: Access-to-Transplant Scores (ATS)¹⁵ (<i>Target: Maintain Equity Improvements);</i> System level

¹⁵ "Equity in Access to Transplant," OPTN, Public Dashboard Web Page, accessed December 20, 2023, https://insights.unos.org/equity-in-access/.

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

39 patients.

Objectives	Metrics
Refine the policy development and implementation process to be more efficient and strategically aligned.	 Timeliness of policy development (Target: decrease in time stratified by project complexity) Alignment of policy work with the strategic plan (<i>Target: % of policy work aligned with the strategic plan</i>) Stakeholder satisfaction with policy development improvements including structure, process, and outcomes. (<i>Target: Improved member satisfaction; this will be a new data collection point for the OPTN</i>)
Enhance OPTN data collection: increasing availability of actionable data while reducing member burden.	 Milestone: Establish data optimization roadmap (including, prioritization of known data gaps, identification of additional data gaps, data removal, and data addition) (<i>Target: Milestone Achievement by XX DATE</i>) Milestone: Achievement of milestones in data optimization roadmap (<i>Target: % achievement of identified gaps</i>)

#