Policy Oversight Committee Report to the Board of Directors

Jennifer Prinz, Chair
June 12, 2024

This report reflects the work of the Policy Oversight Committee (POC) from December 2023 - May 2024.

Overview

The POC is an operating committee of the OPTN comprised of the Vice Chairs of all OPTN policy development committees. As stated in the committee's charge, the POC "advises the Board of Directors and Executive Committee in: developing strategic policy priorities; prioritizing and coordinating policy and committee projects that have broad implications across OPTN committees; evaluating policy and committee proposals prior to public comment; assessing the impact of implemented policy proposals; and ensuring that OPTN committees justify proposals in compliance with policy development requirements."

This report focuses on the POC's activities from December 2023 - May 2024. The primary work of the POC falls within three major categories:
1. Committee Project Review
2. Project Portfolio Evaluation
3. Policy Priorities

Committee Project Review

The POC reviews committee projects, with a focus on three key points in the policy development life cycle:
1. New Project Review
2. Pre-Public Comment Review
3. Post-Implementation Review
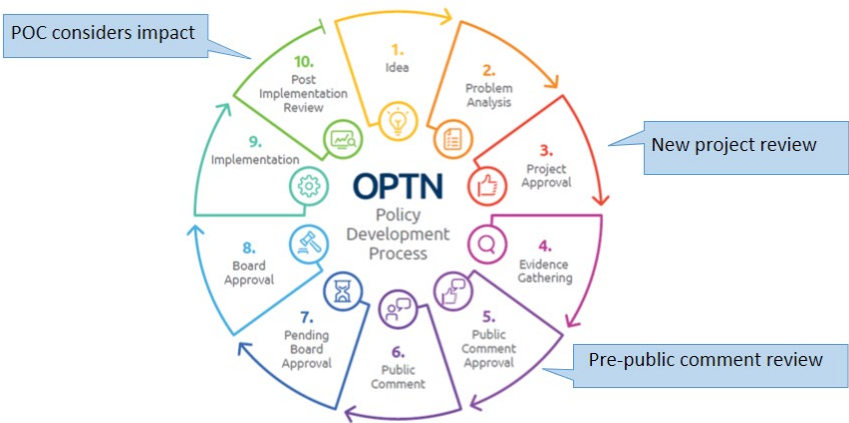
New Project Review

The POC evaluates new projects from policy development committees in order to make a recommendation to the Executive Committee as to whether to approve a new project. New projects are evaluated by the POC on the following:

- Alignment within the Strategic Plan and Policy Priorities
- Involvement of relevant collaborating committees
- Project sequencing within committee and overall OPTN efforts
- Measurability of the intended effects and identification of key metric(s)
- Potential risks or unintended consequences
- Technical implementation resources required
- Overall assessment of cost and benefit

- Cost/Benefit
- Policy Priorities
- Resource Capacity
- Sequencing

3. Project Approval

As the 2024-2027 Strategic Plan is adopted and goes into effect in July, the POC will continue to ensure alignment with the new Strategic Plan is considered for new project review.

Table 1: New Projects Reviewed Since December 2023

Project Title	Sponsoring Committee	Outcome
Requirements for Communicating Post-Transplant Disease	Disease Transmission Advisory Committee	POC recommended approval Executive Committee approved
Ethical Analysis of Allocating Organs Out of Sequence	Ethics Committee	POC recommended approval Executive Committee approved
White Paper on Examining Ethical Considerations in Access to Living Donation	Ethics Committee	POC recommended approval Executive Committee declined approval
Reduce HLA Critical Discrepancies and Require Reporting to the OPTN	Histocompatibility Committee	POC recommended approval Executive Committee approved
Updates to National Liver Review Board Guidance and Further Alignment with LI-RADS	Liver & Intestine Committee	POC recommended approval Executive Committee approved
Promote Efficiency of Lung Donor Testing	Lung Committee	POC recommended approval Executive Committee approved
Centralized Reporting of Extra Vessels	Operations and Safety Committee	POC recommended approval Executive Committee declined approval

Pre-Public Comment Approval

The POC evaluates Public Comment documents from policy development committees to make a recommendation to the Executive Committee on their release for public comment. Public Comment

documents are evaluated on the following:
- Does the proposal address the purpose of the project?
- Is there a sufficient foundation in evidence for the solution?
- Were identified or necessary stakeholders sufficiently engaged?
- Does the proposal sufficiently explain the reasoning and the solution?
- Are there any additional questions for community feedback that should be included?

Table 2: Projects Recommended for Public Comment since December 2023

Project Title	Sponsoring Committee	Outcome
Concepts for OPO Referral Evaluation Process Data Collection	Data Advisory Committee	POC recommended approval Executive Committee declined approval
Standardize the Patient Safety Contact and Reduce Duplicate Reporting	Disease Transmission Advisory Committee	POC recommended approval Executive Committee approved
Update on Heart Continuous Distribution	Heart Transplantation Committee	POC recommended approval Executive Committee approved
Update Post-Transplant Histocompatibility Data Collection	Histocompatibility Committee	POC recommended approval Executive Committee approved
National Liver Review Board Updates Related to Transplant Oncology	Liver and Intestine Transplantation Committee	POC recommended approval Executive Committee approved
Promote Efficiency of Lung Allocation	Lung Committee	POC recommended approval Executive Committee approved
Standardize Six-Minute Walk for Lung Allocation	Lung Committee	POC recommended approval Executive Committee approved
Refit Kidney Donor Profile Index without Race and Hepatitis-C	Minority Affairs Committee	POC recommended approval Executive Committee approved
Concepts for Modifying Multi-Organ Policies	Multi-Organ Transplant Committee	POC recommended approval Executive Committee approved
Modify Effect of Acceptance Policy	Multi-Organ Transplant Committee	POC recommended approval Executive Committee approved
Clarify Requirements for Pronouncement of Death	Organ Procurement Organization Committee	POC recommended approval Executive Committee approved

In addition to evaluating proposals submitted by policy development committees, the POC has also reviewed and stayed informed of ongoing efforts of the Executive Committee including:
- 2024-2027 OPTN Strategic Plan
- Proposal to Address the Relationship of the OPTN and OPTN Contractor Boards
- Expedited Placement Variance
- Establish Code of Conduct and Whistleblower Protection Bylaws

Post-Implementation Review

The POC's charge includes assessing the impact of implemented projects. To promote consistency and clarity in this process, the POC created a Post-Implementation Subcommittee to help identify:

- When the POC engages with post-implementation review
- What committees are requested to provide to the POC at final post-implementation review
- A process for formalizing POC review of committee feedback and providing a memo back to the sponsoring committee

- **2023 POC Goal - hone process for accountability in project post implementation review:**
  - Lessons learned
  - Unexpected outcomes
  - Needed next steps

10. Post Implementation Review

In March, the POC reviewed and approved the recommendations of the Post-Implementation Subcommittee as follows:

- *When is the POC Post-Implementation Review Process?* The POC Post-Implementation Subcommittee identified that the POC Post-Implementation Review Process occurs at the end of the monitoring period according to the approved project monitoring plan. This allows the sponsoring committee and the POC to have a holistic view of the impact of the project.
- *What are committees requested to provide to the POC at final post-implementation review?* When committees conduct a final post-implementation review, they should discuss and identify whether:
  - o The project was successful according to a key metric(s)
  - o There were any unintended consequences
  - o There were any mitigating factors or limitations in the monitoring analysis
- Once the sponsoring committee conducts their analysis, the POC reviews takeaways from the final monitoring report and the conclusions from the sponsoring committee. With its membership including vice-chairs from all the committees, POC is in a position to provide feedback to the committee regarding implications on other projects or priorities within the policy portfolio, identify any gaps or opportunities for improvement in the committee review process, or recommend project ideas that may be informed by the analysis. POC feedback is summarized and then shared with the sponsoring committee for further consideration.

