

Task Order 3: Patient Safety

Current State Assessment, Gap Analysis, & Recommendations

August 2024

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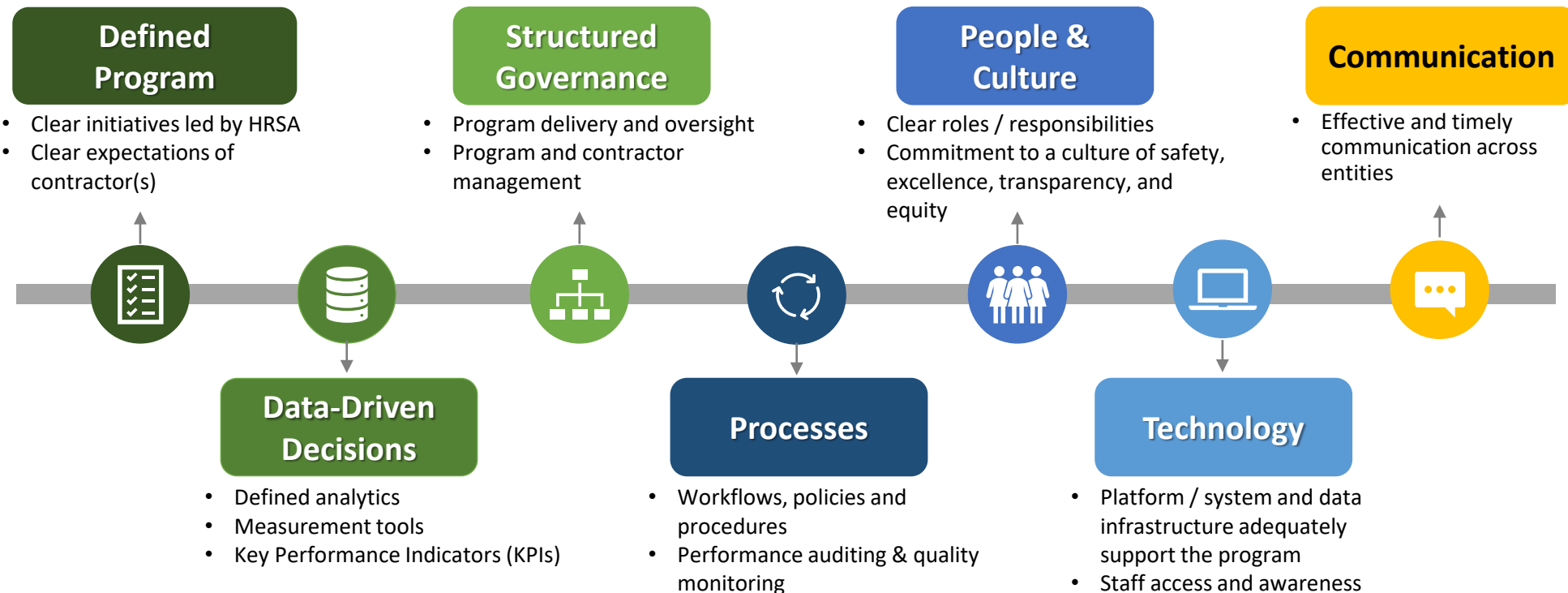
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Gap Analysis Observational Framework




*This presentation highlights Patient Safety standards of excellence, gaps and observations, and associated recommendations aligned to HRSA modernization efforts. Leveraging the seven domains below, the project team conducted a gap analysis to perform a holistic review of the patient safety framework ecosystem, comprised of HRSA and their contractor. The project support team reviewed patient safety documents, available data, and facilitated conversations with HRSA and stakeholders to **identify areas for improvement, critical gaps in processes, constraints to improvement, essential stakeholders, and leading practice standards.***

