Final Evaluation Framework and Methodology

Contract Number: 75FCMC23D004
COR's Name: Aaron Fisher
Deliverable Number/Product Name: 2.1.6 Version 1.1
Due Date: 9/29/2025
Date of Submission: 9/9/2026 (draft), 9/26/2025 (final)

Executive Summary

The U.S. Department of Health and Human Services (HHS) oversees the Organ Procurement and Transplantation Network (OPTN), the national system responsible for allocating and distributing procured organs. Recent congressional and scientific reports have underscored the urgent need to improve the quality, transparency, and performance of the U.S. organ procurement and transplantation system.[1,2] Despite nearly 200 new policies implemented over the past decade, persistent challenges remain: as of August 28, 2025, 106,895 individuals were on the organ transplant waiting list, and thirteen people die each day waiting for a transplant.[3,4] Early monitoring reports indicate improvements in waitlist mortality and transplant rates but also highlight limitations in current analyses and the need for deeper evaluation of organ allocation policies.

To address these challenges, HHS engaged MITRE, operator of the Health Federally Funded Research and Development Center (Health FFRDC) to develop a rigorous Organ Allocation Policy Evaluation Framework ("Framework"). This Framework provides structured guidance for evaluating organ allocation policies, aiming to promote consistency and transparency, inform future policy development, and ultimately improve patient outcomes.

The Framework builds on existing OPTN monitoring activities and introduces several key advancements:

- **Comprehensive Evaluation Design:** Assesses policy content, implementation processes, and impacts to generate a comprehensive understanding of the policy.
- **Integrated System-Level Approach:** Evaluates impacts for patients in need of transplant, donor patients, and OPTN members, considering both expected and unanticipated consequences.
- **Enhanced Analytic Methods:** Moves beyond descriptive analytics to incorporate qualitative investigation, adjustment for confounders, and inferential statistics.

The Framework is adaptable for HHS to use for different organ allocation policies. It focuses on three primary evaluation objectives, which are assessed using **18 core evaluation questions**:

1. **Assess Policy Content:** Five evaluation questions examine the context, required changes, implementation guidance, and anticipated impacts of organ allocation policies.
2. **Assess Policy Implementation:** Five evaluation questions explore how OPTN members understand, adopt, comply with, and implement organ allocation policies.
3. **Assess Policy Impact:** Eight evaluation questions analyze changes in patient populations, outcomes across the transplant pathway, organizational impacts, and financial implications of organ allocation policies.

The Framework leverages robust data sources, including the OPTN Database, CMS Annual Organ Procurement Organization (OPO) Performance Reports, cost reports, and stakeholder input. It recommends a combination of qualitative and quantitative analytic methods, including risk-adjusted models and stratified analyses, to ensure valid and actionable insights.

By equipping HHS with a comprehensive, flexible, and methodologically sound evaluation tool, the Framework supports federal health leaders in strengthening the transparency, performance, and efficiency of the organ procurement and transplantation system, with the ultimate goal of saving lives and improving outcomes for patients and their families.

Table of Contents

Table of Figures

Tables of Tables

1. Introduction

Task Order 75P00124F80166 issued to the MITRE Corporation on September 30, 2024, is contracted under the Centers for Medicare & Medicaid Services (CMS) Alliance to Modernize Healthcare Federally Funded Research and Development Center (Health FFRDC). This task order engages MITRE, the Health FFRDC operator, to develop an enduring, unbiased, and rigorous Organ Allocation Policy Evaluation Framework ("Framework"). The Framework provides a way for the U.S. Department of Health and Human Services (HHS) to assess organ allocation policies following their release and to provide critical insights to inform future policy formulation and decision making.

The Introduction provides overview and background information on the Organ Allocation Evaluation Framework. It explains why the Framework is needed, who the intended users are, how it was developed, and describes the general context for organ allocation policy changes and how recent policy changes were monitored.

1.1 Purpose and Significance

The purpose of the Framework is to provide HHS with structured guidance for evaluating organ allocation policies to promote consistency and transparency in the organ allocation system and inform future policy development.

This Framework builds on existing monitoring efforts in three innovative ways.

4. **Comprehensive evaluation design:** Assesses the outcomes associated with an organ allocation policy and aspects of the policy content and implementation that might affect those outcomes.
5. **Integrated system-level approach:** Considers organ allocation policy outcomes, focusing on patients in need of transplant, donor patients, OPTN members, and both expected and unanticipated consequences.
6. **Enhanced analytical methods:** Includes methods and approaches to move beyond descriptive analysis of policy outcomes, using qualitative investigation, adjustment for confounders, and inferential statistics to provide deeper insights about organ allocation policy impacts.

1.2 Primary User

The Framework is designed for HHS, as the federal agency providing oversight of the Organ Procurement and Transplantation Network (OPTN), or its contractors, to implement the evaluation.

Ideally, evaluation teams implementing the evaluation will include individuals with collective expertise across the following areas:

- **Organ procurement and transplantation**, including policies, functions, stakeholders, and capabilities to interpret data and provide recommendations.
- **Healthcare systems**, including deep knowledge of clinical operations, workflows, and infrastructure for OPTN member organizations.
- **Evaluation research**, including skills in conducting policy content, implementation, and impact evaluations.

- **Data analytics,** including proficiency in conducting thematic analysis of qualitative data (e.g., key informant interview notes) and advanced statistical analysis of quantitative data (e.g., risk adjustment models, time series analyses for patient outcomes).

1.3 Approach

HHS and MITRE developed the Framework based on best practices in policy and program evaluation, input from key stakeholders and experts, and review of existing literature. The development process included the following key activities:

- Conducted a thorough environmental scan of relevant literature, reports, existing measures, and other resources to inform the Framework's design.
- Conducted in-depth, semi-structured group interviews to solicit feedback from key stakeholders on the Framework's design, content, and usability.
- Developed and refined the Framework objectives, questions, measures, and guidance, based on stakeholder engagement and overall environmental scan findings.

Context for Evaluating Organ Allocation Policies

The U.S. Congress established the OPTN as the national public-private partnership responsible for allocating and distributing procured organs with the National Organ Transplant Act, P.L. 98-507 (1984).[5]

HHS, charged with oversight of the system, members of the OPTN, and any contractors, grantees, or mechanisms that provide for the continued operation of the OPTN, implemented the OPTN Final Rule (42 CRF Part 121) in 2000 to establish a regulatory framework for OPTN's structure and operations.

Patient demand for organs far exceeds availability, making access to transplants a persistent challenge. As of August 28, 2025, 106,895 individuals were on the waiting list for organ transplant across the U.S.; thirteen people die each day waiting for an organ transplant.[3,4] Congressional and scientific reports have highlighted the urgency and growing need to improve the quality and performance of the U.S. organ procurement and transplantation system.[1,2]

Continuous Distribution Framework

To improve national procurement and transplantation system outcomes, OPTN approved a continuous distribution (CD) framework as a model for developing future organ allocation policies in December 2018.[6] Since then, OPTN released the first CD policy for lung allocation in March 2023, and is considering organ allocation policy changes for kidney, pancreas, liver, intestine and heart allocation.[2,7,8] In July 2025, OPTN paused all new policy work related to CD to focus on implementing evidence-based policies to remediate observed issues with allocation out of sequence (AOOS) and uphold fairness and integrity across the system.

Prior to CD policies, the prior classification-based system gave points to transplant candidate patients—based on criteria defined for specific patient characteristics or attributes—at various steps of a sequence in the organ offer process.[2] However, evaluating a candidate patient sequentially resulted in hard boundaries that prevented some candidate patients from being prioritized if they did not score favorably on a single attribute early in the sequence. In contrast, CD considers multiple attributes

simultaneously to allow a more holistic consideration of candidate patients and removes the boundaries that may deprioritize candidates based on a single attribute. The goals of the new CD framework are to:

- Prioritize the sickest candidate patients first to reduce waitlist deaths.
- Improve long-term survival after transplant.
- Increase transplant opportunities for patients who are medically harder to match.
- Increase transplant opportunities for candidate patients with distinct characteristics, such as candidate patients under the age of 18 or prior living donor patients.
- Promote the efficient management of organ placement.[2]

OPTN Policy Monitoring Reports

OPTN produces post-implementation policy monitoring reports using data submitted by OPTN member organizations and supplemented with outside sources.[9,10] Policy monitoring reports serve a vital function by enabling OPTN to ensure new policies are producing the desired effects six, 12, and 18 months following the change and will continue to do so annually for three years.[11,12,13] These reports focus on a specific set of key outcome measures such as waiting list mortality, number of transplants, organ utilization rates, and distance from the donor hospital to transplant program. The reports also examine patient attributes that form the basis for the CD-based composite allocation scoring to determine if transplants are consistent with the new allocation policy.

Since the lung CD policy was implemented in 2023, the OPTN monitoring reports state that, overall, waitlist mortality decreased,[13,14] lung transplant rates increased,[13,14,15] lung utilization rates increased slightly for Donation after Circulatory Death donor patients,[13,15] and median distance from the donor hospital to transplant program increased.[12,13,15] Furthermore, while the most medically urgent candidate patients had the highest rates of waiting list removals due to death or being too sick for transplant;[14] they also had the highest rates of transplant, the shortest median waiting time for a transplant,[14] and the greatest median travel distance [12,13] from the donor hospital to transplant program. [12,14]

While the OPTN monitoring reports shed light on key aspects of organ allocation policy change, the analyses are limited in scope and depth and do not answer all of HHS's questions about the effects of the new CD policies. Specific limitations include gaps in the following areas:

- **Policy Impacts:** The methods do not address impacts on the broader organ procurement and transplantation system or variations in policy implementation over time and across OPTN member organizations (e.g., transplant programs, Organ Procurement Organizations [OPOs], histocompatibility labs).
- **Analytic Methods:** The analytic methods used in the reports do not account for confounding factors to reveal regional, patient population-specific, or OPTN member organization variations in policy implementation. The applied methods also preclude opportunities to identify associations between policy changes and observed outcome changes. For example, additional analysis could explore the extent to which increases in the number of lung transplants are attributed to the policy change versus other factors, such as an increase in the number of organ donor patients, greater utilization of advanced organ recovery methods, and changes in organ utilization rates.

- **Efficiency Complexities:** The analyses of organ allocation efficiency, such as distance from the donor hospital to transplant program, do not sufficiently examine complex organ procurement issues, including logistics and transportation, cold ischemic time, preservation techniques, organizational impacts, workforce implications, and associated medical and non-medical costs.
- **Policy Non-Compliance:** The reports do not adequately assess OPTN members' compliance with established allocation policies, including instances of AOOS. According to the OPTN's current operational definition, AOOS occurs when an organ is offered, accepted, and/or transplanted in a way that deviates from the match run and is not consistent with OPTN policy.[16] The issue of AOOS is of particular concern given: (1) a critical comment letter Health Resources and Services Administration (HRSA) provided to OPTN in 2024 concerning the activities related to "expedited" allocation of organs;[17,18] (2) a substantial increase in the number of lung-related exception requests since the lung allocation policy change and (3) an increase in the final sequence at acceptance for lung transplants from the pre-policy to the post-policy era.

As the federal agency with system oversight responsibilities, HHS seeks to supplement OPTN's policy monitoring efforts and inform future policy development with in-depth and comprehensive evaluation studies that examine a broader range of measures and employ analytical strategies that promote consistency and transparency within the organ allocation system.

2. Evaluation Framework

The Framework incorporates foundational elements to help HHS evaluate organ allocation policies. These elements are flexible, enabling tailoring of evaluation plans for any organ program. Use of this Framework will support conceptual and methodological consistency across future evaluation studies.

The Framework, shown in Figure 1, includes the following elements:

- **A clear purpose and set of objectives** to help scope evaluations of OPTN organ allocation policy content, implementation, and impact.
- **A common set of evaluation questions and sub-questions,** directly related to the objectives, that define what the evaluation will investigate.
- **Measures, data sources, and analytic methods** needed to answer evaluation questions.

