Health FFRDC Organ Transplant Innovation Project

Evaluation of Organ Allocation Policy

Engagement Findings Summary

OPTN
Modernization

Contents

- Executive Summary
- Background & Methods
- Engagement Session Feedback Summary
  - Overall Evaluation Framework
  - Policy Content
  - Policy Implementation
  - Policy Impact
- Future Considerations

OPTN
Modernization

Executive Summary: Stakeholder Input into the Organ Allocation Policy Evaluation Framework

Evaluation Framework Overview

The Health FFRDC is developing an **objective and comprehensive framework** for evaluating organ allocation policies to promote consistency and transparency in the organ allocation system and inform future policy development.

Solicit Input in Evaluation Framework Development

Stakeholders provided feedback on the framework's design and elements in **two rounds of engagement sessions with 34 participants**, including organ procurement and transplantation system-level experts, organ-specific leadership (e.g., OPOs, clinicians), frontline workers, and patients.

The Health FFRDC **incorporated stakeholder feedback into the Evaluation Framework,** including in the evaluation questions, measures, and guidance provided to assess future organ allocation policies.

Feedback Key Themes

Stakeholders agreed with the comprehensive evaluation design, and robust qualitative and quantitative analytical methods. They asked for **continued stakeholder involvement**. They also **agreed with assessing**:

Policy Content

- Policy goals and the policy development process.
- The clarity and completeness of the policy and its implementation guidance.

Policy Implementation

- Methods to disseminate policy information to all stakeholders.
- Trends, variation, and potential drivers of policy non-compliance, such as offer and acceptance practices, implementation challenges (e.g., logistics, transition timing), and resources needed.
- A policy's burden, including data collection, workforce changes, and spending.

Policy Impact

- Patient access to the waitlist and variations in access.
- Variations in pre- and post-transplant outcomes and impacts across the transplant pathway through short- and long-term evaluation.
- System-level impact and support needed (e.g., multi-year spending analyses).

OPTN
Modernization

# Background & Methods

OPTN
Modernization

Overview of the Organ Allocation Policy Evaluation Framework

Purpose: To provide guidance for evaluating organ allocation policies to promote consistency and transparency in the organ allocation process.

The framework offers guidance, evaluation questions, measures, and analytic methods to support HHS in developing robust policy evaluation plans that address three objectives:

Objective 1. Assess Policy Content
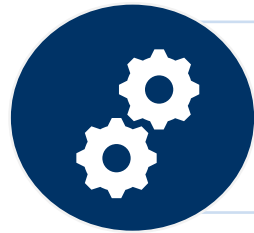
Objective 2. Assess Policy Implementation

Objective 3. Assess Policy Impact

OPTN
Modernization

Overview of Evaluation Framework Development & Engagement Approach

MITRE facilitated two rounds of stakeholder engagement sessions while developing the Evaluation Framework. Feedback was analyzed and used to inform content included in the final framework.

Evaluation Framework Development

Stakeholder Engagement

Developed framework
objectives, key questions, and measure domains.

October 2024 – February 2025

Gathered feedback
from participants on objectives, key questions, and measure domains.

March 2025

Analyzed feedback
and incorporated it into the initial Evaluation Framework draft.

March – May 2025

Gathered feedback
from participants on the initial Evaluation Framework draft.

June – July 2025

Analyzed feedback
and incorporated it into the revised Evaluation Framework.

June – August 2025

Finalized Evaluation Framework
and delivered to HRSA.

September 2025

OPTN
Modernization

Stakeholder Engagement Sessions

The purpose of the engagement sessions was to gain insights from a broad range of stakeholders to inform a credible and comprehensive Evaluation Framework and to build support and transparency in the evaluation process.

34 stakeholders participated in engagement sessions. Participants represented a wide range of roles and organizations across the organ procurement and transplant system, including:
- **System-level experts:** Researchers, evaluators, third-party contractors, and end-stage organ disease care specialists
- **Organ-specific leadership:** Organ Procurement Organization (OPO) leaders, transplant leaders, and clinicians
- **Frontline workers and patients:** Transplant coordinators, nurses, administrators, patients, organ donors, and patient advocacy organizations

During engagement sessions, MITRE facilitated semi-structured, individual, and small group interviews. Participants were asked about the Evaluation Framework approach, objectives, evaluation questions, measures, analysis methods, and dissemination of findings.