Committee Project Portfolio Evaluation

The POC continues to refine their evaluation of the overall policy project portfolio, with a focus on maximizing benefit to the community and improving sequencing and future planning capabilities. These efforts include finalizing a benefit scoring metric to assess project benefit during new project reviews, developing a cost-benefit analysis to chart the overall impact a new project would have compared with its technical implementation hours, and bundling of projects for enhanced efficiency of project review.

The POC continues to work with the MPSC to improve accountability, effective communication, and responsiveness on referred projects. To date, the MPSC has sent twelve referrals to six committees: the Ad Hoc Disease Transmission Advisory Committee (DTAC), the Operations and Safety Committee (OSC), the Organ Procurement Organization Committee (OPO), the Data Advisory Committee (DAC), the Kidney

Committee, and the Minority Affairs Committee (MAC).[1] Two of the referrals will be reviewed by the Board in June:

- Standardize the Patient Safety Contact and Reduce Duplicate Reporting, DTAC
- Clarify Requirements for Pronouncement of Death, OPO Committee

Additionally, POC is engaged with the OPTN Executive Committee's Policy Prioritization Workgroup efforts. The Workgroup is charged with developing a prioritization process that provides effective and efficient oversight and resource management of OPTN work. The discussions have highlighted the important work that the POC is already doing, while also identifying opportunities for improvement to the policy development process. The Prioritization Workgroup received examples of POC's operational process documentation that may inform the Workgroup's efforts, and which are included here as appendices:

- Appendix A: Project Form
- Appendix B: New Project Review Presentation
- Appendix C: Project Benefit Scoring
- Appendix D: Public Comment Review Presentation
- Appendix E: Post-Implementation Review Memo

Policy Priorities

The Executive Committee previously approved the following three strategic policy priorities to guide evaluation and coordination of committee work:[2]

1. Continuous distribution
2. More efficient donor/recipient matching to increase utilization
3. Improve multi-organ allocation

The POC previously constructed a work plan for each policy priority to ensure collaboration and overall sequencing for these projects, and now many of the projects are actively in development with OPTN committees and workgroups. In March 2024 the POC discussed the current strategic policy priorities during their review of the *2024-2027 OPTN Strategic Plan* proposal. The POC supported maintaining the strategic policy priorities in progress to allow these projects to continue to completion.
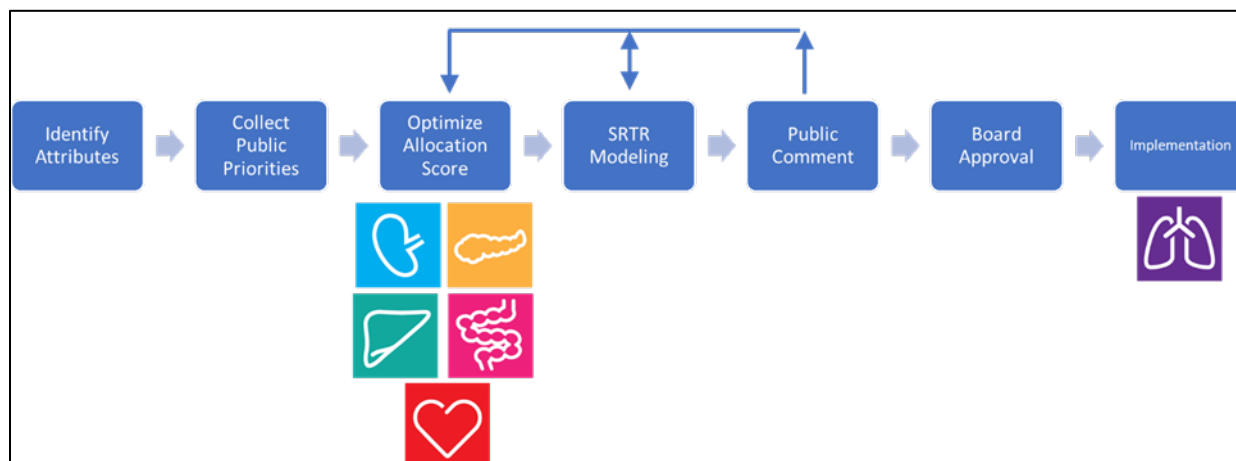
Continuous Distribution

In 2018, The OPTN Board of Directors adopted continuous distribution as the allocation framework "best suited for future OPTN organ allocation policies".[3] Continuous distribution encompasses an effort to transition each organ allocation type from a classification-based system to a dynamic, points-based framework, creating a holistic composite allocation score that considers both candidate and donor characteristics. **Figure 1** shows the current status of the continuous distribution projects.

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[1] For more information on referred projects, please see the accompanying MPSC Board Report.
[2] OPTN Board of Directions. 2019, October 8. Meeting Summary.
[3] OPTN Board of Directors. 2018, December 3-4. Executive Summary.

Figure 1: Status of Continuous Distribution Projects

For more detail on each organ committee's progress to date on their respective continuous distribution projects, please see the accompanying Update on the Continuous Distribution of Organs Board Report. The POC will continue to monitor work on continuous distribution efforts, while ensuring alignment with efficiency efforts and Board priorities.

More Efficient Donor/Recipient Matching to Increase Utilization

The POC continues to monitor and coordinate projects to increase utilization through more efficient donor/recipient matching. Numerous proposals recently released for public comment and to be reviewed by the Board in June promote efficiency efforts, including:

- Clarify Requirements for Pronouncement of Death, Organ Procurement Organization Committee
- Modify Effect of Acceptance Policy, Multi-Organ Transplant Committee
- Promote Efficiency of Lung Allocation, Lung Transplantation Committee
- Standardize Six-Minute Walk for Lung Allocation, Lung Transplantation Committee
- Standardize the Patient Safety Contact and Reduce Duplicate Reporting, Disease Transmission Advisory Committee

Additionally, four new projects recently approved by the POC and the Executive Committee directly impact efficiency:

- Promote Efficiency of Lung Donor Testing, Lung Committee
- Reducing and Reporting Critical HLA Discrepancies, Histocompatibility Committee
- Remove Death Notification Registration and Align with HHS OPO Performance Data Directive, OPO Committee
- Requirements for Communicating Post-Transplant Disease, Disease Transmission Advisory Committee

The Efficient Matching policy priority dovetails with the Expeditious task force's initiative, and there has been significant project progress since the priorities were approved in 2019. In March 2023, the POC held substantial discussion surrounding ideas for policy revision projects that were solicited by the task force. The policy ideas were divided into three themes for focused discussions and are summarized as follows:

Table 3: Summary of POC Review of Policy Ideas, March 18, 2024

Policy Idea Theme	POC Member Feedback
Non-use of organs	The overarching themes are improving data transparency, revising risk metrics, increasing appropriate utilization of viable organs currently stigmatized as "high risk", and incorporating living donation pathways - all aimed at increasing overall transplant rates. Some specific suggestions: • Critical need for accurate and comprehensive data collection to identify barriers, justify policy changes, and understand variances in organ acceptance/turndowns • Better data needed to evaluate late organ turndowns and high KDPI kidney utilization patterns • Support for revising or replacing the KDPI metric to better reflect true graft quality and outcomes for kidneys currently labeled as "high risk". • Support maintaining consent requirements for higher risk KDPI kidneys • Explore a "safety net" pathway for placing high risk organs, potentially expanding beyond kidneys
OPO Efficiency	Overall, there was a drive to empower OPOs/centers with better tools and data to make efficient decisions, while increasing standardization, and utilizing trials/variances to rapidly test new processes - with a goal of increasing organ utilization and transplant volumes. Some specific suggestions: • Strong support for eliminating the requirement to use the OPTN Organ Center for national kidney offers, and instead having mandatory offer filters that transplant programs can apply directly • Prioritizing the development of improved, patient/center-specific offer filters across all organ types was preferred • Provide more data (e.g. showing impact on offer volume), education, and incentives to drive center adoption of offer filters • Increase virtual crossmatching practices • Develop policies to incentivize entering unacceptable antigens for better virtual crossmatching • Consider requirement for donor human leukocyte antigens (HLA) typing for match runs • Enhance biopsy processes and digitizing slides for more seamless remote readings as • Consider centralized biopsy reading services • Review donor testing protocols
Transplant Program Efficiency	The Committee discussed key challenges and tradeoffs in organ allocation policies, especially balancing the goals of increasing transplant numbers/efficiency while maintaining equity, safety, and optimized organ placements.

The POC will continue to support the Expeditious task force through review of relevant policy and data collection, feedback on sequencing considerations, and cross-collaboration with committees.

Improve Multi-Organ Allocation

In January, Ad Hoc Multi-Organ Transplantation Committee released two papers for public comment. The *Modify Effect of Acceptance Policy* proposal will be reviewed by the Board in June. The *Concepts for Modifying Multi-Organ Policies* request for feedback is currently under the Committee's review as they develop a future proposal.

The *Modify Effect of Acceptance Policy* proposal was developed in part based on public comment feedback from a previous concept paper released for public comment by the MOT Committee in January 2023. While the Committee was initially focused on potential changes to kidney multi-organ policies to coincide with development of the kidney and pancreas continuous distribution proposals, the Committee has since shifted its focus towards broader efficiency concerns in multi-organ allocation based on community feedback and changes to the timelines for the continuous distribution proposals. The Committee is working on developing policy to provide clearer direction to organ procurement organizations on how to work across the different organ match runs to comply with policy requirements for multi-organ allocation without impeding the ability of OPOs to place organs efficiently.

OPTN

New Committee Project Review

Updates to National Liver Review Board Guidance and Further Alignment with LI-RADS

OPTN Liver and Intestinal Organ Transplantation Committee

Intent

The main goals of the proposal are to update the Adult Model for End-Stage Liver Disease (MELD) Exception Review guidance document, by using current literature to update content and develop score recommendations for certain diagnoses. Additionally, this proposal intends to align hepatocellular carcinoma (HCC) policy and guidance with Liver Imaging Reporting and Data System (LI-RADS) by updating imaging classification criteria and adding contrast-enhanced ultrasound as an acceptable adjunct diagnostic tool for HCC.

Background

The NLRB Subcommittee frequently updates policy and guidance related to the NLRB. The Subcommittee has decided to review current diagnoses in guidance and determine if a score recommendation needs to be updated, or in some cases, developed using evidence-based literature or data.

Additionally, through collaboration with the American College of Radiology, it was suggested that HCC policy and guidance should include contrast-enhanced ultrasound (CEUS) as an acceptable adjunct diagnostic tool. This was discussed during NLRB Subcommittee meetings with support to incorporate this change.[1] Initially, it was part of the *NLRB Updates related to the Transplant Oncology* project approved by the OPTN Policy Oversight and Executive Committees in 2023. However, with the broadened scope of that project, the approved resource estimates were ultimately used to support the expansion of an Adult Transplant Oncology Review Board which was the proposal submitted for public comment during the winter of 2024.[2] The decision at the time was to address CEUS updates in a future project. An additional suggestion from the American College of Radiology included modifying HCC imaging criteria, currently in Table 9-9: Classification System for Lesions Seen on Imaging of Livers to align with LI-RADS language.[3]

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[1] https://optn.transplant.hrsa.gov/media/cnjgzgjy/20230608_liver_nlrb_summary_final.pdf
[2] https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/national-liver-review-board-nlrb-updates-related-to-transplant-oncology/
[3] https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf

Proposal

This project intends to update National Liver Review Board (NLRB) guidance, to add contrast-enhanced ultrasound (CEUS) as an acceptable adjunct diagnostic tool for hepatocellular carcinoma (HCC), and to modify HCC imaging classification criteria to align with LI-RADS.

The updates to diagnoses in NLRB guidance include revising content/language based on new literature and adding associated score recommendations. The Committee reviewed all diagnoses in the Adult Model for End-Stage Liver Disease (MELD) Exception Review guidance document to prioritize which sections require updates. To inform the prioritization, they reviewed whether the diagnosis had an associated score recommendation as well as the timeframe of the most recent updates. After performing this review, the Committee recommends the following diagnoses warrant review and potential updates in NLRB guidance:

- Budd Chiari
- Hepatic Epithelioid Hemangioendothelioma (HEHE)
- Hepatic Hydrothorax
- Hereditary Hemorrhagic Telangiectasia
- Hepatic Adenomas
- Neuroendocrine Tumors
- Portopulmonary Hypertension (remove)
- Primary Sclerosing Cholangitis and Secondary Sclerosing Cholangitis
- Metabolic Disease
- Post-Transplant Complications: Small for Size Syndrome (maybe)
- Post-Transplant Complications: Diffuse Ischemic Cholangiopathy (maybe)
- Post-Transplant Complications: Late Vascular Complications

Adding CEUS into HCC policy as an acceptable adjunct diagnostic tool will require a response option to be added on the initial and extension HCC exception forms. The Committee is also interested in updating the imaging classification criteria in Table 9-9 in Policy 9.5.I.vi[4] to align with Liver Imaging Reporting and Data System (LI-RADS). This would simplify some imaging classification criteria to say "LI-RADS 5", rather than listing multiple criteria that have the potential to evolve. These language changes would also require updating the imaging classification response options on the HCC initial form to align with LI-RADS 5.