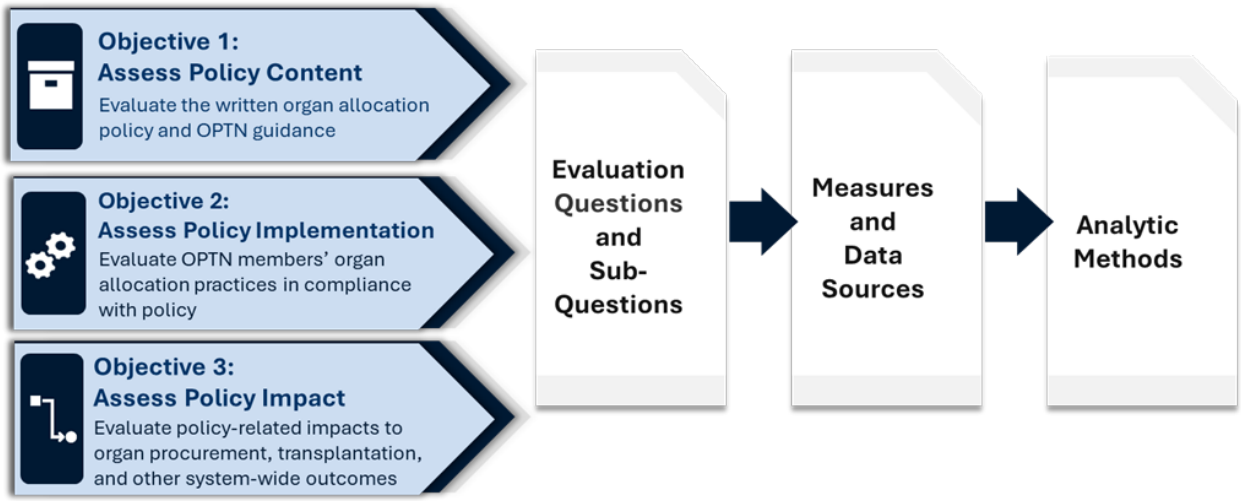

Figure 1. Foundational Elements of the Organ Allocation Evaluation Framework

The Framework complements the 10-step OPTN Policy Development Process, which includes Post Implementation Review of policy effectiveness as its final step.[19]

The Framework takes a flexible approach to assessing effectiveness, allowing evaluators to tackle one or more evaluation objectives, either concurrently or sequentially, depending on priorities, urgency, and available resources. A comprehensive Evaluation Framework Measures Database (Appendix B) accompanies the Framework. It identifies qualitative and quantitative measures to capture answers to the evaluation questions. The measures included in the tables in the main body of this guide are examples of measures contained in the database.

Objective 1. Assess Policy Content

The Framework's first objective focuses on policy content and context—which will enable evaluators to understand the policy's goals. Understanding policy content also provides a baseline against which to evaluate its success in achieving its intended outcomes. Insights gained from assessing policy content will identify strengths and limitations of the written organ allocation policy and help inform future HHS policy decision making.

Policy Content Evaluation Questions

The Framework's content evaluation questions and sub-questions (see Table 1. Evaluation Questions to Assess Policy Content) assess the policy's planned changes, anticipated impacts, affected stakeholders, and planned implementation support. The answers to these questions will help explain how the policy guides organ allocation and the extent to which the policy sufficiently articulates that guidance. Evaluation teams can use all these questions or select a smaller group that corresponds to the scope of their particular evaluation.

Table 1. Evaluation Questions to Assess Policy Content

Policy Content Evaluation Questions
1.1 What does the policy state it will change about organ allocation? a. Which of these changes are required by the policy? Which are recommended? b. How does the policy differ from the previous policy? c. Why is a policy change necessary? 1.2 What guidance did OPTN provide about how the policy should be implemented? a. What implementation guidance did OPTN provide in the original policy? b. What additional implementation guidance did OPTN provide since it released the policy and why? c. Are there any gaps or ambiguities in OPTN's guidance that could lead to inconsistencies in implementation by OPTN members? d. What timeframe were OPTN members allowed to transition to the policy? 1.3 What does the policy state about how OPTN members will allocate and manage resources during implementation? 1.4 What guidance did OPTN provide about monitoring policy implementation and outcomes? a. What are the requirements or expectations for OPTN members about implementation and outcome monitoring? 1.5 What are the expected impacts of the policy? a. How are pre-transplant outcomes expected to change? b. How are transplant and post-transplant outcomes expected to change? c. How is the policy expected to address documented inconsistencies in organ allocation between subgroups of patient populations? d. What evidence does the policy or policy development materials provide that the policy will achieve the anticipated impact? e. What are the potential unintended effects identified during the policy development process?

Evaluation Measures

The Framework provides measures (Table 2 to Table 6) to answer the content evaluation question and sub-questions. The measures help evaluators to identify the presence or absence of specific information within organ allocation policy documents and to describe qualitative information about that policy content.

The following categories of measures are included for the content evaluation:

- Required Policy Changes
- Recommended Policy Changes
- Comparison to Previous Policy
- Reason for Policy Change
- Implementation Guidance

- Planned Implementation Resources
- Planned Monitoring and Evaluation
- Expected Impacts
- Policy Strategy

EQ 1.1 What does the policy state it will change about organ allocation?

a. Which of these changes are required by the policy? Which are recommended?
b. How does the policy differ from the previous policy?
c. Why is the policy change necessary?

Table 2. Measures for Evaluation Question 1.1

EQ	Category	Measures
1.1 a, b	Required Policy Changes *Policy-mandated actions for implementers including OPTN-member roles/responsibilities, organ offer requirements, data practices, patient engagement*	• Indicate (y/n) whether the policy includes the following and describe (qualitative): ○ OPTN member requirements ○ Allocation score attributes ○ Allocation score calculation
1.1 a, b	Recommended Policy Changes *Policy-recommended actions for implementers*	• Indicate (y/n) whether the policy includes the following and describe (qualitative): ○ OPTN member recommendations
1.1 b	Comparison to Previous Policy *Summary of ways policy implementation changes guidance from previous policies*	• Indicate (y/n) whether the policy includes the following and describe (qualitative): ○ Differences between the new policy and the previous policy ○ Other organ allocation policies affected by the policy enactment
1.1 c	Reason for Policy Change *Justification for developing and implementing policy changes*	• Indicate (y/n) whether the policy includes the following and describe (qualitative): ○ Primary problem addressed ○ Reason for policy change

EQ 1.2 What guidance did OPTN provide about how the policy should be implemented?

a. What implementation guidance did OPTN provide in the original policy content?
b. What additional implementation guidance did OPTN provide since the policy was released and why?
c. Are there any gaps or ambiguities in OPTN's guidance that could lead to inconsistencies in implementation by OPTN members?
d. What timeframe were OPTN members allowed to transition to the policy?

Table 3. Measures for Evaluation Question 1.2

EQ	Category	Measures
1.2 a, b, c, d	Implementation Guidance *OPTN policy implementation instructions or directions to OPTN members*	• Indicate (y/n) whether the policy includes the following and describe (qualitative): ○ Original implementation guidance ○ Modifications to original implementation guidance (and reason for modifications) ○ Additional implementation guidance offered after policy enactment date (and reason for additional guidance) ○ Implementation protocol

EQ 1.3. What does the policy state about how OPTN members will allocate and manage resources during implementation?

Table 4. Measures for Evaluation Question 1.3

EQ	Category	Measures
1.3	Planned Implementation Resources *Types of tools or supports needed to effectively implement the policy as intended*	• Indicate (y/n) whether the policy includes the following and describe (qualitative): ○ Type(s) of organization(s) implementing the policy ○ Technical assistance offered ○ Financial resources offered ○ Technology support offered ○ Coordination across policies offered ○ Implementation support programs offered ○ Duration of additional resource availability

EQ 1.4 What guidance did OPTN provide about monitoring policy implementation and outcomes?

a. What are the requirements or expectations for OPTN members about implementation and outcome monitoring?

Table 5. Measures for Evaluation Question 1.4

EQ	Category	Measures
1.4 a	Planned Monitoring and Evaluation *Processes planned to track progress, measure results, and assess the effectiveness of the policy*	• Indicate (y/n) whether the policy includes the following and describe (qualitative): ○ Planned policy monitoring procedures ○ Planned policy evaluation procedures ○ Evaluation measures

EQ 1.5. What are the expected impacts of the policy?

a. How are pre-transplant outcomes expected to change?
b. How are transplant and post-transplant outcomes expected to change?
c. How is the policy expected to address documented inconsistencies in organ allocation between subgroups of patient populations?
d. What evidence does the policy or policy development materials provide that the policy will achieve the anticipated impact?
e. What are the potential unintended effects identified during the policy development process?

Table 6. Measures for Evaluation Question 1.5

EQ	Category	Measures
1.5 a, b, e	Expected Impacts *Possible policy outcomes including intended goals and unintended consequences for OPTN stakeholders*	• Indicate (y/n) whether the policy includes the following and describe (qualitative): ○ Policy goals (pre-transplant to post-transplant) ○ Potential unintended effects (pre-transplant to post-transplant)
1.5 c, d	Policy Strategy *Data, research, or documented observations providing evidence for how the policy will achieve its intended goals*	• Indicate (y/n) whether the policy includes the following and describe (qualitative): ○ Strategy to address documented allocation inconsistencies in organ allocation (e.g., AOOS) ○ Scientific evidence the new policy will achieve goals

Data Sources

Collecting data for the content evaluation measures will require abstracting narrative text from the official OPTN policy notice and supplemental policy documents to perform a qualitative analysis of the policy content. OPTN policy documents are available directly on the OPTN organization website.[20] Create a data abstraction table or electronic form or use qualitative analysis software to organize the policy information compiled to answer the content evaluation questions.

Key content evaluation data sources include:

- Official OPTN policy notice
- Public documentation on OPTN Policies
- OPTN committee and Board of Director meeting minutes where the policy development was discussed
- Public commentary on the policy

Analytic Methods

Qualitative Analyses

EQs 1.1–1.5: The policy content analysis will primarily involve reviewing and compiling textual and qualitative information. The evaluation team will apply qualitative data analysis techniques to identify, synthesize, and summarize issues and themes relevant to the evaluation questions and measures. As the team reviews each source, they will code or tag relevant information according to the measures outlined in Table 2. The team will then examine all information assigned to each code to develop descriptive summaries that answer the evaluation questions. In some cases, thematically coding the data collection for a measure will answer the question, while other questions, such as question 1.5 e, will require analyses focusing on finding gaps and ambiguities in the language (e.g., a "n" response indicates a gap).

Quantitative Analyses

EQs 1.1–1.5: Descriptive statistics will use binary measures (yes/no) to summarize the presence or absence of specific topics within the policy documents. These analyses will examine whether the policy clearly specifies the important policy information (e.g., required and recommended policy changes, reasons for policy changes, expected impacts).

Objective 2. Assess Policy Implementation

The Framework's second objective focuses on understanding policy implementation. It examines how OPTN members implement the national organ allocation processes defined in the evaluated policies to identify areas for improvement. It also examines how the intended policy changes compare to actual policy implementation. Insights derived from the implementation evaluation will help HHS understand how policy implementation may have played a role in achieving, or not achieving, the desired impacts, and ways to improve program efficiencies and policy impact.

Policy Implementation Evaluation Questions

The Framework's implementation evaluation questions and sub-questions (Table 7) assess organ allocation policy implementation and compliance across OPTN members. These questions also explore factors that affect implementation and policy monitoring and evaluation activities. This, in turn, strengthens organ allocation policies and improves long-term implementation of policy changes.