Gap Analysis Observational Framework







Executive Summary

*The Patient Safety Gap Analysis identifies areas of opportunity and recommendations to improve the effectiveness and efficiency of how patient safety concerns and incidents are addressed by HRSA and its partners. **This analysis incorporates people, process, and technology tactics to identify opportunities for improvement and drive outcomes in patient safety.***

		Observations & Gaps	Recommendations
	Defined Program	<ul style="list-style-type: none">• Program goals and improvement targets need additional clarity for both the agency and contractor• Minimal documentation around contractor's program management (e.g., metrics, processes, etc.)• OPTN has ensured a level of transparency by providing publicly-available patient safety resources online	<ul style="list-style-type: none">• Evaluate existing program goals and establish programmatic improvements based on HRSA initiatives within OPTN• Regularly review and evaluate contractor documentation of processes and metrics to ensure contractor accountability• Continue to not only provide access, but ensure adequate awareness and transparency of online patient safety resources
	Data-Driven Decisions	<ul style="list-style-type: none">• Limited transparency of contractor data and data quality are variable• Limited ability to track and trend outcomes of OPTN member activities related to patient safety• Current contractor data documentation practices hinder data quality and accessibility	<ul style="list-style-type: none">• Contractor(s) can develop a comprehensive, HRSA-accessible dashboard of key metrics, complaint tracker, and repository for member-specific files• HRSA and contractor(s) can evaluate data documentation standards and practices to ensure high-quality, consistent data
	Structured Governance	<ul style="list-style-type: none">• Limited routine communication between HRSA and contractor Patient Safety teams hinders HRSA's ability to evaluate and enhance program management, standards, reporting, and outcomes	<ul style="list-style-type: none">• Consider implementing a joint operations committee (JOC) between HRSA and contractor(s) with structured standing agenda items to ensure transparency and alignment on patient safety cases, KPIs, and monitoring effectiveness• Suggest contractor responsibilities into future HRSA oversight requirements

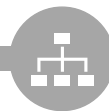
Executive Summary

		Observations & Gaps	Recommendations
	Processes	<ul style="list-style-type: none"> • Opportunity for contractor to standardize and document processes surrounding complaint triage, assignment, and HRSA notification/communication • Limited transparency of contractor processes and complaint outcomes hinders HRSA's ability to ensure contractor compliance and performance 	<ul style="list-style-type: none"> • HRSA could define certain documentation standards if multiple contractors are utilized to ensure consistency across patient safety programs (e.g., risk criteria, turndown/referral/case criteria, etc.) • Contractor(s) can clearly define and document patient safety processes for routine HRSA evaluation and review
	People & Culture	<ul style="list-style-type: none"> • HRSA Patient Safety team clearly understands and is committed to program goals and vision • Current uncertainty around individual roles, responsibilities, and specialized skillsets results in potential inefficiencies 	<ul style="list-style-type: none"> • Continue to encourage individual growth within roles by providing and leveraging resources intentionally and providing opportunities for greater autonomy • HRSA can align job descriptions, processes, and policies to optimize patient safety staff roles, skillsets/licensure, and work activities
	Technology	<ul style="list-style-type: none"> • Data transparency and timely reporting are hindered by contractor's lack of HRSA-accessible comprehensive digital platforms to track complaints, store member-specific files, and access key metrics 	<ul style="list-style-type: none"> • Contractor(s) can develop a single complaint tracker, a single repository for member-specific files, and a single dashboard for KPIs • Comprehensive digital platforms could be HRSA-accessible to allow passive access
	Communication	<ul style="list-style-type: none"> • Lack of routine communication between HRSA and the contractor hinders relationship development and transparency into patient safety investigations and initiatives 	<ul style="list-style-type: none"> • Consider enhancing bidirectional communication between HRSA and contractor(s) patient safety teams by implementing touchpoints to ensure alignment around initiatives, investigations, role expectations, and role delineation




Defined Program

Evaluation of goals and role clarity within HRSA's Patient Safety team.