Type of Project

- Guidance Document
- Policy/Bylaw
- Technical Systems Implementation

Source of Project Idea

- Committee Member
- Conference/Presentation
- Journal/Publication

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[4] https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf

New Committee Project Review

- Public

Timeline

Anticipated Public Comment Date:
2025-January

Anticipated Board Date:
2025-June

Collaborating Committee(s)
N/A

Key Metric

- Key Metric 1: Increased consistency in score recommendations for exception candidates by diagnosis
- Key Metric 2: Increased access to HCC exception with alignment of recommendations

Impact Statement

- Transplant candidates, Liver, 25-49%
- General system enhancement (ex. Efficiency efforts)

Impact to Target Population

With the addition of score recommendations in NLRB guidance, liver transplant candidates with similar clinical situations who are seeking non-standard exceptions should have more equitable access to the same level of medical urgency points. As such, these score recommendations will reduce variation and increase efficiency of exception application and review.

Liver candidates with HCC receiving care at a transplant program that utilizes contrast-enhanced ultrasound as an adjunct diagnostic tool will be able to access the standard exception pathway for HCC exceptions.

Vulnerable Populations
N/A

Impact to Vulnerable Populations

There is no expected impact on vulnerable populations.

Status

- Project Approval

Alignment with OPTN Priorities

Primary Strategic Plan Goal:
Increase equity in access to transplants

Strategic Plan Impact:
By clarifying the guidance document with new score recommendations for all diagnoses, liver candidates will receive more equitable score adjustments for their non-standard exceptions. With the

addition of CEUS, liver candidates who are listed at transplant programs utilizing this diagnostic tool as an adjunct means will be able to access the standardized exception pathway for HCC.

Strategic Policy Priority:
N/A

Types of Organizations Impacted:
Transplant Hospital

Authority Explanation
The Committee submits the proposed changes to policy under the authority of NOTA, which states, "The Organ Procurement and Transplantation Network shall…establish…medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria…"[5], and the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[6] The potential changes included in this project will ensure that transplant programs and NLRB reviewers have updated and accurate clinical guidance regarding medical criteria when submitting and reviewing exception requests, specifically score recommendations.

The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed "in accordance with §121.8," which requires that allocation policies "(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;…(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section." This proposal:

• **Is based on sound medical judgment**[7] because it is an evidenced-based change relying on the collective clinical experience of the Committee to align the terminology with LI-RAD per the recommendation of the experts at the American College of Radiology.
• **Is designed to…promote patient access to transplantation**[8] by giving similarly situated candidates equitable opportunities to receive an organ offer by making the requirements for exception requests for the listed diagnoses more clear and thus more consistently applied.

By updating the score recommendations and further aligning with LI-RADS, the proposal will help provide priority for candidates in similar clinical situations as well as allow more up-to-date technologies to be used while diagnosing indications for liver transplantation.

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[5] 42 USC 274(b)(2)(B).
[6] 42 CFR §121.4(a)(1).
[7] 42 CFR §121.8(a)(1).
[8] 42 CFR §121.8(a)(5).

Compliance Explanation

42 CFR Part 121.8(a)(1) : 3.3 Support the OPTN Policy Development Process

Staff Point of Contact

Meghan McDermott

Example

EXAMPLE - New Project: Review

Example

Project Purpose (Liver/Intestine Committee)

- Purpose: Update NLRB guidance to align with emerging literature

- Transplant benefit for certain oncological diagnoses has been shown in research, however calculated MELD scores remain low resulting in lack of access to liver transplants
  - Develop guidance for the following diagnoses:
    - *Unresectable Colorectal Liver Metastases*
    - *Unresectable Intrahepatic Cholangiocarcinoma Less Than Two Centimeters*
    - *Unresectable Downstaged Intrahepatic Cholangiocarcinoma*

- Research has shown that contrast enhanced ultrasound (CEUS) is a technology that can accurately diagnosis HCC
  - Update hepatocellular carcinoma (HCC) policy and guidance language to incorporate CEUS as an acceptable imaging tool for HCC diagnosis in addition to dynamic-enhanced CT and MRI
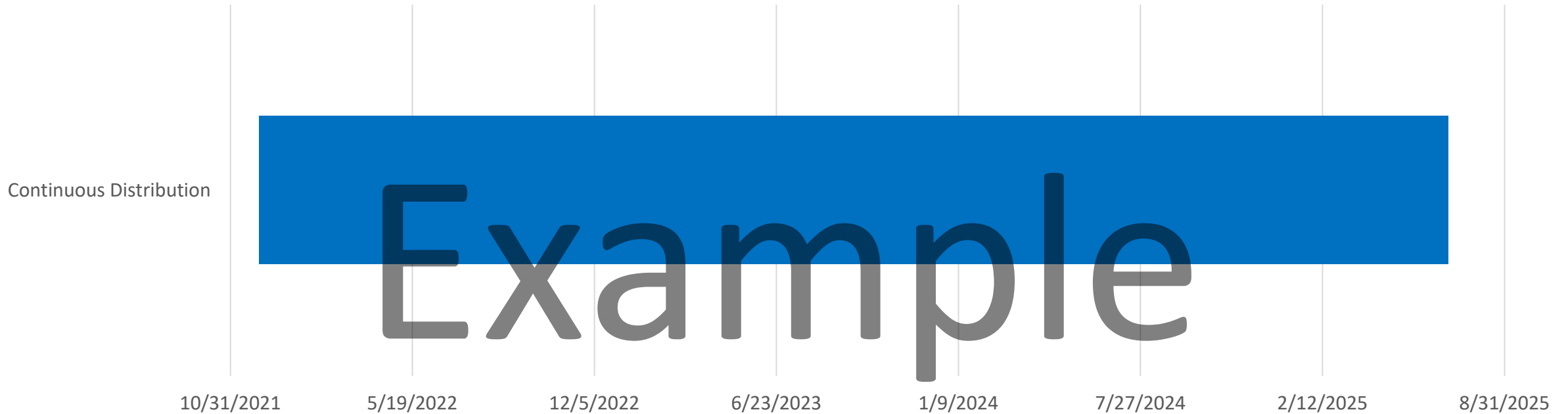
Key Metric (Liver/Intestine Committee)

- Strategic Goal: Increase equity in access to transplant

- Metrics

  - For each of the three diagnoses:

    - Increase in transplant counts

    - Increase in status at transplant

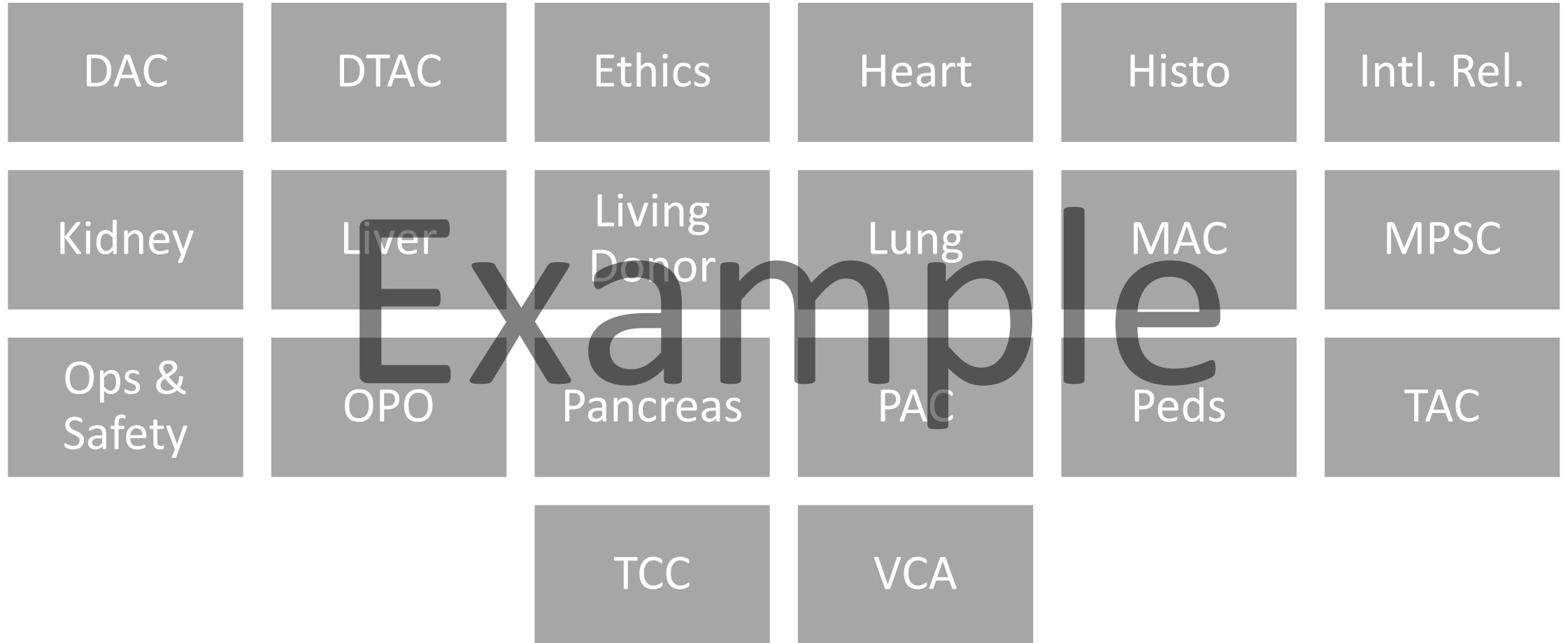- Rationale: To evaluate increase in access to transplant

Example
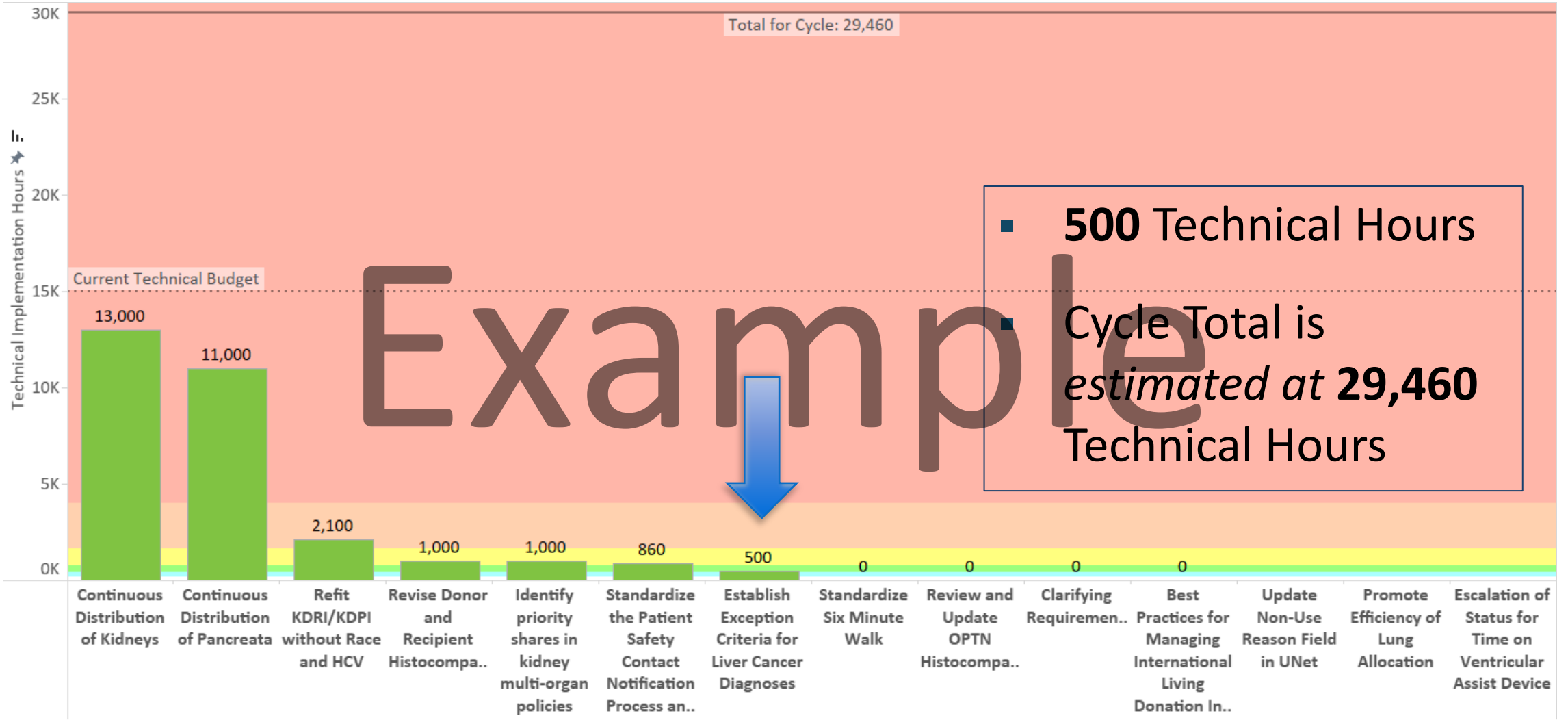
Liver & Intestine Committee Projects