MITRE analysts organized feedback session notes into key themes based on the Evaluation Framework elements discussed and the related topic areas. MITRE refined the Evaluation Framework based on stakeholder feedback.

OPTN
Modernization

Engagement Session Feedback Summary

OPTN
Modernization

Stakeholder Feedback Organized into Topic Areas

Findings are organized by topic areas within the four evaluation framework elements.

Evaluation Framework Component	Overall Evaluation Framework	Policy Content	Policy Implementation	Policy Impact
Topic Area	• Approach & Design • Evaluation Methods • Analytic Considerations	• Policy Context & Goals • Implementation Guidance	• Policy Information Sharing • OPO Policy Compliance • OPO Logistics Challenges • Implementation Transition Period • Workforce Preparation • Stakeholder Coordination • Data Collection Burden • Organ Offer Process • Acceptance & Refusal	• Patient Pre-Transplant Outcomes • Patient Transplant Outcomes • System-Level Impacts • Cost Considerations

OPTN
Modernization

Stakeholder Feedback Key Takeaways for Evaluation Framework

Overall Evaluation Framework

- Use a comprehensive evaluation design and objectives, and robust qualitative and quantitative analytical methods.
- Continue stakeholder involvement in evaluation implementation.

Policy Content

- Assess policy goals and the policy development process, including stakeholder involvement and input into the process.
- Consider the clarity and completeness of the policy and its implementation guidance.

Policy Implementation

- Consider all stakeholders, including patients, when disseminating policy information.
- Identify trends, variation, and potential drivers of policy non-compliance, such as offer and acceptance practices, implementation challenges (e.g., logistics, transition timing), and resources needed.
- Assess the policy's burden, including data collection, workforce changes, and spending.

Policy Impact

- Include assessment of patient access to the waitlist and variations in access.
- Assess variations in pre- and post-transplant outcomes and impacts across the transplant pathway through short- and long-term evaluation.
- Assess system-level impact and support needed, including in-depth, multi-year spending analyses.

OPTN
Modernization

Engagement Session Feedback Summary
Overall Evaluation Framework

OPTN
Modernization

11

Overall Evaluation Framework: Approach & Design
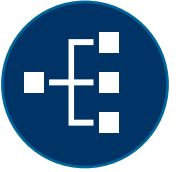
Summary of Findings

- Supported the Evaluation Framework's comprehensive design and its policy content, policy implementation, and policy impact evaluation objectives.

- Recommended that some evaluation questions address multiple evaluation components (e.g., links between policy content and implementation) to support a systems approach.

- Advocated for including a wide range of organ procurement and transplant stakeholders (e.g., patients, clinical experts, logistics experts) in developing, completing, and interpreting policy evaluations.

Addressed in Framework

- ✓ Continued with the comprehensive evaluation design and objectives of the framework.

- ✓ Enhanced evaluation questions to identify connections between policy content, implementation, and impact.

- ✓ Expanded guidance to evaluators for engaging stakeholders at various steps in the policy evaluation process.

Select Quote

"A lot of what happens with allocation policies is there are always gray areas, and we don't have a live referee. A lot of the policy review happens after the fact."

OPTN
Modernization

Overall Evaluation Framework: Evaluation Methods
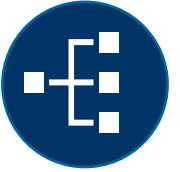
Summary of Findings

- Requested that Evaluation Framework data collection be feasible and minimally burdensome for reporting organizations.
  - Suggested including measures already collected by OPTN members or other organizations but underutilized in existing OPTN reports (e.g., number of offers, preservation techniques).
- Emphasized including a mix of qualitative and quantitative data to understand the impact of policy changes.
- Described the importance of assessing early policy effects within the first three to six months of the policy enactment date to identify and respond to unintended consequences.
- Suggested it might take at least a year to observe broader policy impacts.

Addressed in Framework

- ✓ Included qualitative and quantitative analysis methods to understand the impact of policy changes.
- ✓ Included a recommendation to conduct rapid evaluations during first year post policy implementation and to reserve full policy evaluations for at least a year following the policy implementation.