Gap Analysis & Recommendations: Defined Program

Evaluation Criteria: Standard of Excellence	Current State Analysis: Observations & Gaps	Leading Practice Standards: Recommendations
<ul style="list-style-type: none">Clearly defined program goals and standards of excellence guide the program	<ul style="list-style-type: none">Program goals and improvement targets are not clearly defined for the agency or its contractor(s) based on programmatic standards	<ul style="list-style-type: none">Establish targeted programmatic improvements based on key HRSA initiatives within OPTN and aligned to HRSA agency and HHS goals broadlyEvaluate existing program goals and define Program Tenets <p> <i>Reference Document: Patient Safety Program Tenets</i></p>
<ul style="list-style-type: none">Defined program monitoring process to ensure up-to-date information, program robustness, and consistency	<ul style="list-style-type: none">Unclear expectations and metrics for documentation of activities for contractor accountability	<ul style="list-style-type: none">Perform a regular review to monitor and audit documents/ definitions/processes to ensure they're up-to-date and remain aligned to leading practiceRoutine monitoring and auditing improves transparency and monitoring effectiveness to ensure high reliability principles and build an environment of continuous improvement
<ul style="list-style-type: none">Mature programs have clearly defined terminology, easily accessed by all parties	<ul style="list-style-type: none">No clearly defined glossary of terms or clearly outlined documentation of all processes from the contractor perspective; within the patient safety process triage form , there are three risk levels (1-Exceptional, 2-Priority, and 3-Common), but only risk level 1 has details and a definition	<p>  Contractor(s) can offer documentation of all processes, criteria, forms, glossary of terms/definitions, etc. for HRSA review; HRSA can then thoroughly review and align to the leading practice standard</p>
<ul style="list-style-type: none">Public access to information should be a core tenet of patient safety and transparency of the program	<ul style="list-style-type: none">There are many patient safety resources OPTN has published online and are accessible to the public	<ul style="list-style-type: none">HRSA could evaluate the OPTN online presence to enhance patient safety education resources and ensure continued alignment with modernization initiatives



Quick Win



Suggested HRSA Oversight Requirement



Reference Document: Patient Safety Program Tenets

The patient safety program is dedicated to **fostering a just culture and ensuring accountability**. By **promoting an environment of continuous learning** and improvement, the program drives **high reliability** in quality and safety.

- 1 Leadership Commitment:** Leadership is committed to patient safety, setting clear expectations of the patient safety team, and providing necessary resources.
- 2 Culture of Safety:** Promote a culture where safety is a priority, encouraging open communication about errors, near misses, and potential risks.
- 3 Standardization of Practices:** Develop and implement standardized protocols and procedures to ensure consistent and high-quality patient safety oversight
- 4 Continuous Education & Training:** Provide ongoing education and training to OPTN members on patient safety principles and best practices, including routine review of case studies and engagement with patients and their families.
- 5 Data Analysis:** Establish robust systems for analyzing and sharing data on patient safety incidents to identify trends, root causes, and areas for improvement.
- 6 Risk Management:** Implement an overarching risk management strategy to proactively identify and mitigate potential patient safety issues.
- 7 Communication & Transparency:** Ensure clear, consistent, and transparent communication within and between organizations.
- 8 Accountability & Measurement:** Set clear accountability and measure performance against established metrics.
- 9 Collaboration & Coordination:** Foster collaboration and coordination within and among all agencies and contractors to ensure optimal patient care and safety throughout the transplantation process.
- 10 Regulatory Compliance:** Ensure contractors adhere to relevant regulations, standards, and federal agency requirements.





Data-Driven Decisions

Evaluation of the structures, processes, and quality of Patient Safety data management to help drive changes and improvements.