Table 7. Evaluation Questions to Assess Policy Implementation

Policy Implementation Evaluation Questions
2.1 How were relevant stakeholders informed of the policy? a. How did the organ procurement and transplant stakeholders respond to the policy? 2.2 How did OPTN members implement the policy? a. How did OPTN members prepare for the policy prior to its effective date? b. How did OPTN members transition to the policy after the policy became effective? c. How did OPTN members sustain implementation of the policy since its effective date? 2.3 To what extent did OPTN members comply with the required actions within the policy? 2.4 What factors impacted policy implementation and compliance? a. What OPTN member characteristics were associated with implementation of required and recommended policies? 2.5 How did the OPTN monitor and evaluate policy implementation?

Evaluation Measures

A selected set of quantitative and qualitative data measures answer each implementation question and sub-question (Table 8 to Table 12). Where possible, measures focus on using secondary data to minimize undue data collection burden to evaluators and OPTN members. In some instances, assessing insufficiently monitored policy implementation processes may require primary data collection.

The following categories of measures and covariates are included for the implementation evaluation:

- Policy Communication
- Policy Response from Stakeholders
- OPO Organizational Changes
- Transplant Center Organizational Changes

- Histocompatibility Labs Organizational Changes
- Organ Allocation Policy Implementation
- Organ Allocation Policy Compliance
- Implementation Factors
- OPTN Member Monitoring and Evaluation
- OPTN Member Characteristics

EQ 2.1 How were relevant stakeholders informed of the policy?

a. How did organ procurement and transplant stakeholders respond to the policy?

Table 8. Measures for Evaluation Question 2.1

EQ	Category	Measures
2.1	Policy Communication *Policy dissemination to OPTN stakeholders*	• Number of policy notifications + • Types of policy notifications + • Intended audience of policy notification (qualitative)
2.1 a	Policy Response by Stakeholders *Policy perceptions and feedback from OPTN stakeholders*	• Positive sentiment within public comments (qualitative) • Negative sentiment within public comments (qualitative) • Negative sentiment within HHS critical comment letters and directives to OPTN [17] (qualitative)

+ Proposed new measure from existing OPTN member data

EQ 2.2 How did OPTN members implement the policy?

a. How did OPTN members prepare for the policy prior to its effective date?
b. How did OPTN members transition to the policy after the policy became effective?
c. How did OPTN members sustain implementation of the policy since its effective date?

Table 9. Measures for Evaluation Question 2.2

EQ	Category	Measures
2.2 a, b, c	OPO Organizational Changes *Actions taken by OPOs before the effective date, during the specified transition period, and for sustainment after the transition period to implement the policy*	• Proportion of OPO staff trained ++ • Types of OPO staff trained (qualitative) • Description of OPO workflow changes (qualitative) • Types of OPO training provided (qualitative) • Types of OPO technology changes (qualitative)

EQ	Category	Measures
2.2 a, b, c	Transplant Center Organizational Changes *Actions taken by transplant centers before the effective date, during the specified transition period, and for sustainment after the transition period to implement the policy*	• Proportion of transplant center staff trained ++ • Type of transplant center staff trained (qualitative) • Transplant center workflow changes (qualitative) • Types of transplant center training provided (qualitative) • Types of transplant center technology changes (qualitative)
2.2 a, b, c	Histocompatibility Lab Organizational Changes *Actions taken by histocompatibility labs before the effective date, during the specified transition period, and for sustainment after the transition period to implement the policy*	• Proportion of histocompatibility lab staff trained ++ • Type of histocompatibility lab staff trained (qualitative) • Histocompatibility lab workflow changes (qualitative) • Types of histocompatibility lab training provided (qualitative) • Types of histocompatibility lab technology changes (qualitative)
2.2 b, c	Organ Allocation Policy Implementation *Measures reported by OPTN member organizations during the policy transition period and sustainment*	• Number of OPO offers made for each procured organ before acceptance + • Offer modality ++ • Time from offer to clamp • Final sequence at acceptance + • Offer acceptance rate • Cold ischemic time • Number of offer complaint reports associated with an offer +

+ Proposed new measure from existing OPTN member data

++ Proposed new measure not currently collected

EQ 2.3. To what extent did OPTN members comply with the required actions within the policy?

Table 10. Measures for Evaluation Question 2.3

EQ	Category	Measures
2.3	Organ Allocation Policy Compliance *Adherence to organ allocation policy requirements by OPTN member organizations*	• AOOS rate + • Number of exceptions requested + • Number of exceptions granted + • OPO compliance with data reporting requirements + • Transplant center compliance with data reporting requirements + • Histocompatibility lab compliance with data reporting requirements + • OPO adherence to multi-organ allocation policy requirements + • Number of organs procured for transplant but used for medical research

+ Proposed new measure from existing OPTN member data

EQ 2.4 What factors impacted policy implementation and compliance?

a. What OPTN member characteristics were associated with implementation of required and recommended policies?

Table 11. Measures for Evaluation Question 2.4

EQ	Category	Measures
2.4	Implementation Factors *Factors that influenced OPO and transplant center adherence to organ allocation policy requirements and recommended actions*	• External ecosystem circumstances (e.g., national health emergencies or societal shifts) (qualitative) • OPO perspectives on factors impacting policy implementation and compliance (qualitative) • Transplant center perspectives on factors impacting policy implementation and compliance (qualitative) • Histocompatibility lab perspectives on factors impacting policy implementation and compliance (qualitative)
2.4 a	OPTN Member Characteristics (Covariates for analysis) *OPTN member characteristics associated with organ allocation policy implementation and compliance*	• OPO characteristics * • Transplant center characteristics *

EQ	Category	Measures
2.4 a	Organ Allocation Policy Implementation *Measures reported by OPTN member organizations during the policy transition period and sustainment*	• Number of OPO offers made on each procured organ before acceptance by transplant center + • Offer modality ++ • Time from offer to clamp • Final sequence at acceptance + • Offer acceptance rate • Cold ischemic time • Number of offer complaint reports associated with an offer +
2.4 a	Organ Allocation Policy Compliance *Adherence to organ allocation policy requirements by OPTN member organizations*	• AOOS rate + • Number of exceptions requested + • Number of exceptions granted + • OPO data reporting compliance + • Transplant center data reporting compliance + • Histocompatibility lab data reporting compliance + • OPO adherence to multi-organ allocation policy requirements + • Number of organs procured for transplant but used for medical research

+ Proposed new measure from existing OPTN member data

++ Proposed new measure not currently collected

**See Appendix C: List of Covariates for a description of characteristics to include recommended for analyses*

EQ 2.5 How did the OPTN monitor and evaluate policy implementation?

Table 12. Measures for Evaluation Question 2.5

EQ	Category	Measures
2.5	OPTN Member Monitoring and Evaluation *Processes implemented by OPTN and OPTN members to track progress, measure results, and assess the effectiveness of the policy*	• Description of monitoring and evaluation process (qualitative) + • Time from policy effective date to first evaluation • Number of OPTN monitoring and evaluation reports publicly disseminated + • Number of modifications to policy after policy enactment +

+ Proposed new measure from existing OPTN member data

Data Sources

Evaluations can include qualitative and quantitative data collection from primary and secondary data sources to establish a comprehensive understanding of organ allocation policy implementation by OPTN members.

Qualitative data sources include findings from the content evaluation, document reviews, and stakeholder engagement. Qualitative data from the content evaluation provide an ideal starting place for understanding how the policy makers intended for stakeholders to implement the policy. Evaluators should use insights from the content evaluation findings related to implement guidance (EQ 1.2a), resource support (EQ 1.3) and monitoring and evaluation expectations (EQ 1.4a) as an important comparison point to describe implementation compliance (EQ 2.3) and OPTN's actual monitoring and evaluation activities (EQ 2.5).

Conducting reviews of policy documents and public comments will yield qualitative data on how policy information dissemination activities (EQ 2.1), stakeholder responses to policy changes (EQ 2.1a), factors that hindered or facilitated implementation (EQ 2.4), and policy monitoring activities and modifications were enacted based on that monitoring (EQ 2.5).

Conducting qualitative key informant interviews with representatives of OPTN member organizations and other stakeholder groups will provide information on how they were informed of the policy (EQ 2.1), their reactions to the policy (EQ 2.1a), how their organizations adapted to and implemented the policy (EQ 2.2), what factors hindered or facilitated implementation (EQ 2.4), and how policy monitoring affected their ongoing implementation of the policy (EQ 2.5). Key stakeholders to engage may include: OPTN organ committee or Board members, representatives from transplant programs, OPOs, histocompatibility laboratories, subject matter experts, and patient advocacy organizations.

Quantitative data collected from secondary data sources will also be needed to describe OPTN members' policy implementation activities (EQ 2.2), compliance with policy requirements (EQ 2.3), and to identify factors impacting implementation (EQ 2.4).

Key implementation evaluation data sources include:

- OPTN Database [21,22]
- CMS Annual OPO Performance Reports [23,24]
- OPTN Member Data [21]
- Public Documentation on OPTN Policies
- Other Public Data Sources (e.g., other relevant federal policies)

Analytic Methods

Qualitative Analyses

EQs 2.1–2.5: Use qualitative analytic methods to answer evaluation questions informed by textual data. Thematic analysis can be used to identify, synthesize, and summarize data from stakeholder interviews, public comments, and policy documentation to identify patterns, challenges, facilitators, and unintended consequences. [25,26] Examine all information to assess if the findings align with intended policy changes.

Quantitative Analyses

Descriptive Analyses

To support the quantitative analysis, describe and understand measurable changes in implementation and compliance before and after the allocation policy change. Calculate frequencies, proportions, and descriptive statistics for key implementation activities, such as number of policy notifications using data from the OPTN database, member documentation, and public policy notices. Assess compliance through measures such as the number of exceptions granted or AOOS rate; calculate rates before and after the policy effective date.

Comparative Analyses and Risk Adjustments

Leverage descriptive analyses to compare implementation and compliance across OPOs and transplant centers. This analysis can provide insight into localized differences in implementation that are less apparent when examining centralized trends from national data. If you identify differences in baseline measures between groups or regions during this stratified analysis, use risk-adjusted models to account for external factors to provide a more accurate comparison of outcomes. Such external confounders should be controlled whenever possible. Additional information on risk-adjusted analyses is provided in the Analytic Methods discussions for Objective 3.

It is of the utmost importance to consider which measures are included in any risk adjustment analysis. Relevant covariates for adjustment will likely depend on the organ of interest and must be based on the evaluator's assessment of relevance to scope of the evaluation and the findings from descriptive and stratified analysis. In addition, measures included in the analysis should be as quantitative and specific as possible. If measures are subjective or can be interpreted in a way that might be manipulated for high reporting scores, then models incorporating those measures may not be reliable and their findings may not give an accurate depiction of the impact of policy changes.

Application of Methodology

EQs 2.1–2.3: Use data from the OPTN database, member documentation, and public policy notices to calculate frequencies, proportions, and descriptive statistics for measures including the number of policy notifications, number of OPO offers made for each procured organ before acceptance, offer acceptance rate, compliance with data reporting requirements, and offer modality. Identify central tendencies of these measures through the descriptive analysis and then stratify them by OPO and transplant center to observe any center-specific or geographic differences in implementation.

EQ 2.2–2.4: Compare descriptive statistics to assess OPTN member compliance with required actions under the organ allocation policy, focusing on measures such as AOOS rate, number of exceptions granted, and adherence to multi-organ allocation policy requirements. Compare compliance rates before and after policy implementation, stratified by OPO and transplant center. Use risk-adjusted models where necessary to account for confounding geographic factors to ensure that any compliance differences are not solely due to external circumstances. Special attention will be given to AOOS events as a key indicator of non-compliance, with findings summarized and potentially stratified for subgroups (e.g., OPO characteristics) to identify patterns and areas for improvement across the system.

EQ 2.5: Assess compliance monitoring and evaluation of policy implementation through a review of measures including the time from policy effective date to first evaluation and the number of OPTN monitoring and evaluation reports publicly disseminated.

A high-level summary of quantitative analytic techniques that should be included in an analysis is provided in Table 13. Refer to the Evaluation Framework Measures Database for additional granularity on how specific measures and covariates map to individual evaluation questions.