Liver & Intestine Committee is collaborating on *Prioritization between kidney multi-organ transplant and single-organ transplant candidates* (MOT); and *Update Non-Utilization Reason field in UNet* (DAC); *Ethical Analysis of NRP* (Ethics)
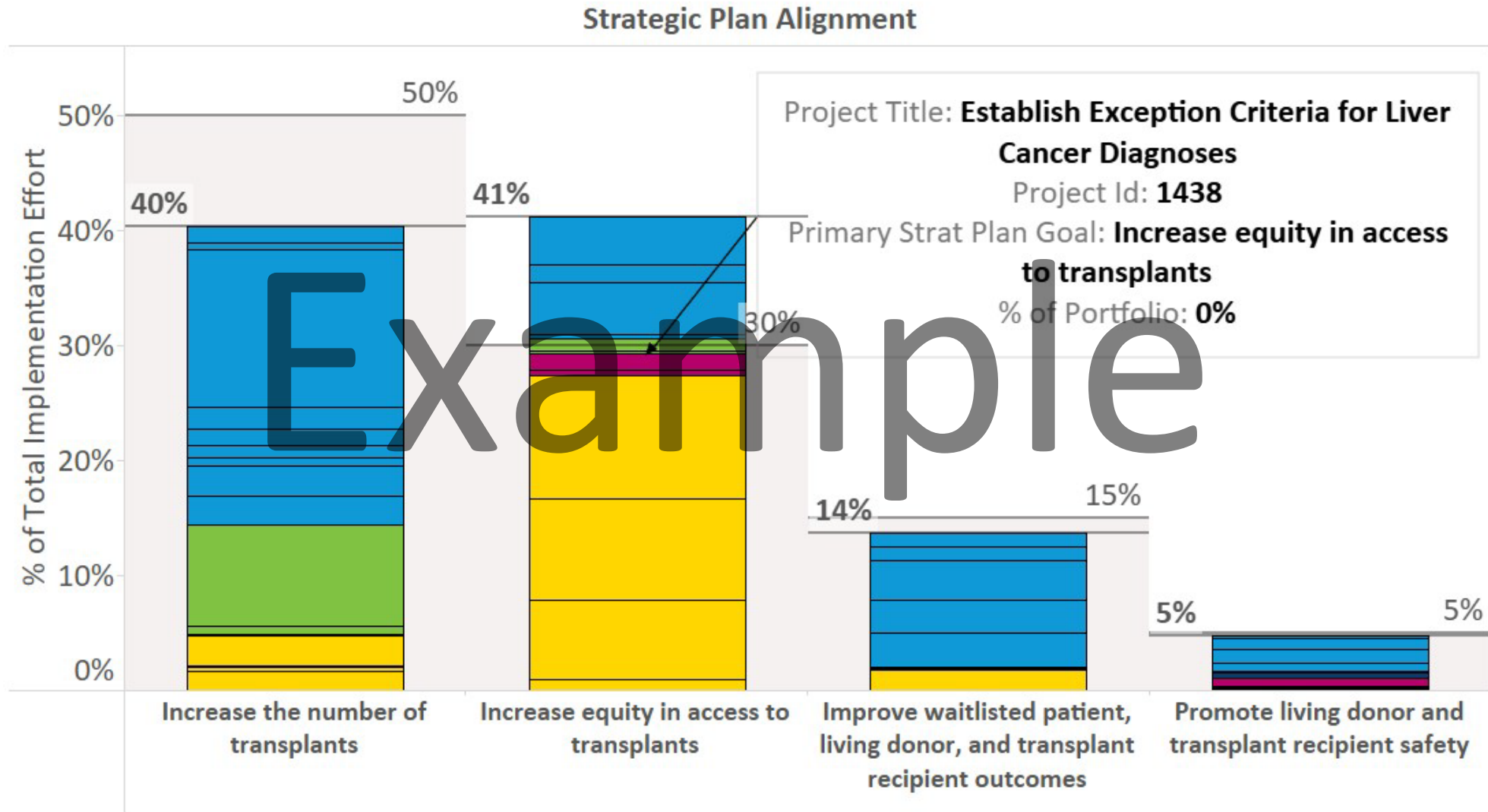
Collaborating Committees

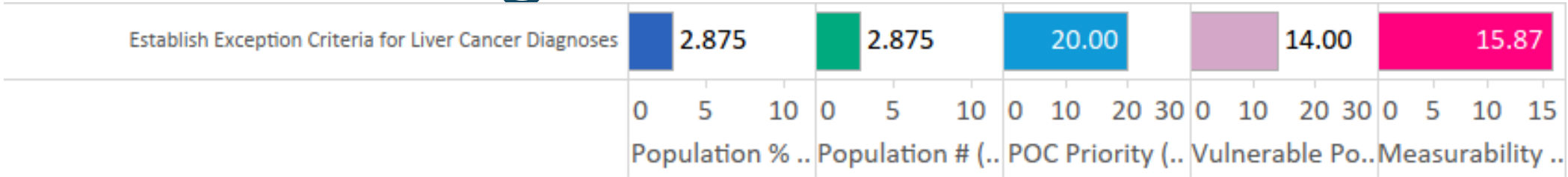|					
DAC	DTAC	Ethics	Heart	Histo	Intl. Rel.
Kidney	Liver	Living Donor	Lung	MAC	MPSC
Ops & Safety	OPO	Pancreas	PAC	Peds	TAC
		TCC	VCA		

Example

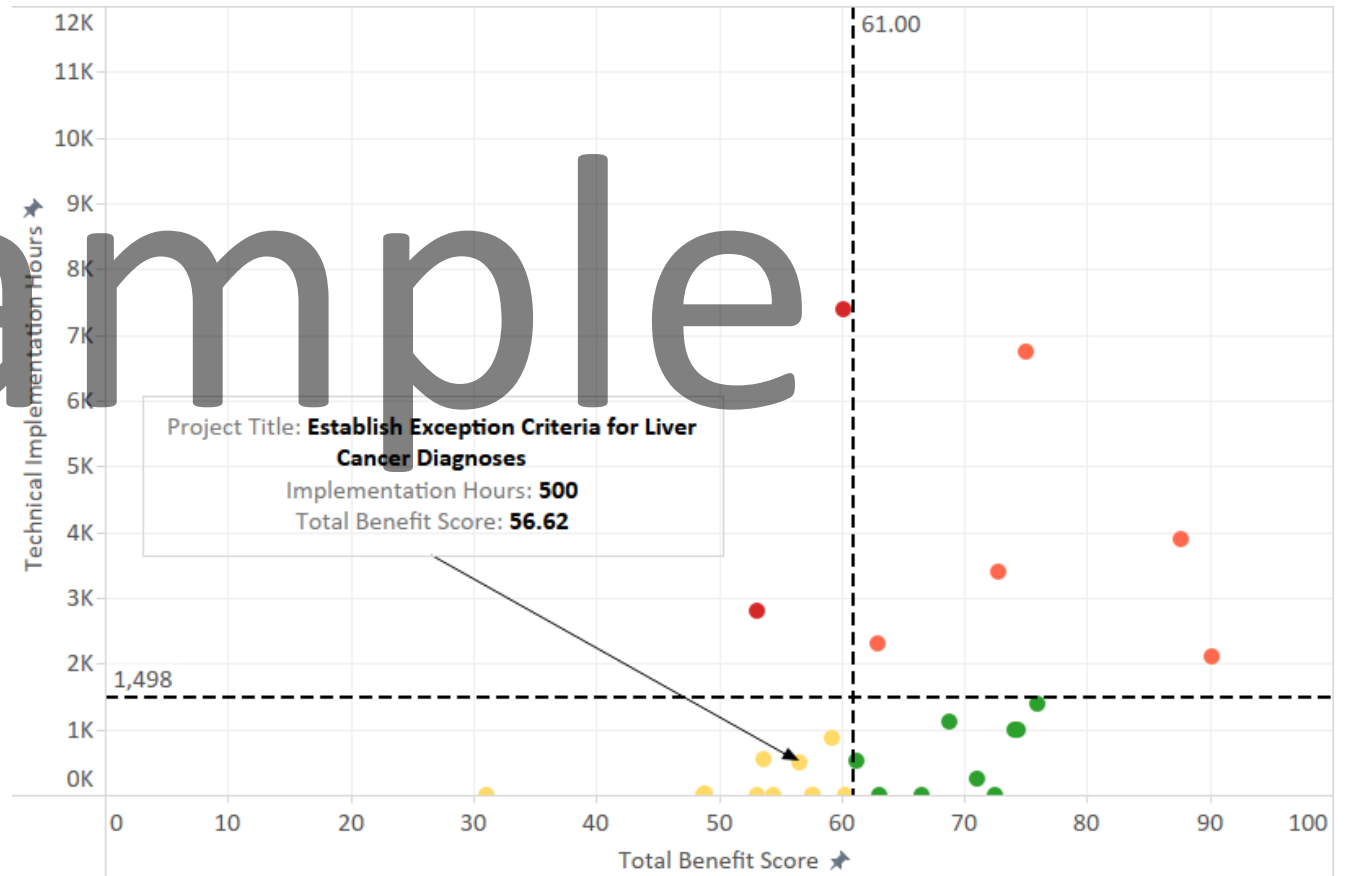# Technical Implementation, June 2024 BoD

Strategic Plan Alignment

Benefit Scoring

- Benefit Score = **57**

- Technical Hours = **500**

- Low Cost/Low Benefit

Discussion

- Is this the right timing for this project in the context of other work?