Gap Analysis & Recommendations: Data-Driven Decisions

Evaluation Criteria: Standard of Excellence	Current State Analysis: Observations & Gaps	Leading Practice Standards: Recommendations
<ul style="list-style-type: none">Centralized source of regularly updated KPIs and information to guide decision-making and provide transparency	<ul style="list-style-type: none">There is no current dashboard nor KPIs to measure program outcomes and to track/trend casesData are housed in different places by the contractor, making it infeasible to access and trend over timePatient safety complaints, investigations and outcomes are documented in multiple files and systems (e.g., MCL, performance review data, case management systems, etc.); UNOS has had multiple case management systems over a five-year period	<ul style="list-style-type: none"> Contractor(s) can develop a comprehensive dashboard of key metrics populated by the contractor that HRSA staff can passively access to track and trend patient safety data Contractor(s) can develop a single complaint tracker that fully captures the narrative of the case, case status, dates for each step of the investigative process, and outcomes; this can be used to see high-level case statuses and member complaint history Contractor(s) can develop a single repository for member-specific files that encapsulates medical records, case notes, correspondence, member-provided reports, etc.; this can be used to access case- and member-specific documentationComplaint and investigation details could be housed as structured data to feed the HRSA-accessible comprehensive dashboard (e.g., complaint type, status, policy violations, investigation outcomes, etc.), including MPSC investigation outcomes data
<ul style="list-style-type: none">Clear data governance processes and roles to provide high-quality data for decision-making	<ul style="list-style-type: none">Opportunity for enhanced program tracking through key metrics: current limited data availability impacts the ability to make data-driven decisions; contractor does not have resources solely dedicated to data collection and reporting	<ul style="list-style-type: none">Contractor(s) could supply and measure key metrics, collaboratively developed by HRSA and uniformly understood by all parties <p> <i>Reference Document: KPI Development Framework</i></p>





Gap Analysis & Recommendations: Data-Driven Decisions

Evaluation Criteria: Standard of Excellence	Current State Analysis: Observations & Gaps	Leading Practice Standards: Recommendations
<ul style="list-style-type: none">• Data standardization of KPIs and definitions across all reporting entities to support data reliability and cleanliness	<ul style="list-style-type: none">• Transparency of data received by contractor is limited and data quality are variable• Common terms are not defined in documentation and often have multiple definitions for each term leading to confusion in communication; e.g., “substantiation” can indicate a complaint has merit for further investigation, or it can signify the complaint was valid after investigation• A directory listing member names, member codes, and hospital numbers is currently unavailable• MPSC investigation outcomes are not documented in the MCL, and the absence of a case identifier does not allow complaints to easily be tied to outcomes in the Performance Review Data file• Complaints, outcomes, and performance data are documented at the member level, restricting UNOS or HRSA from reviewing, tracking, and trending surgeon-level patient safety and performance data• The absence of surgeon-level data presents a challenge in monitoring surgeons with a history of policy violations and/or poor outcomes when they transition to other member organizations	<ul style="list-style-type: none">• Contractor(s) may develop a data dictionary to accompany the Master Case List that documents each field, its meaning, and appropriate data format (e.g., numbers, free text, etc.)•  Minimum standards for reporting and data quality can be developed by HRSA and subsequently met by contractor(s)• HRSA could collaboratively develop a standardized glossary of terms to provide to contractor(s) to minimize confusion and ensure clarity in communication★ Contractor can develop a HRSA-accessible member directory with all identifiers★ Contractor can assign unique identifiers to all complaints, ensuring the identifier remains associated with the respective complaint throughout the investigative process• Contractor can incorporate a discrete data field to track surgeon name and NPI in the case management system, MCL and dashboard• Surgeon-level patient safety and outcome data could be reviewed on an annual basis, at minimum, to ensure individual accountability as appropriate and available