Table 13. Summary of Implementation Evaluation Quantitative Analysis Techniques

EQ	EQ Content	Quantitative Analysis Techniques
2.1	How were relevant stakeholders informed of the policy?	Calculate descriptive statistics where relevant (e.g., counts) and conduct stratified comparisons across OPOs where possible.
2.2	How did OPTN members implement the policy?	Calculate descriptive statistics where relevant (e.g., counts, percentages, central tendencies, free text response themes). Conduct comparisons before and after policy intervention and stratified comparisons across OPOs or transplant centers using t-tests, chi-square tests.
2.3	To what extent did OPTN members comply with the required actions within the policy?	Calculate descriptive statistics where relevant (e.g., counts, proportions, central tendencies, rates). Conduct comparisons before and after policy intervention and stratified comparisons across OPOs or transplant centers using t-tests, chi-square tests.
2.4	What factors impacted policy implementation and compliance?	Calculate descriptive statistics where relevant (e.g., free text themes). Conduct comparisons before and after policy intervention and stratified comparisons across OPTN member characteristics using t-tests, chi-square tests. Conduct multivariable regression-based approaches including linear/logistic regression for quantitative and binary outcomes respectively to account for external factors such as CMS ranking, geographic location, and rurality.
2.5	How did the OPTN monitor and evaluate policy implementation?	Calculate monitoring and evaluation measures (e.g., counts, time measures).

Objective 3. Assess Policy Impact

The Framework's third objective evaluates outcomes and other impacts of an organ allocation policy. It examines whether the policy achieved its intended goals and identifies unanticipated consequences. The impact assessment captures changes in outcomes for patients across the organ procurement and transplant pathway by comparing key outcomes before and after the policy's effective date and any subsequent policy updates.

Policy Impact Evaluation Questions

The Framework's impact evaluation questions and sub-questions (Table 14) assess the impact of the organ allocation policy on patients, organizations, and other stakeholders.

Table 14. Evaluation Questions to Assess Policy Impact

Policy Impact Evaluation Questions
Patient Outcomes Across the Organ Transplant Pathway
3.1. How did the composition of patient populations engaged in the transplant pathway change after the policy took effect? a. What evidence is there of reduced access to transplant for any specific patient populations?
3.2. How did patient outcomes change across the transplant pathway after the policy took effect? a. What factors are associated with these changes? b. Which patient populations saw improved or declined patient outcomes? Why?
Impacts on Organ Procurement from Deceased Donor Patients
3.3. How did the composition of deceased donor patient populations change for outcomes across the organ procurement pathway?
3.4. How did the quality of procured organs change?
3.5 How did organ procurement outcomes from deceased donor patients change? a. What factors are associated with these changes?
Impacts on Organ Procurement and Transplantation System
3.6. How did the policy impact OPTN members and other organizations? (Consider impacts to key organizational resources, activities, and operations.)
3.7. How did the policy impact changes in organ procurement and transplantation spending? (Consider medical and non-medical spending.)
3.8. How did organ procurement from living donor patients change following implementation of the organ allocation policy?

Evaluation Measures

Each impact evaluation question and sub-question is associated with selected quantitative and qualitative measures to answer these questions (Table 15 through Table 21). Quantitative data collection will primarily use secondary data from the OPTN database. Qualitative data collection may

include abstracting narrative text from written OPTN documents and key informant interviews with stakeholders.

The following categories of measures and covariates are included in the impact evaluation:

- Transplant Pathway Progression
- Patient Characteristics (Potential Candidate, Candidate Patient, Recipient Patient)
- Pre-Waitlist Patient Outcomes
- Waitlist and Transplant Patient Outcomes
- Post-Transplant Patient Outcomes
- Organ Procurement Pathway Progression
- Donor Patient Characteristics (Deceased Donor Patient, Living Donor Patient)
- Procured Organ Characteristics (Deceased Donor Patient, Living Donor Patient)
- Organ Procurement Outcomes from Deceased Donor Patients
- OPTN Member Characteristics
- OPO and Transplant Center Impacts
- Organ Procurement and Transplantation Spending
- Organ Procurement and Transplant Outcomes from Living Donor Patients

---

EQ 3.1 How did the composition of patient populations engaged in the transplant pathway change after the policy took effect?

a. What evidence is there of reduced access to transplant for any specific patient populations?

Table 15. Measures for Evaluation Question 3.1

EQ	Category	Measures
3.1 a	Patient Characteristics *Description of patient demographic and clinical attributes*	• Number of potential candidate, candidate, and recipient patients by: ○ Age ○ Sex ○ Race ○ Ethnicity ○ Citizenship ○ Country of residence ○ Geographic region ○ Diagnosis ○ Comorbidities ○ Blood type ○ Calculated Panel Reactive Antibody (CPRA) ○ Pediatric status ○ Multi-organ failure ○ Organ type(s) ○ Height ○ Weight ○ Number of waitlisting centers (multi-listing) ○ Insurance status/type ○ Neighborhood poverty level ○ Rurality ○ Education level
3.1 a	Transplant Pathway Progression *The composition of potential candidate, candidate, and recipient patient populations at progressive stages of the transplant pathway for organ transplants from deceased donor patients*	• Number of patients completing the following stages of the transplant pathway for transplants from deceased donor patients: Potential candidate patients ○ Referral to transplant center +++ ○ Completion of evaluation process +++ ○ Waitlisting selection committee convened +++ Candidate patients ○ Waitlisted for transplant ○ Receipt of at least one primary organ offer + Recipient patients ○ Transplant performed ○ 1-year survival after transplant ○ 2-year survival after transplant

+ Proposed new measure from existing OPTN member data

+++ Proposed new measure. Data collected by the pre-waitlist "Referral and Evaluation Registration Form." This data collection mechanism is in development and data availability date is TBD.

EQ 3.2 How did patient outcomes change across the transplant pathway after the policy took effect?

a. What factors are associated with these changes?
b. Which patient populations saw improved or declined patient outcomes? Why?

Table 16. Measures for Evaluation Question 3.2

EQ	Category	Measures
3.2 a, b	Pre-Waitlist Patient Outcomes *Transplant pathway stages prior to waitlisting for transplants from deceased donor patients*	• Potential candidate patient ○ Preemptive referral (kidney only) ○ Referred for transplant +++ ○ Reason not referred for transplant+++ ○ Death after pre-waitlist removal +++ ○ Completed evaluation process +++ ○ Waitlisting selection committee convened +++ ○ Reason declined for waitlist
3.2 a, b	Waitlist and Transplant Patient Outcomes *Transplant pathway stages from when patient is registered on the waitlist until when an organ procured from a deceased donor patient is surgically placed into a recipient patient*	• Candidate patient ○ Waitlisted ○ Days on waitlist ○ Reason for waitlist removal ○ Status at waitlist removal ○ Deaths after waitlist removal ○ Number of primary organ offers received + • Recipient patient ○ Transplant performed
3.2 a, b	Post-Transplant Patient Outcomes *Transplant pathway stages after transplant surgery is performed with an organ procured from a deceased donor patient*	• Recipient patient ○ Post-transplant mortality ○ Post-transplant survival ○ Acute rejection within one year ○ Length of hospital stay post-transplant ○ Rate of post-transplant hospital re-admission
3.2 a, b	Patient Characteristics (Covariates for analysis) *Demographic and clinical attributes of potential candidate, candidate, and recipient patients for organ transplants from deceased donor patients*	• Potential candidate, candidate, and recipient patient characteristics *

+ Proposed new measure from existing OPTN member data

+++ Data collected by the pre-waitlist "Referral and Evaluation Registration Form." This data collection mechanism is in development and data availability date is TBD.

**See Appendix C: List of Covariates for a description of characteristics to include recommended for analyses*

EQ 3.3 How did the composition of deceased donor patient populations change for outcomes across the organ procurement pathway?

EQ 3.4 How did the quality of procured organs change?

Table 17. Measures for Evaluation Questions 3.3 and 3.4

EQ	Category	Measures
3.3, 3.4	Organ Procurement Pathway Progression *The composition of potential deceased donor patient populations and procured organs characteristics at progressive stages in the procurement pathway*	• Number of potential deceased donor patients or procured organs with completion of the following progressive stages of the organ procurement pathway: Potential deceased donor patients ○ Referred to OPO ○ Authorized to donate Procured organs (from deceased donor patients) ○ Offered to a patient + ○ Accepted for transplant ○ Surgery completed to procure organ for transplant ○ Transported to transplant center ○ Transplanted ○ Graft survival at 1 year post transplant
3.3, 3.4	Donor Patient Characteristics *Clinical and demographic attributes of donor patient populations*	• Number of deceased donor patients by: ○ Age ○ Sex ○ Race ○ Ethnicity ○ Citizenship ○ Geographic region ○ Rurality ○ Organ type(s) ○ Cause of death ○ Comorbidities ○ Blood type ○ Height ○ Weight ○ Brain death or donation after circulatory death
3.3, 3.4	Procured Organ Characteristics *Clinical attributes of procured organs*	• Number of procured organs from deceased donor patients by: ○ Hepatitis C virus (HCV) status ○ Cold ischemic time

+ Proposed new measure from existing OPTN member data

EQ 3.5 How did organ procurement outcomes from deceased donor patients change?

a. What factors are associated with these changes?

Table 18. Measures for Evaluation Question 3.5

EQ	Category	Measures
3.5	Organ Procurement Outcomes from Deceased Donor Patients *Availability and utilization of organs procured from deceased donor patients*	• Number of organs authorized from deceased donor patients • Number of organ offer refusals • Organ offer refusal reasons • Number of organs procured from deceased donor patients • Number of organs procured per deceased donor patient • Number of organs transplanted from deceased donor patients • Organ nonuse from deceased donor patients
3.5 a	Donor Patient Characteristics (Covariates for analysis) *Clinical and demographic attributes of donor patient population*	• Deceased donor patient characteristics *
3.5 a	Procured Organ Characteristics (Covariates for analysis) *Clinical attributes of procured organs*	• Procured organ characteristics from deceased donor patients *
3.5 a	OPTN Member Characteristics (Covariates for analysis) *OPTN member characteristics associated with organ allocation policy impact*	• OPO characteristics * • Transplant center characteristics *

**See Appendix C: List of Covariates for a description of characteristics to include recommended for analyses*

EQ 3.6 How did the policy impact OPTN members and other organizations? (Consider impacts to key organizational resources, activities, and operations.)

Table 19. Measures for Evaluation Question 3.6

EQ	Category	Measures
3.6	OPO Impacts *Ways that the policy impacted OPO operations, practices, and resource needs beyond the intentional changes made to comply with the policy*	• CMS defined donation rate (all organs) • CMS defined transplant rate (all organs) • CMS performance tier
3.6	Transplant Center Impacts *Ways that the policy impacted transplant center operations, practices, and resource needs beyond the intentional changes made to comply with the policy*	• Number of patients waitlisted • Offer acceptance rate (all organs) • Transplant rate (all organs) • Annual transplant number (all organs)

EQ 3.7. How did the organ allocation policy impact changes in organ procurement and transplant spending? (Consider medical and non-medical spending)

Table 20. Measures for Evaluation Question 3.7

EQ	Category	Measures
3.7	Organ Procurement and Transplantation Spending *Medical and non-medical costs associated with organ procurement and transplantation*	• OPO annual costs • Procurement travel and logistics costs • Organ preservation and perfusion costs for evaluated organ types • Organ preservation and perfusion costs for all procured organ types • Transplant center annual budget

EQ 3.8 How did organ procurement from living donor patients change following implementation of the organ allocation policy?