Select Quote

*"**[There is a] real need for qualitative data.** So much of what happens needs to be qualitative to hear what is really happening and what the challenges are. How much [information] gets lost in real time is amazing. [There is a] real opportunity to capture … experience[s] from people who lived it."*

OPTN
Modernization

13

Overall Evaluation Framework: Analytic Considerations
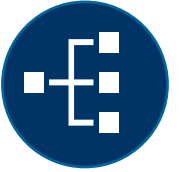
Summary of Findings

- Recommended robust analytic methods to explore causal inferences and explain how policy changes contribute to observed outcomes.
- Described limitations with previous OPTN monitoring and evaluation reports' analysis methods which primarily compared outcomes before and after policy changes were implemented.
- Recommended using transparent and easy-to-interpret risk adjustment practices (e.g., perform risk adjustment across all data, explain the meaning of risk-adjusted data).

Addressed in Framework

- ✓ Confirmed analytic methods include qualitative investigation, adjustment for confounders, and inferential statistics to inform deeper impact insights.
- ✓ Expanded guidance on applying advanced analytic methods to explore causal inferences.

Select Quote

"When we look at mortality [findings] … I like to think that this is because of the new policy, but how do we know that this is true?"

OPTN Modernization

Engagement Session Feedback Summary
Policy Content

OPTN
Modernization

Policy Content: Policy Context & Goals

Summary of Findings

Recommended assessing:

- The context for and process of policy development, including the reported problem being addressed, the policymakers engaged, overall policy goals, and the proposed strategy to achieve intended goals.

- Policy changes and their rationale.

- Organizational and system-level outcomes, as well as patient outcomes.

- Intended outcomes (e.g., stated goals) and unintended consequences.

Addressed in Framework

To further understand the policy context, addressed:

- ✓ Primary problem the policy aims to solve.

- ✓ Policy goals and anticipated outcomes, including multi-level outcomes.

- ✓ Strategy for achieving policy goals.

- ✓ Policy development process and policy modifications made.

Select Quote

"Before anything is developed, one has to understand what the rationale is. What are we trying to solve? It's a lot of effort to do these things. ... We have to be very thoughtful about what we're trying to do and what the gap is."

OPTN
Modernization

Policy Content: Implementation Guidance

Summary of Findings

Recommended assessing:

- Clarity and completeness of policy guidance (e.g., language describing essential resources, actions required to implement new policies, key policy concepts/term definitions).
- The policy's data collection requirements and associated burden (e.g., mandated volume, frequency, staffing, spending).
- OPTN's policy implementation role (e.g., OPTN-provided training or support for implementation).

Addressed in Framework

To further assess policy implementation guidance, addressed:

- ✓ Implementation guidance provided and accompanying resources.
- ✓ Resource allocation and staffing requirements.
- ✓ Data collection requirements, including recommended data sources.

Select Quote

"If I have to rewrite and define for staff what the policy actually means, that is a big fail. That currently happens. **[Evaluators should] measure if policy is clear to the people doing the work***."*

OPTN
Modernization

Engagement Session Feedback Summary
Policy Implementation

OPTN
Modernization

Policy Implementation: Policy Information Sharing

Summary of Findings

Recommended assessing the methods and timing for disseminating policy information to relevant stakeholders.

Shared current practices:

- OPTN members receive emails about new policies that they find dense with information and difficult to understand.
- Non-OPTN member stakeholders (e.g., dialysis centers, logistics organizations) do not receive formal communications from OPTN about policy changes.
- Patients do not receive consistent information about policy changes. They must inquire with a physician or search online resources (e.g., OPTN website), which can be difficult to interpret.

Addressed in Framework

To further assess policy information sharing, addressed:

- ✓ Policy dissemination content, timing, and frequency to OPTN stakeholders.
- ✓ Number and type of organizations that receive formal notifications of new allocation policies.

Select Quote

*"**Dissemination of policy change in [the] transplant [system] is patchwork, at best.** Even at the provider/center level, understanding changes in organ allocation [policy] are not well understood – to say nothing of how well patients and referring physicians understand it."*

OPTN
Modernization

Policy Implementation: OPO Policy Compliance

Summary of Findings

- Described the need for better data collection, monitoring, and reporting on policy non-compliant allocation to achieve policy goals and improve trust in the allocation system.

