OPTN Modernization Discovery Task Summary
Patient Safety Analysis

Introduction

HRSA is leading a historic modernization of the Organ Procurement and Transplantation Network (OPTN), designed to improve transparency, performance, governance, and efficiency. As part of this effort, HRSA engaged an independent contractor, Summome, to perform detailed analyses of patient safety information and data captured, processed, and managed by the OPTN operations contractor. This summary encompasses project engagements in 2024 and 2025, with four final documents delivered to HRSA and shared here.

Purpose

In 2024, HRSA asked Summome to obtain, study, and describe all existing patient safety information and data to strengthen HRSA's oversight of the national system. This initial quantitative analysis report was intended to improve HRSA's understanding of how patient safety events are reported, tracked, and resolved, and by identifying potential areas for data, process, and governance improvement.

Also in 2024, Summome examined HRSA's patient safety oversight framework—governance, data systems, workflow, communication, staffing, and culture—to identify opportunities to enhance transparency and consistency in program management. Summome's findings in these areas are in the 2024 assessment report.

After reviewing Summome's 2024 work, and adopting interim process improvements to address the most urgent concerns, HRSA determined that additional analyses were warranted. Summome completed a second project in 2025 to review an updated data set and engage in qualitative analysis of information and data regarding alleged safety and compliance issues among OPTN members.

In total, Summome analyzed 2,856 patient safety complaints recorded in the OPTN contractor's **Master Case List (MCL)** from 2019 through 2024:

- **Quantitative Analysis** assessed complaint volumes, classifications, risk levels, and data completeness

- **A subsequent Qualitative Thematic Analysis** applied structured manual and natural-language processing (NLP) coding of free-text narratives to identify trends and root causes

Together, the 2024 and 2025 analyses offer a system-level picture of patient safety reporting, documentation, and governance in the OPTN. This summary reflects Summome's findings across these time periods and mixed methods analyses reports.

Disclaimer

This document summarizes the findings and recommendations of the contractor. It is provided for informational and transparency purposes only and does not represent the official policy or endorsement of the U.S. Department of Health and Human Services (HHS) or the Health Resources and Services Administration (HRSA). All final decisions regarding solicitations, requirements, and implementation rest solely with the U.S. Government. Additionally, HRSA will ensure that the OPTN, through close collaboration with the Board of Directors and other stakeholders, advises, reviews, and provides necessary input to enable HRSA to match vendor services to the needs of the OPTN.

Contractor's Current-State Findings

Summome's analysis of the OPTN's current patient safety approach is categorized into five key areas:

1. Data Quality and Completeness

Summome found that the quality, consistency, and accessibility of patient safety data varied significantly, limiting the Government's ability to conduct longitudinal oversight.

- **Completeness and Consistency**
  - Of 2,856 complaints, 17 % lacked a recorded risk rating, 13 % contained blank or unknown classifications, and many pre-2022 records were missing key lifecycle dates (e.g., HRSA notification, closure, referral to MPSC)
  - Documentation improved modestly in 2022 onward, but no master data dictionary or change log was maintained to track evolving field definitions
- **Standardization Gaps**
  - Terms such as *case, referral,* and *turndown* were used inconsistently across systems and years
  - New classification categories added in 2022 (e.g., "Organ and Extra Vessels") lacked cross-mapping to previous labels, complicating trend analysis
- **Multiple Systems and Identifiers**

        - Three different case-management systems were used between 2019 and 2024, each with unique identifiers
        - Historical records lost timestamps and notes during data migrations, and no single universal case identifier existed to link related complaints across systems
    - **Narrative Limitations**
        - Although 95 % of records included free-text fields, nearly 40 % were too brief or ambiguous to classify cause or outcome reliably
        - About 40 % of sampled events were "unclassifiable", often because narratives lacked descriptions of what occurred or what actions followed
    - **Oversight Implications**
      Incomplete and non-standardized data limit HRSA's ability to:
        - Measure timeliness of investigations
        - Track recurrence of similar safety events
        - Identify members with repeated or systemic issues

2. Complaint and Event Patterns (2019 – 2024)

Despite documentation challenges, Summome's analysis revealed consistent trends in who reports safety events, where they occur, and what types of issues recur.