Table 21. Measures for Evaluation Question 3.8

EQ	Category	Measures
3.8	Organ Procurement and Transplantation Outcomes from Living Donor Patients *Availability and use of organs procured from living donor patients*	• Number of organs procured from living donor patients • Number of procured organs transplanted from living donor patients
3.8	Donor Patient Characteristics (Covariates for analysis) *Clinical and demographic attributes of donor patient populations*	• Living donor patient characteristics *

**See Appendix C: List of Covariates for a description of characteristics to include recommended for analyses*

Data Sources

The impact evaluation builds off findings from the policy content and implementation evaluations. The OPTN database is the key data source for the impact evaluation measures. Other recommended data sources include secondary data collection opportunities from public OPTN documentation and members.

Key data sources could include:

- OPTN Database [21,22]
- CMS Annual OPO Performance Reports [23,24]
- CMS Healthcare Cost Report Information System

  - *Hospital Cost Reports* [27]
  - *OPO Cost Reports* [28]
- OPTN Member Data [21]
- Public Documentation on OPTN Policies

In addition to secondary data and existing documentation, primary data collection from key informant interviews will be necessary to understand the policy impacts. Key stakeholders to engage may include OPTN organ committee or Board members, representatives from transplant programs, OPOs, histocompatibility laboratories, subject matter experts, and patient advocacy organizations.

Analytic Methods

Qualitative Analyses

EQ 3.1–3.8 Conduct qualitative analysis of data from key informant interviews with stakeholders. Thematic analysis can be used to identify patterns, challenges, facilitators, and unintended impact on donor and recipient patients, OPOs, transplant centers, and system-wide outcomes.

Quantitative Analyses

Descriptive Analyses

To describe and understand any potential changes in composition of patient populations, summarize patient characteristics at each stage of the transplant pathway for comparable time periods before and after the allocation policy change. This analysis helps identify central trends in how the populations of patients eligible for transplants, recipient patients, and deceased donor patient organs have changed before and after the policy implementation. It is important to describe patient population characteristics and pre-transplant outcomes (i.e., transplant referral/evaluation/waitlisting) prior to interpreting outcomes further along the organ procurement and transplantation pathway, as the impact of those earlier factors will trickle down to later outcomes.

Comparative Analyses and Risk Adjustments

The descriptive analyses can be leveraged to compare populations at each stage of the transplant pathway to identify unanticipated changes in candidate or donor patient populations. This analysis can provide insight into changes in transplant outcomes that may be unique to certain populations or demographic groups, and less apparent when examining the entire population. For instance, broader organ distribution may result in increased availability for subpopulations with increased comorbidities or geographic areas with unique coverage features.

When comparing transplant outcomes (e.g., post-transplant survival), consider both unadjusted and risk-adjusted comparisons of populations.

- *Unadjusted comparisons* directly compare the outcomes before and after the policy change, which incorporates the impact of the policy as well as the non-policy related factors. This comparison can be performed for an entire population but should also be performed across strata based on the results of the comparison of patient population characteristics. For example, stratification can reveal disparities in outcomes associated with geographic regions that are difficult to detect when examining nationwide data.

- *Risk-adjusted comparisons* typically involve the comparison of outcomes (in this case, outcomes before and after implementation of an allocation policy) using a model that accounts for differences in underlying characteristics that could influence the outcome. An allocation policy change can impact these underlying characteristics, such as patient waitlist characteristics. As a result, the model effectively indicates the impact of the allocation policy on transplant outcomes while holding the characteristics of the waitlist population or the deceased donor patient organs constant. While this may be advantageous for comparing outcomes, it may obscure important changes in the patient populations and should be used in combination with the stratified analysis described above.

Review the existing scientific literature assessing outcomes associated with organ allocation policy changes for the organ in question. Individual studies often attempt to address relevant demographic and clinical confounders—such as age, sex, race, body mass index (BMI), blood type—and secular trends by adjusting for them in models. Some note the importance of adjusting for confounders while being careful not to adjust for mediators through which the policy intervention impacts populations and outcomes.[29]

If differences are identified in baseline measures between groups during the descriptive analysis that could affect the observed outcomes, use risk-adjusted models to account for these differences and provide a more accurate comparison of outcomes. Given the robust number of quantitative measures involved in the impact evaluation, carefully assess the assumptions and limitations of various risk-adjusted models, including those developed by the Scientific Registry of Transplant Recipients (SRTR), and select the most appropriate approach for each outcome measure to ensure valid inferences. Also consider external factors that should be adjusted for in the model because they covary with the policy change, as well as those that could potentially confound assessing the impact of that change.

Consider which measures are critical to include for risk adjustment analysis. Relevant covariates for adjustment will likely depend on the organ of interest and must be based on the evaluators assessment of clinical relevance and findings from descriptive analysis. In addition, measures included in the analysis should be as quantitative and specific as possible. If measures are subjective or can be interpreted in a way that might be manipulated for high reporting scores, then models incorporating those measures may not be reliable and their findings may not give an accurate depiction of the impact of policy changes. Additionally, while the literature tends to use regression adjustment to develop a regression model that includes the confounding variables in the model, alternative models can be considered based on the focus of the evaluation. Covariate matching is an option to compare an outcome for pre and post policy change groups that have similar distributions of covariates. Mixed effect models could also be developed, to include related or clustered covariates in their models, such as regional environmental factors or patient characteristics. The completeness of the data should also be thoroughly investigated when selecting an analytic approach and in disseminating the results. It is likely that data will be missing in some instances, and patterns or trends in missing data may be as important to identify as analysis results.

Application of Methodology

EQ 3.1–3.2: Assess the impact on patient outcomes across the organ transplant pathway by leveraging the descriptive statistics described above to assess any comparative statistical differences. Stratify this data over progressive steps in the transplant pathway as well as geographically to assess if any underlying differences occur at the OPO or transplant center level. Compare patient characteristics such

as diagnosis, comorbidities, and CPRA across transplant centers. Also consider comparing patient characteristics across transplant organ types to ensure the policy is driving the change in patient population and not an external driver of all patient demographics. Next, develop risk adjusted models to adjust for any factors that may be impacting the outcomes, such as underlying changes in patient characteristics, regional differences, or secular trends, that are external to the change in policy.

EQ 3.3–3.5: Assess the impact on organ procurement from deceased donor patients by assessing the descriptive statistics of the deceased donor patient population composition (e.g., donor patient clinical characteristics including comorbidities) and procured organ quality (e.g., cold ischemic time and donor patient HCV status) across the pathway and stratifying those statistics by OPO. Compare trends and stratified statistics to understand the proportions of organ transplant and organ non-use out of the total number of organs procured. Adjust for external donor patient characteristics, regional differences, and secular trends through risk adjusted models.

EQ 3.6–3.8: Assess the impact on the organ procurement system by looking at differences in OPTN member impact measures (e.g., OPO CMS defined transplant rates), living donor patient characteristics (e.g., organs procured and transplanted from living donors), and spending compared through stratified analysis by OPO and transplant center. Consider and compare, where possible, OPO annual costs and transplant center annual budgets, preservation and perfusion costs, and both medical and non-medical spending.

A high-level summary of quantitative analytic techniques that should be included in an analysis is provided in Table 22. Refer to the Evaluation Framework Measures Database for additional granularity on how specific techniques map to individual measures.

Table 22. Summary of Impact Evaluation Quantitative Analysis Techniques

EQ	EQ Content	Quantitative Analysis Techniques
3.1	How did the *composition* of patient populations engaged in the transplant pathway change after the policy took effect?	Calculate descriptive statistics across the series of measures pre- and post-policy change. Conduct statistical tests (e.g., t-test, chi-square test) to compare composition before and after policy intervention. Use difference-in-difference methods to compare pre- and post-intervention across patient populations.
3.2	How did patient *outcomes* change across the transplant pathway after the policy took effect?	Calculate descriptive statistics where relevant (e.g., days on waitlist) and conduct comparisons pre- and post-policy intervention within patient population using t-tests, chi-square test. Use Difference-in-Difference methods to evaluate policy impact between patient populations. Use multivariable regression-based approaches including Cox Proportional Hazards for time to event (e.g., survival) outcome, and linear/logistic regression for quantitative and binary outcomes, respectively. Explore factors of the population with respect to their influence on outcomes.

EQ	EQ Content	Quantitative Analysis Techniques
3.3	How did the *composition* of deceased donor patients change for outcomes across the organ procurement pathway?	Calculate descriptive statistics across the series of measures before policy and then after policy. Conduct statistical tests (e.g., t-test, chi-square test) to compare composition before and after policy intervention. Use Difference-in-Difference methods to compare pre- and post- intervention across patient populations.
3.4	How did the *quality* of procured organs change?	Calculate descriptive statistics across the series of measures pre- and post-policy change. Conduct statistical tests (e.g., t-test, chi-square test) to compare composition before and after policy intervention. Derivation may be required for some measures to capture quality (e.g., ratio of organs recovered to organs transplanted).
3.5	How did organ *procurement outcomes* from deceased donor patients change?	Calculate descriptive statistics across the series of measures pre- and post-policy change. Conduct statistical tests (e.g., t-test, chi-square test) to compare composition before and after policy intervention. Derivation may be required for some measures to capture procurement. Use multivariable regression-based approaches including linear/logistic regression for quantitative and binary outcomes respectively.
3.6	How did the policy impact OPTN members and other organizations?	Traditional descriptive statistics to be calculated pre/post intervention and compared using statistics (t-tests, chi-square tests, etc.).
3.7	How did the policy impact changes in organ procurement and transplantation spending?	Traditional descriptive statistics to be calculated pre/post intervention and compared using statistics (t-tests, chi-square tests, etc.).
3.8	How did organ procurement from living donor patients change following implementation of the organ allocation policy?	Calculate descriptive statistics across measures of living donor patient characteristics and outcomes pre- and post-policy change. Conduct statistical tests (e.g., t-test, chi-square test) to compare composition before and after policy intervention. Use Difference-in-Difference methods to compare pre- and post- intervention across living donor patient populations.

3. Using the Evaluation Framework

This Evaluation Framework can help HHS evaluate organ allocation policies as they are published, implemented, and subsequently updated. Its structured guidance promotes consistency and transparency in organ allocation policy evaluation, which in turn can inform future policy development. The Framework is flexible and can be adapted to the objectives of the specific organ allocation policy being evaluated. It can be used to conduct different levels of evaluation, from modest to more robust. Scope the evaluation according to the current strategic priorities, timeline, and available resources.

Developing Your Evaluation Plan Based on the Framework

Confirm Evaluation Purpose and Scope

Develop a statement of the evaluation's purpose and scope based on the Framework's objectives. Use the flexibility of the Framework to choose one or more of the three objectives and decide if evaluators will tackle them concurrently or sequentially:

1. Objective 1: Assess policy content.
2. Objective 2: Assess policy implementation.
3. Objective 3: Assess policy impacts.

Establish Timelines and Allocate Resources

Establish the overall policy evaluation timeline and allocate appropriate resources to complete the activities. The timing of an evaluation relative to the effective date of a new policy may vary from one policy to the next, so it is important to consider how the policy and evaluation timelines overlap. Allow sufficient time to engage stakeholders in the process (See Engaging Stakeholders).

Appendix A provides additional guidance related to scoping, timelines, and resources.

Describe Evaluation Methods

Once you have scoped the evaluation, develop a written plan to assess the organ allocation policy's content, implementation, and impact (as it aligns with your scope). Use the Framework to select and adapt evaluation questions and measures for objectives in scope and decide how you will gather and analyze measures data.

Engaging Stakeholders

Stakeholder engagement is critical for ensuring that the evaluation produces meaningful outcomes. Engaging them early in the evaluation planning will ensure the evaluation's quality, relevance, and effectiveness. Direct engagement with stakeholders captures perspectives that are not documented in written sources, especially from those whose voices are not frequently represented. Direct engagement also provides opportunities to build collaboration and consensus around recommendations for the organ allocation policy and future evaluation.

Think about engaging stakeholders to help determine evaluation objectives, to help gather primary data for measures, and to validate your evaluation findings. This can be done through interviews, listening sessions, or focus groups.