- Recommended assessing:
  - Reasons for allocation-out-of-sequence (AOOS).
  - Offer practices that contribute to AOOS (e.g., delayed offers, offers with incomplete data).
  - Number of offers by transplant center type (e.g., size) and whether OPOs favor certain types or specific organizations.

- Noted observing AOOS from some OPOs to patients at specific transplant centers based on existing relationships.

- Suggested that the CMS OPO performance metrics require additional context or data to discern if better performance is driven by policy non-compliance (e.g., maximizing organ utilization rates by prioritizing offers to patients at higher-resourced transplant centers).

Addressed in Framework

- ✓ Added descriptions of organ allocation policy compliance and non-compliance.
- ✓ To further assess policy compliance, addressed:
  - Number of declines, refusal codes, and exception requests.
  - Offer acceptance rate.
  - OPO offers by transplant center, with incomplete data, in batches, and after cross-clamp time.
  - OPO performance metrics.
  - Transplant center characteristics.

Select Quote

*"**Organ optimization is subjective [and] hard to track**. We've had OPOs play games and don't want to do extra testing or optimization if another center will take the organ as it is."*

OPTN
Modernization

Policy Implementation: OPO Logistics Challenges

Summary of Findings

- Highlighted logistical challenges as a barrier to policy compliance, with organs traveling longer distances under the continuous distribution framework.

- Recommended better data collection and communication about organ allocation, acceptance, and logistics.

- Recommended assessing the impact of policy changes on:
  - Organ logistics, including travel time and distance
  - Cold ischemic time

- Recommended assessing changes in optimization techniques (e.g., perfusion) and other emerging technologies to understand whether they lead to improved outcomes.

Addressed in Framework

- ✓ To further assess the impact of policy implementation on logistics challenges, addressed:
  - Cold ischemic time
  - Organ preservation and perfusion techniques

Select Quote

*"If you **can't get an organ moved** from Point A to Point B], it **doesn't matter if you offer it broader**."*

OPTN
Modernization

Policy Implementation: Implementation Transition Period

Summary of Findings

- Recommended assessing:
  - The transition time needed to implement a new policy change in comparison to the timelines specified in the policy.
  - How transition periods vary across different OPTN member organizations.
- Expressed that implementing a new policy takes time and that time is often underestimated.
- Indicated some organizations begin implementing organizational changes in anticipation of a policy's approval, while others will not begin until after the policy enactment date. Recommended evaluators account for this variation when interpreting implementation findings.

Addressed in Framework

- ✓ To further assess policy implementation time, addressed:
  - Policy compliance timelines.
  - Lead time needed to reach full policy compliance, including variations by OPTN member organizations.

Select Quote

*"[We] tend to underestimate how long it takes an organization to do some of these things ... **'How long before full compliance deadline did [the] OPO** seek to reorient practices and protocols to **align with new policies**?'"*

OPTN
Modernization

Policy Implementation: Workforce Preparation

Summary of Findings

Recommended assessing:

- Policy implementation impact on workforce challenges (e.g., staff shortages and burnout).
- Policy-related staffing changes, including re-organizations and existing staff role changes, in addition to measuring the number and type of new staff.
- New policy training methods, frequency, and effectiveness:
  - OPTN members indicated inadequate policy training or educational material provided by the OPTN, leading to variability in policy understanding.
  - OPO leaders described that transplant center training on new policies is often limited to brief calls or emails due to frontline staff time constraints, yet transplant centers are responsible for implementing the policy.

Addressed in Framework

- ✓ To further assess policy implementation impact on workforce, addressed:
  - Staff allocation and labor costs.
  - Engagement with the policy development process.
  - OPTN policy training resources.

Select Quote

*"Continuous Distribution in general **prompted a new department for specialized coordinators**. [We] have a more specialized team focused on allocation now. The other impact with lung was procurement teams. [We also] needed [a] preservation team to be trained. **There was a big impact on staffing**."*

Policy Implementation: Stakeholder Coordination

Summary of Findings

- Recommended assessing stakeholder coordination as a key component of implementation (e.g., interactions between donor hospitals, OPOs, transplant centers, third-party contractors, logistics organizations, and technology organizations).

- Described challenges in working with new organizations, necessitated by continuous distribution.