- **Volume and Disposition**
    - Total complaints nearly doubled (331 → 640) from 2019 to 2024 (+93 %)
    - 72 % became formal cases; 8 % were referred to other OPTN functions (Allocations or Site Survey), and 13 % were closed as outside scope
    - Documentation of "unknown" statuses decreased after 2021, suggesting maturing practices
- **Reporter and Subject Profiles**
    - Transplant Centers (46 %) and OPOs (43 %) were the primary subjects of complaints
    - The same groups were also major reporters—transplant centers filed 45 % of complaints, OPOs 18 %, labs 2 %
    - Self-reporting averaged 31 % overall (68 % for OPOs vs. 38 % for transplant centers), reflecting differing organizational cultures
- **Risk Levels**
    - 76 % "common," 4 % "priority," 3 % "exceptional." Seventeen percent had no recorded risk rating
    - Risk designation did not always correlate with outcome severity — some fatal events were still tagged as "common"
- **Event Types and Phases**

- Four categories made up ≈ 75 % of coded events:
  1. **Administrative/Documentation Errors** – 44 % of no-harm cases (data entry, labeling, reporting delays)
  2. **Organ Procurement Errors** – 56 % of procurement events involved organ injury or packaging issues
  3. **Organ Allocation Errors** – Allocation out of sequence (35 %), late declines (27 %), and communication issues (12 %)
  4. **Transport/Logistics Failures** – ≈ 11 % of procurement events involved delays or lost shipments
     - Most incidents occurred during Procurement (56 %) and Transplant (31 %) phases — the most complex, time-sensitive points of the process
     - Living donor phases accounted for 12 % of events but had the highest proportion of severe outcomes (24 %), largely due to mandatory OPTN reporting rules

- **Severity and Harm**
  - 46 % of events = no detectable harm; 22 % = indirect harm (delays or inefficiencies); 8 % = physical harm; < 5 % = death
  - Most deaths occurred in living donor cases, many unrelated to transplant procedures
  - Harm categories were applied inconsistently, often by inference rather than evidence
- **Geographic Patterns**
  - Eight states (CA, TX, NY, FL, PA, OH, TN, NC) produced ≈ 50 % of complaints, reflecting transplant volume distribution
  - Adjusted for transplant activity, NV, AL, IA, KY, and NM showed higher-than-average complaint rates (> 2 %), possibly indicating stronger reporting cultures or process variability

3. Root Causes and Contributing Factors

Summome's qualitative analysis coded events across six dimensions (impacted individual, outcome, phase, event type, responsible party, cause). Patterns point to systemic — not isolated — drivers of patient safety risk.

- **Process and System Design**
  - The most common root cause, present in ≈ 35 % of all classifiable events, was Process or System Design failure

        - Within this category, Policy/Protocol Deviations greatly outnumbered Deficiencies, signifying that policies exist but are not consistently followed
        - These findings suggest a need for compliance auditing and training rather than new policy creation
    - **Human Factors**
        - Accounted for ≈ 12 % of weighted events overall, but 21 % during living donor phases
        - Typical issues included skill-based errors (organ handling, surgical technique, documentation accuracy) and inattention during time-critical activities
        - Fatigue-related errors were rare but noted in a small number of transplant center cases
    - **Communication Failures**
        - Comprised 10–15 % of weighted events, primarily during allocation and handoffs between OPOs and transplant centers
        - Delayed or incomplete information transmission was a major source of indirect harm and operational inefficiency
    - **Responsible Parties**
        - Transplant Centers (36 %) and OPOs (30 %) were most frequently identified as responsible entities
        - Labs and transport vendors were involved less often but their errors frequently cascaded downstream
        - 12 % of cases had an "unclassifiable" responsible party, which correlated with incomplete narratives
    - **Systemic Implications**
        - The analyses show that OPTN patient safety risks are predominantly process-driven, not policy-driven
        - Enhancing policy adherence, verification steps, and inter-system communication may yield greater improvement than creating new rules
        - Key risk points include organ handoffs, allocation decisions, and transport logistics — where time pressure and multi-party coordination create vulnerability

4. Governance and Oversight

Summome found that HRSA's oversight was limited by lack of real-time data access and reliance on periodic reports.

5. People, Culture, and Technology

Summome found that HRSA's patient safety team demonstrated commitment and expertise but would benefit from clearer role delineations and standardized onboarding materials.

Contractor's Future-State Recommendations

Summome identified six future-state recommendations to improve patient safety oversight:

1. **Data Management**
   - Develop a comprehensive HRSA-accessible complaint dashboard and repository
   - Adopt a data dictionary and version control
   - Introduce unique case IDs and minimum data-entry standards for all contractors
2. **Governance**
   - Establish a Joint Operations Committee to coordinate HRSA–contractor oversight of patient safety
3. **Process Standardization**
   - Define and align triage, risk scoring, and documentation requirements across all OPTN contracts
4. **Culture and Workforce**
   - Promote a just culture of safety
   - Clarify HRSA staff roles using RACI matrices
   - Support staff development and succession planning
5. **Technology and Communication**
   - Implement a secure, centralized platform for complaint intake, tracking, and collaboration
   - Modernize secure email capabilities
6. **Transparency**
   - Encourage periodic publication of aggregate patient safety trends and outcomes to enhance public trust