Quick Win



Suggested HRSA Oversight Requirement



Gap Analysis & Recommendations: Data-Driven Decisions

Evaluation Criteria: Standard of Excellence	Current State Analysis: Observations & Gaps	Leading Practice Standards: Recommendations
<ul style="list-style-type: none">Data reporting processes are defined and consistently managed across all reporting entities	<ul style="list-style-type: none">Data aggregation and report development are highly manual processes for the contractor and therefore time consumingCurrent documentation does not readily capture the full lifecycle of a complaint from its initial identification to the UNOS or MPSC investigation outcomeDocumentation appears to be completed retrospectively by the contractor and there is no clear description of the status of the activities, particularly of open casesLack of versioning prevents tracking of changes in data elements over timeRisk scores are assigned at initial case review, however those changes may or may not be reflected in the MCL, which therefore does not accurately reflect the rationale and/or decision-making by the contractor to move cases between risk levels	<ul style="list-style-type: none">Data entry and point of reporting may be one in the same and tracking could occur systematically until complaint closureContractor(s) can capture the date of the initial risk score, as well as the risk rating; any subsequent actions taken to the risk score can be captured to discretely identify the original value, modified value(s), and date stamps for when each of these modifications occurred★ Versioning can be documented by the contractor(s) to help track changes to data elements over timeContractor(s) can develop a change management document that is updated any time there are modifications to the MCL template or documentation practices, including the addition, removal, or consolidation of fields over timeIn the short term, the current contractor can develop additional documentation defining risk scoring methodology to allow for deeper data dives on complaint riskIn the longer term, HRSA can develop risk scoring methodology for contractor(s) to allow for consistent risk score analyses across contractor(s) <p> <i>Reference Document: Complaint Triage & Risk Level Overview</i></p>



Reference Document: KPI Development Framework

Developing KPIs is essential for measuring and managing the performance of any organization. KPIs provide a clear and objective way to assess progress towards strategic goals, identify areas for improvement, and drive decision-making. The following steps outline a systematic approach to creating meaningful and actionable KPIs that align with organizational objectives.



Define Objectives & Goals

Clearly articulate the objectives and desired goals



Identify Critical Success Factors

Determine the essential areas that must be performed well for the organization to achieve its objectives



Select Relevant Metrics

Select metrics that directly measure the performance of Critical Success Factors; metrics should be specific, measurable, attainable, relevant and time-bound (SMART)



Ensure Data Availability

Verify necessary data is collected and reportable for each metric



Set Targets & Benchmarks

Establish clear targets and benchmarks for each KPI; targets should be realistic and aligned with the overall objective



Assign Responsibility

Assign ownership for each KPI to specific individuals or teams to ensure accountability and responsibility for achieving targets



Develop Reporting & Monitoring Systems

Develop systems and processes for collecting, analyzing, and reporting KPI data



Review & Adjust

Regularly review KPIs to ensure they remain relevant and aligned with strategic objectives



Reference Document: Complaint Triage & Risk Levels Overview

Once complaints are received, the UNOS Patient Safety team completes the Compliance and Safety Investigation Triage Form within two hours of receipt if the complaint is received between 8 am – 10 pm seven days per week. **Complaints are triaged as 1-Exceptional, 2-Priority, or 3-Common.** Risk level is assigned based on the outputs of the Triage Form, and only risk level 1-Exceptional has criteria listed in the Triage Form. The risk level is documented in the Master Case List upon triage. However, **risk level is subject to change throughout the investigative process and the MCL does not denote whether a risk level has been modified since intake.**