Using Evaluation Findings

Document Evaluation Conclusions

Develop evaluation conclusions based on the information you gather using the Framework. While your evaluation may not include multiple objectives (e.g., assessing organ allocation policy content, implementation, and impact), consider how and when to integrate findings across evaluation questions and data sources. For example, OPTN member feedback on a specific organ procurement outcome could provide valuable information on challenges to implementing a step in the organ procurement pathway. Develop a plan to communicate the evaluation methods and key findings to stakeholders to support transparency.

Develop Recommendations to Enhance Organ Allocation

Synthesize evaluation conclusions to develop action-oriented recommendations for each objective selected from the Evaluation Framework. Identify ways to continuously improve future allocation policies and recommend clear, concise actions HHS could make to achieve the policy goals. Consider the organ allocation policy context, feasibility, and alignment with overarching HHS priorities.

Consider recommendations related to the following types of actions:

- Modifications to the evaluated organ allocation policy content.
- Guidance for future organ allocation policy development processes.
- Suggestions for future OPTN member policy compliance incentives or consequences.
- Considerations for OPTN member data collection and reporting processes.

It is critical to engage HHS leaders and other key stakeholders to affirm that proposed recommendations are realistic, feasible, efficient, effective, and relevant.

4. Appendices

The Appendices provide additional background information for the Framework, guidance to support evaluation planning, recommended resources, acronyms, and glossary term definitions.

Appendix A. Timelines and Resource Considerations

Before detailed planning of the evaluation can begin, undertake important preparatory activities to properly establish the purpose and scope of the evaluation. This section expands upon information highlighted in III. Using the Evaluation Framework. Explore this section for guidance to confirm the evaluation purpose and scope and establish timelines and allocate resources for the evaluation.

Establish Timelines and Allocate Resources

After confirming the evaluation's purpose and scope, establish a schedule and budget resources to ensure timely completion of all activities. The timing of an evaluation relative to a policy's effective date is critical and varies depending on the policy. Consider key questions, such as when the evaluation can begin, how long to wait after implementation before collecting data, the duration of evaluation activities, and whether time-sensitive data must be gathered on a specific schedule.

Three potential scenarios for evaluation timing should be considered:

1. **Starting before the policy's effective date**, where preparatory activities, stakeholder engagement, and planning can begin early, enabling faster data collection and reducing overall evaluation time.
2. **Starting at the policy's effective date**, where preparation begins with the final policy in hand, allowing some time for planning before data collection, though the evaluation may take slightly longer.
3. **Starting after the policy's effective date**, where retrospective analysis of secondary data is possible, but opportunities for early primary data collection may be missed, potentially delaying findings.

Each scenario has trade-offs, and these factors must be weighed to ensure the most effective and timely evaluation process.

The list below provides some details about scheduling dependencies and assumptions.

1. **Evaluation Planning**: Develop a detailed evaluation plan for each selected evaluation objective. Prioritize policy content evaluation planning so that work can begin before overall planning is completed. Findings from the assessment of policy content will likely inform planning for the implementation and impact evaluations. *Allow time for updates to the final plan after the policy content is completed.*

2. **Policy Content Evaluation**: This objective examines the policy documents and can involve direct engagement with stakeholders. The complexity of evaluated organ allocation policy and the scope of the stakeholder engagement activities will impact your content evaluation timelines. A summary of the findings from this assessment will provide valuable insights for the planning and conduct of the implementation and impact evaluations.

3. **Implementation Evaluation**: This should start after the policy content evaluation is completed, since the content evaluation will likely provide valuable insights that inform the implementation evaluation. Assume the policy has been in effect for at least six months before the implementation evaluation begins. Time will be required to obtain data (either from secondary sources or through primary data collection) and then for preparing and analyzing the data. Preparing summaries of the methods and findings should occur as early as possible in anticipation of documenting final evaluation results.
4. **Impact Evaluation**: This should start after the policy content evaluation is completed, since the content evaluation will likely provide valuable insights that inform the impact evaluation. Assume the policy has been in effect for at least six months before the impact evaluation begins. Time will be required to obtain data (either from secondary sources and/or through primary data collection) and then for preparing and analyzing the data. Preparing summaries of the methods and findings should occur as early as possible in anticipation of documenting final evaluation results.
5. **Evaluation Reporting:** This is dependent on completing the evaluation's selected objectives. Provide periodic briefings on findings and progress to date before the final report. Time will be required to prepare the final evaluation report and related materials, including time for review of draft versions, revisions, and clearance for public release. Begin documenting methods and findings for each objective to prepare the final evaluation report and related materials.

Appendix B. The Evaluation Framework Measures Database

This section provides a summary of the Evaluation Framework Measures Database. This document is provided as a supplemental resource to be used with the Framework.

The Evaluation Framework Measures Database (Database) provides a detailed list of quantitative and qualitative measures, their data sources, and other key information that map to the evaluation questions and measure categories outlined in the proposed measures tables of the Evaluation Framework. The Database is designed as a resource for evaluators, researchers, and analysts, who are developing analytic plans to evaluate organ allocation policy based on the objectives outline in the Framework.

After identifying the objectives, evaluation questions, and scope for the policy evaluation, the Database should be used to select specific measures that best address the evaluation needs. Measures, as defined in the Database, describe single quantifiable data points obtained from performing a measurement and include measures that combine more than one individual measure. The Database can be filtered and sorted based on the following information to assist in selection of measures:

- Evaluation Question: Identifier corresponding to the evaluation questions and sub-questions for the objectives included in Section 2.
- Measure Name: Name of measure, which corresponds to measures tables in Section 2.
- Measure Description: Short narrative description or definition for the measure.
- Measure Category: Aggregate categories, which correspond to measures tables in Section 2.
- Organ: Selection of one or more organ options from kidney, pancreas, heart, lung, and liver.
- Data Source: A drop-down selection of originating data sources for measures for organ allocation policy evaluation; "not available" is listed for measures that cannot be found in these data sources.
- Data Type: Categorical/binary, numerical, or free text.

The Database also contains information to support planning analyses. The Database contains information on covariates associated with each evaluation question and measure category. These covariates are primarily patient or OPTN member characteristics that should be accounted for in analytics because they could potentially confound the assessment of the policy. The Database includes the following information for the list of covariates:

Evaluation Question and Sub-question: Identifier corresponding to the evaluation questions and sub-questions for the objectives included in Section 2.

Covariate Name: Name of the covariate, which corresponds to Appendix C.

Covariate Description: Narrative description of how the covariate is represented.

Data Source: A drop-down selection of originating data sources for covariates for organ allocation policy evaluation; "not available" is listed for measures that cannot be found in these data sources.

Data Type: Categorical/binary, numerical, or free text.

Appendix C. List of covariates

This section provides a list of the covariates used for analysis. These covariates are supplemental to the measures.

Table 23. Covariates for Analyses

EQ	Category	Covariate
2.4	OPTN Member Characteristics	OPO airport proximity
2.4	OPTN Member Characteristics	OPO budget
2.4	OPTN Member Characteristics	OPO CMS Performance Tier
2.4	OPTN Member Characteristics	OPO geographic region
2.4	OPTN Member Characteristics	OPO organization type
2.4	OPTN Member Characteristics	OPO rurality
2.4	OPTN Member Characteristics	OPO state
2.4	OPTN Member Characteristics	Transplant center airport proximity
2.4	OPTN Member Characteristics	Transplant center budget
2.4	OPTN Member Characteristics	Transplant center geographic region
2.4	OPTN Member Characteristics	Transplant center patient volume
2.4	OPTN Member Characteristics	Transplant center rurality
2.4	OPTN Member Characteristics	Transplant center state
3.2	Patient Characteristics	Candidate patient age
3.2	Patient Characteristics	Candidate patient blood type
3.2	Patient Characteristics	Candidate patient Calculated Panel Reactive Antibody (CPRA)
3.2	Patient Characteristics	Candidate patient citizenship
3.2	Patient Characteristics	Candidate patient comorbidities
3.2	Patient Characteristics	Candidate patient country of residence
3.2	Patient Characteristics	Candidate patient diagnosis

EQ	Category	Covariate
3.2	Patient Characteristics	Candidate patient education level
3.2	Patient Characteristics	Candidate patient ethnicity
3.2	Patient Characteristics	Candidate patient geographic region
3.2	Patient Characteristics	Candidate patient height
3.2	Patient Characteristics	Candidate patient insurance status/type
3.2	Patient Characteristics	Candidate patient multi-organ failure
3.2	Patient Characteristics	Candidate patient neighborhood poverty level
3.2	Patient Characteristics	Candidate patient number of waitlisting centers (multi-listing)
3.2	Patient Characteristics	Candidate patient organ type(s)
3.2	Patient Characteristics	Candidate patient pediatric status
3.2	Patient Characteristics	Candidate patient race
3.2	Patient Characteristics	Candidate patient rurality
3.2	Patient Characteristics	Candidate patient sex
3.2	Patient Characteristics	Candidate patient weight
3.2	Patient Characteristics	Potential candidate patient age
3.2	Patient Characteristics	Potential candidate patient blood type
3.2	Patient Characteristics	Potential candidate patient Calculated Panel Reactive Antibody (CPRA)
3.2	Patient Characteristics	Potential candidate patient citizenship
3.2	Patient Characteristics	Potential candidate patient comorbidities
3.2	Patient Characteristics	Potential candidate patient country of residence
3.2	Patient Characteristics	Potential candidate patient diagnosis
3.2	Patient Characteristics	Potential candidate patient education level
3.2	Patient Characteristics	Potential candidate patient ethnicity
3.2	Patient Characteristics	Potential candidate patient geographic region

EQ	Category	Covariate
3.2	Patient Characteristics	Potential candidate patient height
3.2	Patient Characteristics	Potential candidate patient insurance status/type
3.2	Patient Characteristics	Potential candidate patient multi-organ failure
3.2	Patient Characteristics	Potential candidate patient neighborhood poverty level
3.2	Patient Characteristics	Potential candidate patient number of waitlisting centers (multi-listing)
3.2	Patient Characteristics	Potential candidate patient organ type(s)
3.2	Patient Characteristics	Potential candidate patient pediatric status
3.2	Patient Characteristics	Potential candidate patient race
3.2	Patient Characteristics	Potential candidate patient rurality
3.2	Patient Characteristics	Potential candidate patient sex
3.2	Patient Characteristics	Potential candidate patient weight
3.2	Patient Characteristics	Recipient patient age
3.2	Patient Characteristics	Recipient patient blood type
3.2	Patient Characteristics	Recipient patient Calculated Panel Reactive Antibody (CPRA)
3.2	Patient Characteristics	Recipient patient citizenship
3.2	Patient Characteristics	Recipient patient comorbidities
3.2	Patient Characteristics	Recipient patient country of residence
3.2	Patient Characteristics	Recipient patient diagnosis
3.2	Patient Characteristics	Recipient patient education level
3.2	Patient Characteristics	Recipient patient ethnicity
3.2	Patient Characteristics	Recipient patient geographic region
3.2	Patient Characteristics	Recipient patient height
3.2	Patient Characteristics	Recipient patient insurance status/type
3.2	Patient Characteristics	Recipient patient multi-organ failure

EQ	Category	Covariate
3.2	Patient Characteristics	Recipient patient neighborhood poverty level
3.2	Patient Characteristics	Recipient patient number of waitlisting centers (multi-listing)
3.2	Patient Characteristics	Recipient patient organ type(s)
3.2	Patient Characteristics	Recipient patient pediatric status
3.2	Patient Characteristics	Recipient patient race
3.2	Patient Characteristics	Recipient patient rurality
3.2	Patient Characteristics	Recipient patient sex
3.2	Patient Characteristics	Recipient patient weight
3.3	Donor Patient Characteristics	Deceased donor patient citizenship
3.3	Donor Patient Characteristics	Deceased donor patient rurality
3.4	Donor Patient Characteristics	Deceased donor patient citizenship
3.4	Donor Patient Characteristics	Deceased donor patient rurality
3.5	Donor Patient Characteristics	Deceased donor patient age
3.5	Donor Patient Characteristics	Deceased donor patient blood type
3.5	Donor Patient Characteristics	Deceased donor patient brain death or donation after circulatory death
3.5	Donor Patient Characteristics	Deceased donor patient cause of death
3.5	Donor Patient Characteristics	Deceased donor patient comorbidities
3.5	Donor Patient Characteristics	Deceased donor patient ethnicity
3.5	Donor Patient Characteristics	Deceased donor patient geographic region
3.5	Donor Patient Characteristics	Deceased donor patient height
3.5	Donor Patient Characteristics	Deceased donor patient organ type(s)
3.5	Donor Patient Characteristics	Deceased donor patient race
3.5	Donor Patient Characteristics	Deceased donor patient sex
3.5	Donor Patient Characteristics	Deceased donor patient weight