- Recommended considering technology companies in the implementation process, as their ability to support implementation has a significant impact on how quickly and smoothly a policy is implemented.

Addressed in Framework

✓ To further assess stakeholder coordination, addressed:
  - Coordination between OPTN members, including offer response time.

Select Quote

"[We] need to educate transplant centers that don't know policy is changing or didn't understand how it would impact them , OPO offers, and their transportation needs. **[We] spent more time getting the transplant center ready than with [our] own OPO**.*"*

OPTN
Modernization

Policy Implementation: Data Collection Burden

Summary of Findings

- Shared that new policies requiring data collection and reporting are burdensome, and highly depend on system functionality (i.e., manual or automated entry) including the extent of interoperability with other systems.
- Recommended assessing data aspects of a policy, including:
  - Overall data completeness.
  - Validity of the data.
  - Relevance and usefulness of the data, including if it can be used to support clinical decision-making.

Addressed in Framework

- ✓ To further assess data collection burden, addressed:
  - The quantity of newly required data elements for a policy, as well as the completeness of required data elements.

Select Quote

*"If [data] need to be filled in by hand, it is a lot more work versus if [the data is] from a database. **Makes a difference in data collection burden**."*

OPTN
Modernization

Policy Implementation: Organ Offer Process

Summary of Findings

- Noted that batch offer sizes vary and the optimal batch offer size is unknown. Offers being made in increasing batch sizes sometimes indicate poor organ quality.

- Recommended assessing:
    - Events that trigger OPOs to initiate expedited ("aggressive") placement actions.
    - Offer timing, such as time between offer and response; acceptance relative to cross-clamp time; time it takes to send out a new offer after the initial offer is refused; and the number of communications between OPOs and transplant centers (with timestamps).

Addressed in Framework

- ✓ To further assess the organ offer process, addressed offers per patient, as well as offer acceptance timing relative to cross-clamp time.

Select Quote

"I have no clue how many offers I made last year, or how that compares to other organizations. Or whether it was the appropriate number."

OPTN
Modernization

Policy Implementation: Acceptance & Refusal

Summary of Findings

- Suggested that higher-resourced transplant centers accept more organs because they can afford organ optimization techniques and complex patient care procedures, while less-resourced centers may lack resources or technology or be concerned with riskier procedures' impact on their performance outcomes.

- Shared that waitlisted patients may refuse organ offers due to social, economic, or clinical reasons. Recommended considering "waitlist readiness" (or "transplant readiness") and how it varies by transplant center.

- Indicated offer timing (e.g., pre-/post-clamp) impacts acceptance decisions; organ offers post-cross-clamp are harder to accept due to time constraints (e.g., preparing the patient, transporting the organ).

- Recommended assessing:

  o Transplant centers' use of offer filters and their impact on the number of offers and acceptance rates.

  o Reasons for organ refusal to enhance offer and match efficiency.

Addressed in Framework

- ✓ To further assess transplant center acceptance and refusals, addressed:

  o Implementation alignment with the policy implementation description.

  o Implementation variation by transplant center characteristics.

  o Time from offer to acceptance.

  o Use of filters.

  o Frequency of "late refusals" and refusal codes.

Select Quote

*"On average, each organ has 12 excess programs notified. **So much noise [and] wasted offers in system**. No way anyone could even evaluate those offers."*

OPTN
Modernization

Engagement Session Feedback Summary
Policy Impact

OPTN
Modernization

Policy Impact: Patient Pre-Transplant Outcomes

Summary of Findings

Recommended assessing policy impacts on patient access to the waitlisting process, including:

- Changes in transplant center waitlisting criteria.
- Patient challenges with completing the transplant evaluation requirements.
- Trends in the types of patients who are referred, evaluated, or waitlisted for transplant.
- Changes in waitlisting time and outcomes.
- Patterns in patient multi-listing at different transplant centers.

Addressed in Framework

- ✓ To further assess patient access to the waitlist, addressed:
  - Waitlist practices (e.g., frequency of preemptive referrals and transplants for kidney, reasons for waitlist removal, number of patients multi-listed).
  - Transplant evaluation rate.