Complaint Risk Levels

1 Exceptional

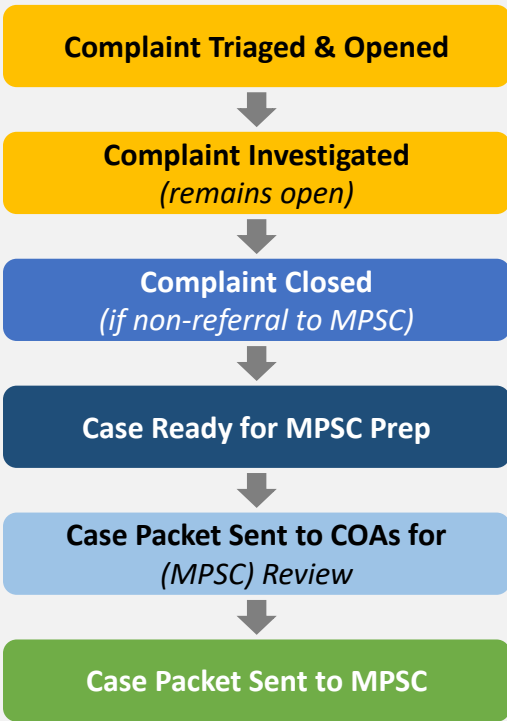
- Living donor death within 1 month of donation and related to donation
- Unintentional transplant of the wrong recipient
- Unintentional transplant of the wrong organ
- Unintentional ABO incompatible transplant
- Failure to obtain donor authorization
- Failure to obtain brain death documentation
- Confirmed unintentional HIV transmission from donor to recipient
- An event that poses a serious or time-sensitive threat to public health or patient safety (including failure to provide a safe environment to patients), regardless of whether there is a suspected or actual violation of OPTN policy or the OPTN final rule

2 Priority

3 Common

Complaint Risk Level Documentation

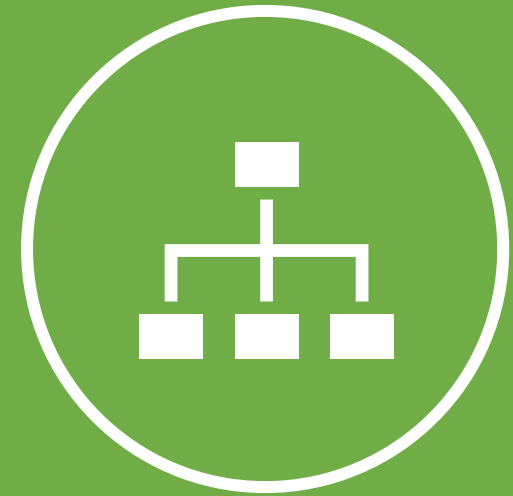
High-Level Complaint Management Process



- Risk is initially determined during complaint intake using the UNOS Compliance and Safety Investigation Triage Form
- Risk is documented in the MCL
- Risk is re-evaluated throughout the investigation process and may be modified at any time
- The revised risk may be updated in the MCL, but **the MCL does not indicate if the documented risk level is initial or revised**




Structured Governance

Evaluation of the Patient Safety program governance to ensure effective contractor oversight.





Gap Analysis & Recommendations: Structured Governance

Evaluation Criteria: Standard of Excellence	Current State Analysis: Observations & Gaps	Leading Practice Standards: Recommendations
<ul style="list-style-type: none"> Agency has clear understanding of contractor(s)' responsibilities to manage patient safety broadly 	<ul style="list-style-type: none"> HRSA has limited visibility into UNOS' monitoring effectiveness Current UNOS reporting does not succinctly track and trend member non-compliance and patient safety complaints over time, making it challenging for HRSA to effectively provide oversight The existing process to evaluate a history of non-compliance relies on a manual review of prior site survey and investigative files, which lacks consistency and introduces subjectivity 	<ul style="list-style-type: none"> Transparency is key and information should be shared freely through passive and active methods from contractor(s) to HRSA  Contractor(s) can succinctly track and trend member compliance and non-compliance over time to properly monitor and manage members systematically and electronically Develop a standing agenda item of "Patient safety monitoring effectiveness review" during newly-created JOC meetings
<ul style="list-style-type: none"> Objective and transparent oversight of operations to identify gaps, needs, and areas for improvement 	<ul style="list-style-type: none"> There is currently no Joint Operations Committee (JOC) within HRSA or with its contractor to periodically evaluate and enhance the program standards, streamline reporting, and track outcomes Minimal public information available regarding the intake and management process for patient safety events 	<ul style="list-style-type: none"> ★ Consider leveraging a bi-monthly leadership/staff JOC to begin standardized program enhancements Contractor(s) can publish information online outlining the patient safety complaint investigation process at a high-level Contractor(s) can publish an annual Patient Safety Report highlighting types of complaints, notable learnings, impact of complaint reporting, and key activities relating to patient safety <p> <i>Reference Document: JOC Framework</i></p>
<ul style="list-style-type: none"> Utilize leading practices to ensure consistent management practices across all contractors 	<ul style="list-style-type: none"> Currently HRSA manages one key contractor for organ transplantation 	<ul style="list-style-type: none"> Explore opportunities to leverage leading practices across contractors and embed responsibilities into future contracts  Recommend contractor(s) use standardized templates and reporting requirements for ease of oversight by HRSA (e.g., complaint tracking fields, risk criteria, complaint classification definition, etc.)