EQ	Category	Covariate
3.5	Donor Patient Characteristics	Deceased donor patient HCV status
3.5	Procured Organ Characteristics	Procured organ cold ischemic time
3.5	Procured Organ Characteristics	Procured organ HCV status
3.5	OPTN Member Characteristics	OPO airport proximity
3.5	OPTN Member Characteristics	OPO budget
3.5	OPTN Member Characteristics	OPO CMS Performance Tier
3.5	OPTN Member Characteristics	OPO geographic region
3.5	OPTN Member Characteristics	OPO organization type
3.5	OPTN Member Characteristics	OPO rurality
3.5	OPTN Member Characteristics	OPO state
3.5	OPTN Member Characteristics	Transplant center airport proximity
3.5	OPTN Member Characteristics	Transplant center budget
3.5	OPTN Member Characteristics	Transplant center geographic region
3.5	OPTN Member Characteristics	Transplant center patient volume
3.5	OPTN Member Characteristics	Transplant center rurality
3.5	OPTN Member Characteristics	Transplant center state
3.8	Donor Patient Characteristics	Living donor patient age
3.8	Donor Patient Characteristics	Living donor patient ethnicity
3.8	Donor Patient Characteristics	Living donor patient geographic region
3.8	Donor Patient Characteristics	Living donor patient highest education level
3.8	Donor Patient Characteristics	Living donor patient procured organ type(s)
3.8	Donor Patient Characteristics	Living donor patient race
3.8	Donor Patient Characteristics	Living donor patient relationship to transplant recipient patient
3.8	Donor Patient Characteristics	Living donor patient sex

Appendix D. Summary of Relevant Data Sources

This appendix outlines the key data sources proposed for assessing the policy content, implementation, and impact of organ allocation policies. These sources provide essential insights into the policy's development, clinical outcomes, financial operations, and implementation activities across the organ procurement and transplantation system.

OPTN Database[21,22]

The OPTN database contains patient-level information about transplant recipient patients, deceased and living donor patients, and waitlist candidate patients back to October 1987. Transplant programs, organ procurement organizations, and histocompatibility laboratories collect the data and update quarterly. All data within the OPTN database is collected via an online web application called UNet. Transplant professionals from hospitals, histocompatibility (tissue typing) laboratories, and organ procurement organizations located across the country use the application to perform the following tasks:

1. Manage their list of waiting transplant candidate patients.
2. Access and complete electronic data collection forms.
3. Add donor patient information and run donor-recipient patient matching lists.
4. Access various transplant data reports and policies.

The data collection forms comprise the largest percentage of the data collected in the system. The 26 different form types combined contain more than 3,500 data fields.

CMS Annual OPO Performance Reports[23,24]

CMS publishes annual OPO performance reports to assess and publicly share how OPOs are performing in key areas of organ procurement and transplantation. These reports are part of a four-year recertification cycle and are integral in promoting transparency and accountability within the organ procurement and transplantation system. The two primary metrics of these reports are the OPO's donation rate (number of actual donor patients per 100 potential donor patients) and the transplantation rate (number of organs transplanted per 100 donor patients). CMS categorizes OPOs into three tiers based on these metrics. These reports use data provided by the National Center for Health Statistics mortality data (potential donor patients) and the OPTN database (actual donors and transplanted organs).

CMS Healthcare Cost Report Information System

Hospital Cost Reports[27]

CMS mandates that each CMS-certified hospital file a CMS-2552-10 (Hospital Cost Report) annually. The CMS-2552-10 is a cost report form used by Medicare-certified hospitals (including transplant hospitals) to report their annual costs and charges related to providing healthcare services. Transplantation-related costs are included in worksheet D4 (Organ Acquisition Cost Centers) and form the basis for the CMS settlement paid to transplantation hospitals.

OPO Cost Reports[28]

The CMS-216-94 is a cost report form used by freestanding OPOs to report their annual financial, operational, and organ acquisition data to CMS. Data includes organ acquisition metrics, financial and cost data, histocompatibility lab data, and information on reimbursement and settlement. The data in this form include reports of cost reporting periods beginning on or after October 1, 2018. The OPO94 Cost Report Data contains cost and statistical data for Organ Procurement Organizations only. The dataset includes only the most precise version of each cost report filed with CMS. The dataset is normally updated quarterly and is available by the last day of the month following the quarter's end.

Medicare Cost Reports data are reported separately by cost center, meaning there are multiple organ-specific costs included in the reports. Data collection is mandatory and standardized, ensuring consistency and transparency in reporting. However, organizations have up to 18 months following the end of the fiscal year to finalize their Cost Reports, which introduces a significant delay in availability of data. Therefore, the data can be useful for retrospective analysis but may not be timely enough to use in the evaluation framework.

OPTN Member Data[21]

OPTN members maintain data that is valuable and informative to organ allocation policy evaluation but not stored, or consistently maintained, in the OPTN database. Investigators may request this data from the OPTN members. Types of data maintained by members that could inform evaluation efforts include:

- Policy and protocol documentation
- Annual budget/cost data
- Waitlisting requirements
- Standard Acquisition charge
- Transportation/logistics data
- Other organ transplant data (e.g., perfusion technique use and cost)
- Patient experience surveys‡
- Program evaluations‡

‡This data is not collected/maintained at all programs. Transplant centers would have to be contacted to identify which ones may have this type of data.

Public Documentation on OPTN Policies

OPTN allows the public, including transplant professionals, patients, donor patient families, and researchers, to comment on proposed policy changes before they are finalized. The proposals and comments are publicly available on the OPTN public comment site.[30] The process is designed to ensure transparency and stakeholder engagement in shaping organ transplantation policies. Additionally, OPTN committee and Board of Directors reports and meeting minutes are also publicly available.[31] These data can provide insights into the intended outcomes of the policy, concerns raised in its development, general perceptions, and can indicate overall awareness of new policies.

Other Public Data Sources

Depending on the scope of the evaluation and/or the content of the policy under evaluation, other publicly available data sources may be of interest to investigators to provide general contextual background that may inform the interpretation of analysis results. Examples include other federal policies that may affect the organ procurement and transplantation system (e.g., policy changes in immunosuppressive drug coverage) or public health data on epidemiological trends or emergencies that may impact system outcomes (e.g., COVID-19).

Appendix E. Acronym List

This appendix provides a list of acronyms used throughout the document to assist readers in understanding the terminology and abbreviations.

Acronym	Definition
AOOS	Allocation Out of Sequence
BMI	Body Mass Index
CD	Continuous Distribution
CMS	Centers for Medicare & Medicaid Services
CPRA	Calculated Panel Reactive Antibody
FFRDC	Federally Funded Research and Development Corporation
HCV	Hepatitis C Virus
Health FFRDC	Health Federally Funded Research and Development Center
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
INR	International Normalized Ratio
MELD	Model for End-Stage Liver Disease
NOTA	National Organ Transplant Act
OPO	Organ Procurement Organization
OPTN	Organ Procurement and Transplantation Network
PELD	Pediatric End-Stage Liver Disease
PTR	Potential Transplant Recipient
SRTR	Scientific Research and Transplant Registry

Appendix F. Glossary

This appendix includes a list of terms related to organ procurement and transplantation. Many of the terms come from the glossary found on Organ Procurement and Transplantation Network's (OPTN) website: https://optn.transplant.hrsa.gov/patients/glossary. Terms with an asterisk (*) have definitions updated from the original source based on HHS input.

Allocation: The process of determining how organs are distributed. Allocation includes the system of policies and guidelines that ensure that organs are distributed in a consistent, ethical, and medically sound manner.[32]

Allocation Policies:* Rules established by OPTN to guide organ allocation and distribution in the United States.[32]

Clamp time: The time at which the flow of blood to a particular organ has been clamped off during a procurement.[32]

Committees: OPTN committees address issues of concern in the transplant community. OPTN currently maintains approximately 20 standing committees, a fluctuating number of ad hoc committees (established by the President to address a specific issue as it arises), subcommittees, and joint subcommittees (created and maintained by standing committees). Committees are comprised of professionals, at least one Patient/Public representative, Minority Affairs Committee Representative, Pediatric Committee Representative, and one or more SRTR representatives.[32]

Critical Comment: A formal written concern submitted to HHS related to the way the OPTN is carrying out duties and/or OPTN policies. To promote greater transparency, HRSA has directed the OPTN to publish critical comments submitted to the OPTN as well as the OPTN responses. The critical comments process is described in 42 C.F.R. part 121.[33] The OPTN webpage provides critical comment letters and directives from HRSA to the OPTN in response to critical comments.[17]

Deceased Donor Patient: An individual from whom at least one solid organ is recovered or the purpose of transplantation after suffering brain death or cardiac death.[32]

Designated Transplant Program: A transplant program that has been found to meet the requirements of § 121.9 and is therefore a member of OPTN.[33]

Direct Offer: An organ offer that is made by a host OPO directly to another OPO or a transplant center for a specific recipient patient.[34]

Donation Service Area: The geographic area designated by Centers for Medicare & Medicaid (CMS) that is served by one organ procurement organization (OPO), one or more transplant centers, and one or more donor hospitals. Formerly referred to as Local Service Area or OPO Service Area.

End-Stage Organ Disease: A disease that leads to the permanent failure of an organ.[32]

Graft Survival: The length of time an organ functions successfully after being transplanted.

Histocompatibility: The examination of human leukocyte antigens in a patient, often referred to as "tissue typing" or "genetic matching." Tissue typing is routinely performed for all donor and recipient patients in kidney and pancreas transplantation to help match the donor with the most suitable recipient patients to help decrease the likelihood of rejecting the transplanted organ.[32]

Living Donor Patient: A living person who donates an organ for transplantation, such as a kidney or a segment of the lung, liver, pancreas, or intestine. Living donor patients may be blood relatives, emotionally related individuals, or altruistic strangers. These may also include domino heart or liver transplants.[32]

Match Run: A computerized ranking of transplant candidate patients based upon donor and candidate patient medical compatibility and criteria defined in OPTN policies.[32]

Model for End-Stage Liver Disease (MELD): The scoring system used to measure illness severity in liver transplant candidate patients. This system is used in the allocation of livers to adults, established in February 2002. The MELD system uses several laboratory values (bilirubin, serum sodium, international normalized ration [INR], albumin, and serum creatinine) [35] to calculate a score that is predictive of the risk of death within three months on the liver waiting list. Livers are allocated to waitlisted patients with chronic liver disease based upon this score. See Pediatric End Stage Liver Disease (PELD) Scoring System.[32]

National Organ Transplant Act (NOTA): The National Organ Transplant Act (1984 Public Law 98-507), approved October 19, 1984, and amended in 1988 and 1990, outlawed the sale of human organs and provided for the establishment of the Task Force on Organ Transplantation; authorized the Secretary of HHS to make grants for the planning, establishment, and initial operation of qualified OPOs; and established the formation of the OPTN and SRTR.[32]

OPTN Board of Directors: The governing body for the OPTN. Directors are elected by the members of OPTN for two- or three-year terms. The general composition of the Board of Directors is set forth in the OPTN Final Rule and includes transplant professionals, Health Resources and Services Administration (HRSA) representatives, members of the public, living donor patients, transplant candidate patients, recipient patients, and their families. (Source: OPTN Management and Membership Policies, Appendix M).