- Is it sequenced appropriately?
  - Are there other projects that should come first?
  - Does this need to go ahead of or concurrent with any current projects to support their work?

- Is there any additional feedback to improve alignment across projects?

- Potential risks or unintended consequences
  - Any risks associated with NOT pursuing this project?
  - Any risks associated with pursuing this project?
  - Any potential unintended consequences to consider?

Discussion Lead: identified POC member

OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Updates to National Liver Review Board Guidance and Further Alignment with LI-RADS

Project
Form: https://unos365.sharepoint.com/sites/bodandcommittees/POC/OPTNMaterials/Forms/Upcoming%20Meetings.aspx?FilterField1=Meeting%5Fx0020%5FDate&FilterValue1=2024%2D05%2D09&FilterType1=DateTime&FilterDisplay1=5%2F9%2F2024&id=%2Fsites%2Fbodandcommittees%2FPOC%2FOPTNMaterials%2F1488%5FUpdates%20to%20National%20Liver%20Review%20Board%20Guidance%20and%20Further%20Alignment%20with%20LI%2DRADS%2Epdf&viewid=008f7f13%2Dc670%2D4670%2Dab65%2D50daa6fdea6b&parent=%2Fsites%2Fbodandcommittees%2FPOC%2FOPTNMaterials

2. Is this project a key initiative in one of the policy priorities? *

Background: Policy Priorities are areas that have been identified as requiring specific POC support and direction in coordinating project development and cross-committee work. The three current policy priorities are:

1. Efficient donor/recipient matching to increase utilization: examples of projects included in this category are *Enhanced Organ Offers* and *Minimum Donor Biopsy Criteria*.
2. Continuous distribution: all organ allocation systems are moving to continuous distribution frameworks. Lung was implemented in March 2023, and Liver & Intestines, Kidney, Pancreas, and Heart are working to develop frameworks further.
3. Improve equity for multiorgan and single-organ candidates: This goal is associated particularly with the work of the Multi-Organ Transplantation (MOT) Committee, and efforts to provide added clarity and equity between multi-organ and single-organ candidates across allocation systems. A recent project is *Identify Priority Shares in Kidney Multi-Organ Allocation*.

◯ Yes

◯ No

3. Does this project positively impact any vulnerable populations? *

Age
Adults with high school education or less
Citizenship status
Economically deprived areas
Highly sensitized/biologically disadvantaged
Incarcerated/paroled populations
LGBTQ
Living donors
Non-contiguous residence
Physical or mental disability/impairment
Public insurance and uninsured groups
Race/ethnicity
Rural
Veterans
Women

◯ Yes

◯ No

4. How many candidates, recipients, or living donors would you expect to be positively impacted? *

The impact statement from the project form: Transplant candidate, Liver, 25-49%

OPTN Data reports there are 9,734 liver candidates as of 04/25/204 https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#

◯ >10,000 patients

◯ 3,000-9,999 patients

◯ 1-2,999 patients

◯ No anticipated impact

5. What percentage of candidates, recipients, or living donors in the listed target population would you expect to be positively impacted? *

   The impact statement from the project form: Transplant candidate, Liver, 25-49%

   OPTN Data reports there are 9,734 liver candidates as of 04/25/204 https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#

   ○ >50%

   ○ 25-49%

   ○ 1-25%

   ○ No anticipated impact

Example

OPTN Policy Oversight Committee Public Comment Review Example

Example

January 2024 Public Comment Review

- Purpose: Recommend to the Executive Committee whether public comment items should be released for January 2024 Public Comment

- Homework: POC members reviewed 1-2 public comment proposals/concept papers each and considered relevant questions

- Objectives of meeting:
  - Review process of pre-public comment review
  - Review estimated technical implementation efforts for January 2024 cycle
  - POC members supply their feedback on each proposal
  - Committee discussion for each proposal
  - Vote whether to recommend each public comment item to Executive Committee for approval

OPTN | ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

2

| Strategic Plan Goal	Public Comment Item
Increase the number of transplants	- Update Guidance on Optimizing VCA Recovery from Deceased Donors - Update HLA Equivalency Tables 2023 - Ethical Analysis of Normothermic Regional Perfusion - Modify Organ Offer Acceptance Limit - Collect Donor CRRT, Dialysis, and ECMO Interventions Data
Increase equity in access to transplants	- Continuous Distribution of Kidneys and Pancreata Committee Update - Continuous Distribution of Hearts Concept Paper - Continuous Distribution of Livers Committee Update - Remove CPRA 99-100% Form for Highly Sensitized Kidney Candidates
Promote living donor and transplant recipient safety	- Clarification of OPO Requirements for Deceased Organ Donors with HIV Positive Test Results Concept Paper - Require Reporting of Patient Safety Events - Granular Review of OPTN Living Donor Data Collection & Collect Living Donor Candidate and Donation Decision Data - Improve Donor Evaluation for Endemic Diseases Guidance Documents Revisions
Improve waitlisted patient, living donor, and transplant recipient outcomes	- Amend Adult Heart Status 2 Mechanical Device Requirements

OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Total Implementation Resources: January 2024 PC
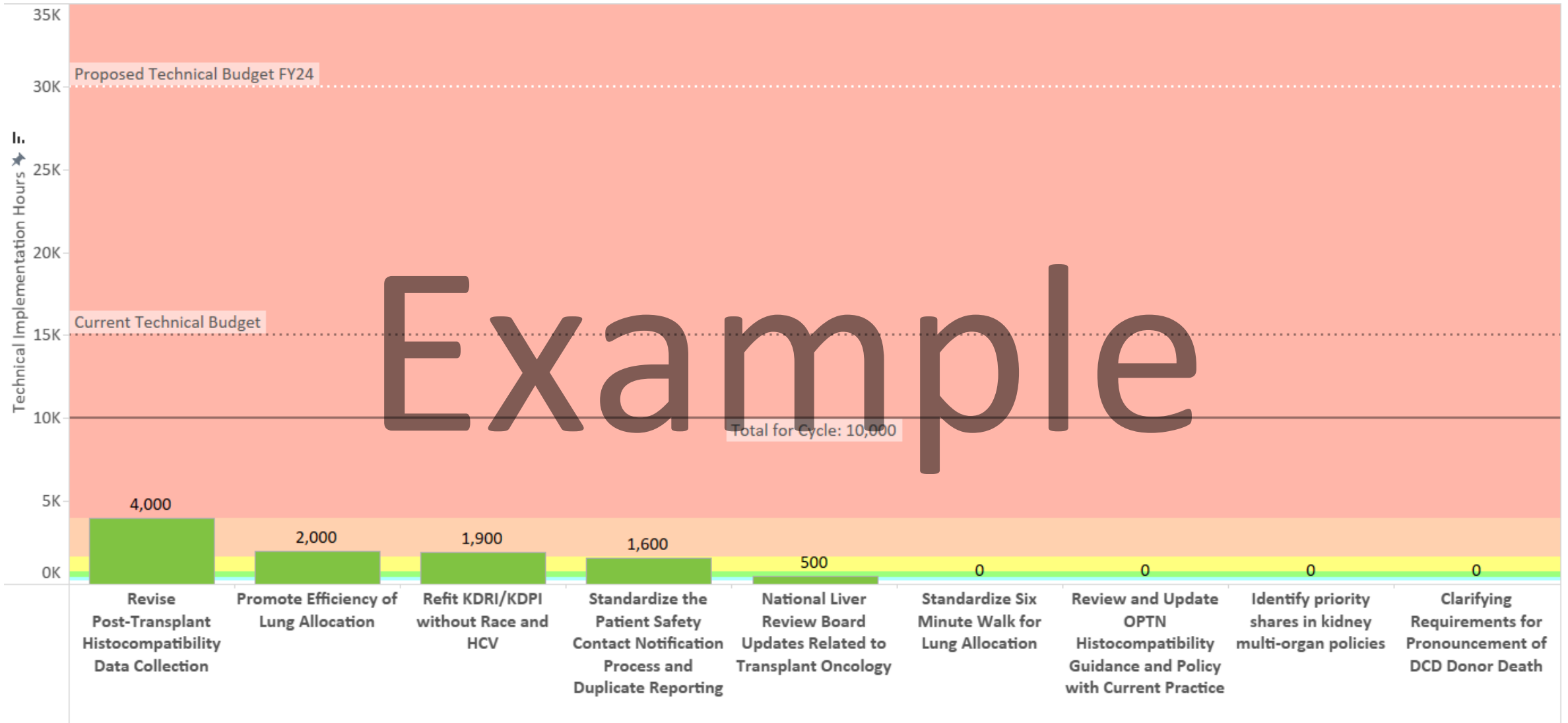
Focus questions

- Does the proposal address the purpose of the project?

- Does the proposal sufficiently explain the reasoning and provide sufficient evidence for the solution?

- Were appropriate stakeholders engaged?

- Are there any questions for community feedback that should be included, but aren't already identified in the proposal?

Memo: POC Review of "Eliminate Use of DSA and Region from Kidney Allocation" Two Year Post-Implementation Monitoring Report and Kidney Committee Report Out

To:

Jim Kim, OPTN Kidney Transplantation Committee Chair

Arpita Basu, OPTN Kidney Transplantation Committee Vice-Chair

Hello Dr. Kim and Dr. Basu,

The POC thanks the OPTN Kidney Transplantation Committee for sharing the two-year monitoring report on "Eliminate Use of DSA and Region from Kidney Allocation" as well as the Kidney Committee's feedback on the project's success, limitations, and unintended consequences. POC is charged with assessing the impact of implemented policy proposals, and has worked in the Post-Implementation Subcommittee to improve the consistency of review, transparency, effectiveness, and accountability. The Post-Implementation Subcommittee met on July 11th and considered the monitoring report in a conversation with the Kidney Committee vice-chair and researchers who prepared the report. Based on that conversation, the POC provides the following feedback and comments to the Kidney Committee for its consideration, along with the Kidney Committee assessment from which the comment stemmed. The POC does not have any specific directives for the Kidney Committee at this time, and all of its comments are advisory.

- **Kidney Committee assessment of success:** Successful with concerns. Increases in transplant rates for all candidates on the waiting list, but particular benefit in % increase in transplant rate for Black (38%), Asian (35%), and Hispanic candidates (35%); pediatric candidates 0-5 years (40%), candidates with 80-97% CPRA (81%), and those candidates with longer waiting times of 3 years or more dialysis time (46%). Overall, kidneys traveled further on average, although more kidneys were transplanted within 250 NM of the donor hospital in the post-implementation era. Fewer kidneys were transplanted in the same DSA and region as the donor hospital. Most DSAs saw an increase in transplant, though some DSAs saw decreases.
  - **POC discussion:** The Post-Implementation Subcommittee Chair suggested may be important to demonstrate specifically how geography is more equitably allocated because of this policy change, if the impetus of the change was DSA and region potentially contributing to inequities in the system. The Kidney Committee identified that the proposal was successful in removing DSA and Region from allocation, which was the original goal, not to fix the inequities in the system.
  - **POC comment:** These data and results speak to the challenges in efficiency and the opportunities in equity that may be reflected in further changes to allocation through continuous distribution. The implications in this policy's success, unintended consequences and limitations should be considered in relation to the active work regarding continuous distribution.
- **Kidney Committee assessment of unintended consequences:** Unintended consequences include increases in cold ischemic time and delayed graft function, though there were no changes to 1 year unadjusted graft and patient survival. The post-implementation era also saw an increase in non-use rates for kidneys. Median cold ischemic time increased from 17.2 to 19.5 hours after policy implementation. Rate of delayed graft function increased from 29.24 percent to 32.89

percent after policy implementation. Non-use rates for kidneys increased from 21 percent to 26 percent after policy implementation. One year post-transplant patient and graft survival did not change.

- o **POC comment:** The most important implications are those that are clinically significant. A difference between 17 and 19 hours cold time may not be as important, but the implications of patients being prone to delayed graft failure could be more clinically significant. It should be clear from the report and Committee discussion which data are clinically significant.
- o **POC comment:** Some of these may have been anticipated consequences, such as increases in cold ischemic time, only the committee composition is different so there may be a lack of context for those previous conversations. There is a difference between knowing a potential outcome and identifying it as acceptable or the project still worth doing and unintended consequences that were not anticipated. POC will clarify its use of "unintended consequences" to note if a consequence as anticipated or not by the sponsoring committee.
- **Kidney Committee assessment of limitations:** It is difficult to fully understand the impact of the policy, with multiple confounding factors with the COVID 19 emergency, the implementation of CPRA changes, the mandate of race-neutral eGFR and related waiting time modifications in the post-implementation era, updates to CMS requirements for OPOs, and an overall increase in donors that cannot be fully attributed to the policy itself.
  - o **POC comment:** it is difficult to know how much to attribute the increase in non-use rate for kidneys due to CMS OPO rules being implemented at the same time as the policy (March/April 2021). Reviewing data by OPO may be helpful since there is variation in approach.

The POC welcomes any follow up questions, and thanks the Kidney Committee again for its efforts to carefully review the effects of this allocation change.

Sincerely,

Jennifer Prinz, OPTN Policy Oversight Committee Chair

Erika Lease, OPTN Policy Oversight Committee Vice-Chair

Nicole Turgeon, OPTN Policy Oversight Committee Immediate Past Chair (Ex Officio)

Jesse Schold, OPTN POC Post-Implementation Subcommittee Chair