Select Quote

*"**We are not looking hard enough at pre-waitlisting services**. This has to do with requirements put in front of patients that [patients] have to meet in order to complete [waitlist] evaluations."*

OPTN
Modernization

Policy Impact: Patient Transplant Outcomes

Summary of Findings

- Recommended assessing how the policy impacts:
  - The distribution of organs to different patient groups, including patients identified as sensitized, pediatric, or needing multiple organs.
  - Post-transplant outcomes, including patient survival and graft function.
  - The timing of graft failure, suggesting that better-functioning grafts improve early graft survival and reduce mortality risk.
- Recommended assessing how patient transplant outcomes differ by organ type, as policy changes for one organ type may unintentionally affect others.

Addressed in Framework

- ✓ Expanded guidance to compare outcomes across patient groups.
- ✓ To further assess policy impacts to patient outcomes, addressed:
  - Patient characteristics (sensitization, pediatrics, multiple organs).
  - Patient survival and graft function timing.

Select Quote

"3-year graft survival is too short. [The] goal of transplant is not to last 90-days or 3 years. Patients want longer survival."

OPTN
Modernization

Policy Impact: System Level Impacts

Summary of Findings

- Recommended assessing:
  - Whether changes in allocation policy for one organ affect others.
  - Broader societal impacts (e.g., trust in the transplant system, willingness to donate organs).
  - Impacts on patient and advocacy groups.
- Suggested system-wide support for training programs, operations, and resources for:
  - Organizations engaged in the organ procurement and transplant system including: OPTN member organizations, OPOs, transplant centers, logistics organizations, dialysis centers, insurance companies and their provider networks, professional organizations, histocompatibility laboratories, and end-stage organ care specialists.
  - Non-healthcare organizations (e.g., academic research, philanthropic, social work, ethics organizations).

Addressed in Framework

- ✓ To further assess organizational impacts, addressed:
  - Organizational and workforce changes and spending.
- ✓ To further assess system-level impacts, addressed:
  - Type of transplant center funding (non-profit vs. for-profit).
  - Number of organizations by type (e.g., OPOs, transplant centers, dialysis centers).

Select Observation

*Participants expressed concerns that perceived inconsistencies in organ allocation will **erode societal trust in the system** and reduce families' willingness to donate organs, which would further limit the availability of deceased donor organs.*

OPTN
Modernization

Policy Impact: Cost Considerations

Summary of Findings

- Recommended assessing cost by considering:
  - Multiple years, rather than single-year comparisons, as some financial impacts will take longer to observe (e.g., reimbursement changes).
  - Spending on organ optimization techniques and whether increased spending contributes to improved patient outcomes.
  - Relationships between policy-related changes in spending and organ procurement and transplantation outcomes.
  - Effects of continuous distribution on transportation costs, given the wider geographic availability of organs.
  - Impacts on non-medical spending, such as patient out-of-pocket costs.

Addressed in Framework

- ✓ To further assess spending and cost, addressed:
  - Multi-year transplant-related spending, including organ optimization spending.
  - Payer spending.
  - Medical and non-medical costs, including patient out-of-pocket spending.
- ✓ Added analyses that consider longer-term effects of policy on transplant spending (multiple years following policy implementation).

Select Quote

*"**We should look at how cost overall is affecting how many transplants are completed**; how it's hurting lower budget transplant centers who can't afford to fly out any organ."*

Future Considerations

OPTN
Modernization

Stakeholder Recommendations for
Future Policy Development Processes

Co-Design Policies with Stakeholders

Involve a broad range of stakeholders (e.g., frontline workers, economists, third-party contractors) in policy design and develop policies collaboratively.

Reduce Data Burden

Reduce data collection burden by focusing on only necessary data, fully using existing and new data collected by OPTN members, system interoperability, and reducing manual entry.

Earlier Evaluation Planning

Plan for evaluation during policy development, considering system-level impacts and run controlled experiments to see what works best for different types of OPTN members.

OPTN
Modernization

Stakeholder Recommendations for
Future Policy Communication

Share Findings Frequently

Promote transparency by sharing evaluation findings regularly to inform and guide decision-making.

Clear Communication

Improve communication tools for OPOs and transplant centers to better capture organ preferences and refusal reasons (nuanced organ offer preferences make efficient use of filters challenging).

Tailor Materials for Stakeholders

Provide tailored policy education and training material for different types of stakeholders and different purposes (awareness vs. implementing).

OPTN
Modernization