OPTN Computer Match Program: A set of computer-based instructions that compares data on a cadaveric organ donor with data on transplant candidate patients on the waiting list and ranks the candidate patients according to OPTN policies to determine the priority for allocating the procured organ(s).[34]

OPTN Member Evaluation Plan: The detailed document describing procedures related to how OPTN assesses OPTN member compliance with OPTN policies and by-laws.[32]

Organ Placement Process: When organs are donated, the host OPO accesses the national transplant computer system online or they contact the OPTN Organ Center. Information about the donor patient is entered into the system and a donor-recipient patient match is run for each donated organ. The resulting match list of potential recipient patients is ranked according to criteria defined in that organ's allocation policy. Each organ has its own specific criteria. Using the match list of potential recipient patients, the host OPO's Organ Procurement Coordinator or the Organ Placement Specialist in the Organ Center contacts the transplant center of the highest ranked patient, based on policy criteria, to be offered the organ. If the organ is turned down, the next potential recipient patient's transplant center on the match list is contacted until the organ is placed. Once the organ is accepted for a patient, transportation arrangements are made, and transplant surgery is scheduled.[32]

Organ Allocation Policy Non-Compliance: When an organ is offered or accepted or transplanted into a transplant candidate or potential transplant recipient in a way that is not consistent with OPTN policy.

This included noncompliance due to deviations from the match sequence (see allocation out of sequence [AOOS]). [16, 36]

Organ Procurement: * The removal or retrieval of organs from a donor patient for transplantation.[32]

Organ Procurement Organization (OPO): * An organization designated by CMS and responsible for the procurement of organs for transplantation and the promotion of organ donation. OPOs serve as the link between the donor patient and transplant recipient patient and are responsible for the identification of donor patients, and the retrieval, preservation, and transportation of organs for transplantation. They are also involved in data follow-up about deceased organ donor patients. OPOs also engage in public education about the critical need for organ donation.[32]

Organ Procurement and Transplantation Network (OPTN): * A non-profit, private sector entity comprised of all U.S. transplant centers, organ procurement organizations, and histocompatibility laboratories. The purpose of OPTN is to improve the effectiveness of the nation's organ procurement and transplantation system by increasing the availability of and access to procured organs for patients with end-stage organ failure.[32]

Patient Survival: The length of time a patient survives after receiving a transplant.[32]

Pediatric End Stage Liver Disease (PELD) Scoring System: A measure of illness severity used in the allocation of livers to pediatric candidate patients, established in February 2002. The PELD system uses three laboratory values (albumin, bilirubin, and INR), a presence of growth failure (at least two standard deviations below average height or weight), and an indicator of whether the patient is less than one year of age to calculate a score predictive of the risk of death within three months on the liver waiting list for candidate patients under the age of 18. See Model for End-Stage Liver Disease (MELD).[32]

Policy Development Process: The continuous process by which OPTN creates, refines, and implements ethical, evidence- and consensus-based policies and standards for the procurement, allocation, distribution and transplantation of organs in the U.S. [32]

Potential Transplant Recipient or Potential Recipient: A transplant candidate patient who has been ranked by the OPTN computer match program as the person to whom an organ from a specific cadaveric organ donor is to be offered.[33]

Public Comment: A pivotal step in the policy making process, public comment assures that the perspectives and concerns of the general public are taken into account and addressed in policy proposals. Generally speaking, the period for public comment is 45 days.[32]

Refusal Reasons: Number codes used on a match run to show the reason an organ was not accepted for a Potential Transplant Recipient (PTR) receiving the offer.[32]

Scientific Registry of Transplant Recipients (SRTR): A national database of transplant statistics developed to support ongoing evaluation of the scientific and clinical status of solid organ transplantation, including kidney, heart, liver, lung, intestine, and pancreas. Data in the registry are collected by the OPTN from hospitals and OPOs across the country.[9]

Transplant Candidate Patient or Candidate Patient: An individual who has been identified as medically suited to benefit from an organ transplant and has been placed on the waiting list by the individual's transplant program.[33]

Transplant Hospital: A hospital in which organ transplants are performed. [33]

Transplant Program: A component within a transplant hospital that provides transplantation of a particular type of organ.[32]

Transplant Recipient Patient: A person who has received an organ transplant.[37]

UNet: A centralized computer network that links transplant hospitals, OPOs, and histocompatibility labs on one secure web-based transplant platform. Transplant professionals use UNet to list patients for transplant, match patients with available organs, and submit required OPTN data.[38]

Waiting List: The OPTN computer-based list of transplant candidate patients.[33]

REFERENCES

[1] Congressional Research Service, "Organ procurement and transplantation: Administration, oversight, and policy issues." CRS Report No. R48426. [Online]. Available: https://www.congress.gov/crs-product/R48426

[2] United States Senate Committee on Finance, "Operation Transplant: Examining the need for oversight in the organ donation system." [Online]. Available: https://www.grassley.senate.gov/imo/media/doc/operation_transplant_staff_report.pdf

[3] Organ Procurement and Transplantation Network, "National data." [Online]. Available: https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#

[4] U.S. Department of Health and Human Services, "Organ Donation System." [Online]. Available: https://www.organdonor.gov/learn/organ-donation-statistics

[5] *National Organ Transplant Act*. 1984. [Online]. Available: https://www.congress.gov/bill/98th-congress/senate-bill/2048

[6] Organ Procurement and Transplantation Network, "Continuous distribution." [Online]. Available: https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/

[7] Organ Procurement and Transplantation Network, "Lung continuous distribution policy." [Online]. Available: https://optn.transplant.hrsa.gov/professionals/by-organ/heart-lung/lung-continuous-distribution-policy/

[8] Health Resources & Services Administration, "Modernization in Action: Advancing Oversight and Policy Reform." [Online]. Available: https://www.hrsa.gov/optn-modernization/updates/july-2025

[9] Scientific Registry of Transplant Recipients, "About SRTR." [Online]. Available: https://www.srtr.org/

[10] S. Leppke *et al.*, "Scientific Registry of Transplant Recipients: Collecting, analyzing, and reporting data on transplantation in the United States." *Transplantation Reviews*, vol. 27, no. 2, pp. 50–56, Apr. 2013, https://doi.org/10.1016/j.trre.2013.01.002

[11] S. Weiss, C. Weibel, and T. Mupfudze, "Lung continuous distribution three month monitoring report." Organ Procurement and Transplantation Network, DHHS Contract No. 250-2019-00001C, July 2023. [Online]. Available: https://optn.transplant.hrsa.gov/media/fzhh1e5r/data_report_lung_committee_cd_07_13_2023.pdf

[12] S. Weiss and C. Weibel, "Lung continuous distribution six month monitoring report." Organ Procurement and Transplantation Network, DHHS Contract No. 250-2019-00001C, Oct. 2023. [Online]. Available: https://optn.transplant.hrsa.gov/media/4feooi1h/data_report_lung_cd_6month_20231027.pdf

[13] S. Weiss and C. Hawkins, "Lung continuous distribution one year monitoring report," Organ Procurement and Transplantation Network, DHHS Contract No. 250-2019-00001C, May 2024. [Online]. Available: https://optn.transplant.hrsa.gov/media/srino34s/data_report_lung_cd_1year_20240509.pdf

[14] S. Weiss and C. Weibel, "Lung continuous distribution – blood type rating scale modification: Three month monitoring report." Organ Procurement and Transplantation Network, DHHS Contract No. 250-2019-00001C, Feb. 2024. [Online]. Available: https://optn.transplant.hrsa.gov/media/s1oj32jz/data_report_lung_cd_abo_3month_20240208.pdf

[15] S. Weiss and C. Hawkins, "Lung continuous distribution 18-month monitoring report." Organ Procurement and Transplantation Network, DHHS Contract No. 250-2019-00001C, Dec. 2024.

[Online]. Available: https://optn.transplant.hrsa.gov/media/ndicxb1i/data_report_lung_cd_18month_20241212.pdf
[16] Organ Procurement and Transplantation Network, "Staying compliant: What you need to know about AOOS." [Online]. Available: https://optn.transplant.hrsa.gov/news/staying-compliant-what-you-need-to-know-about-aoos/
[17] Organ Procurement and Transplantation Network, "OPTN critical comments and directives." [Online]. Available: https://optn.transplant.hrsa.gov/policies-bylaws/optn-critical-comments-and-directives/
[18] Scientific Registry of Transplant Recipients, "Donation and Transplant System Explorer." [Online]. Available: https://www.srtr.org/tools/donation-and-transplant-system-explorer/
[19] Organ Procurement and Transplantation Network, "10-Step policy development process." [Online]. Available: https://optn.transplant.hrsa.gov/media/3115/optn-policy-development-process-explanatory-document.pdf
[20] Organ Procurement and Transplantation Network, "Policies." [Online]. Available: https://optn.transplant.hrsa.gov/policies-bylaws/policies/
[21] Organ Procurement and Transplantation Network, "OPTN database." [Online]. Available: https://optn.transplant.hrsa.gov/data/about-data/optn-database/
[22] Organ Procurement and Transplantation Network, "STAR File Data Dictionary." [Online]. Available: https://optn.transplant.hrsa.gov/media/1swp2gge/star-file-data-dictionary.xlsx
[23] Centers for Medicare & Medicaid Services, "The transplant eco-system: The role of data in CMS oversight of the organ procurement organizations." [Online]. Available: https://www.cms.gov/blog/transplant-eco-system-role-data-cms-oversight-organ-procurement-organizations
[24] Centers for Medicare & Medicaid Services, "Organ Procurement Organizations: Annual Public Aggregated Performance Report." [Online]. Available: https://www.cms.gov/files/document/opo-annual-public-performance-report-2023.pdf
[25] M. Miles, A. Huberman, and J. Saldaña, *Qualitative data analysis: A methods sourcebook*. 4th ed. Sage Publications, 2020.
[26] J. Saldaña, *The coding manual for qualitative researchers*, 2nd ed. Sage Publications, 2013.
[27] Centers for Medicare & Medicaid Services, "Hospital 2552-2010 form." [Online]. Available: https://www.cms.gov/data-research/statistics-trends-and-reports/cost-reports/hospital-2552-2010-form
[28] Centers for Medicare & Medicaid Services, "Organ Procurement Organization." [Online]. Available: https://www.cms.gov/data-research/statistics-trends-reports/cost-reports/organ-procurement-organization
[29] A. B. Massie *et al.*, "Early changes in liver distribution following implementation of Share-35." *Am J Transplant*, vol. 15, no. 3, pp. 659–667, Mar. 2015. https://doi.org/10.1111/ajt.13099
[30] Organ Procurement and Transplantation Network, "Public Comment." [Online]. Available: https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/
[31] Organ Procurement and Transplantation Network, "Committees." [Online]. Available: https://optn.transplant.hrsa.gov/about/committees/
[32] Organ Procurement and Transplantation Network, "Glossary." [Online]. Available: https://optn.transplant.hrsa.gov/patients/glossary/
[33] *42 CFR 121 § Allocation of organs.* 2024. [Online]. Available: https://www.ecfr.gov/current/title-42/part-121
[34] The Alliance, "Terminology & Data References." [Online]. Available: https://www.organdonationalliance.org/resources/terminology-data-references/

References

[35] Organ Procurement and Transplantation Network, "MELD calculator." [Online]. Available: https://optn.transplant.hrsa.gov/data/allocation-calculators/meld-calculator/
[36] Organ Procurement and Transplantation Network, "Allocation Out of Sequence (AOOS)." [Online]. Available: https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/allocation-out-of-sequence-aoos/
[37] U.S. Department of Health and Human Services, "Glossary." [Online]. Available: https://www.organdonor.gov/learn/glossary
[38] Organ Procurement and Transplantation Network, "Programming VCA Allocation in UNet." [Online]. Available: https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/programming-vca-allocation-in-unet/