Reference Document: Joint Operations Committee Framework

Charter

The charter should include the following elements:

- Purpose/Charge
- Objectives
- Scope
- Meeting Cadence
- Governance Structure

Membership

Membership could include the following agency/organization representatives:

- HRSA Patient Safety leadership
- HRSA Patient Safety staff/SMEs
- Contractor Patient Safety leadership
- Contractor Patient Safety staff/SMEs

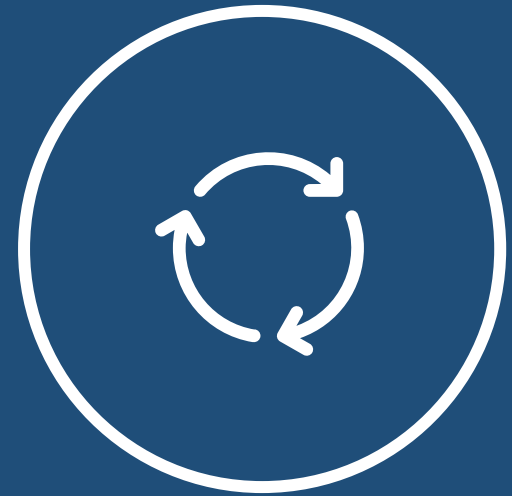
Standing Agenda Items

Standing agenda items are influenced by the meeting cadence, and may include items such as:

- Leader round robin
- Review of new patient safety complaints
- Updates to existing patient safety complaints
- Patient safety monitoring effectiveness review
- Review of KPIs, trends, and patient safety data reports
- Identification of OPTN educational opportunities
- Upcoming key activities or events




Processes

Evaluation of the current processes to support tracking, reporting, and handling of Patient Safety events and data.






Gap Analysis & Recommendations: Processes

Evaluation Criteria: Standard of Excellence	Current State Analysis: Observations & Gaps	Leading Practice Standards: Recommendations
<ul style="list-style-type: none">Clearly defined roles and responsibilities of the entities involved in collaborative and distinct communication processes	<ul style="list-style-type: none">Lack of clarity surrounding specific role responsibilities pertaining to processes such as complaint notification and memo developmentMinimal guidance documented for when HRSA staff are required to develop a memo, what information to include in the memo, and the timeline expectations for memo developmentComprehensive complaint information is not consistently provided by UNOS in the initial complaint notification, thus resulting in the need for multiple back-and-forth communications to gather all required informationLack of clarity around how outcomes are communicated back to the UNOS Patient Safety team if complaints are investigated by other UNOS functional areas (e.g., allocations, patient relations, IT and site survey teams)	<ul style="list-style-type: none">HRSA leadership could define criteria for when memos need to be developed, what information should be included, and establish timeframes for key memo activities Contractor(s) can utilize the newly-developed “Contractor Patient Safety Complaint Notification Form” to effectively communicate all relevant information succinctlyRecommend contractor(s) have established processes to ensure all functional areas are informed of investigation outcomes, as appropriate <p> <i>Reference Document: Contractor Patient Safety Complaint Notification Form</i></p> <p> <i>Reference Document: Patient Safety Complaint Current State Process Map</i></p>








Gap Analysis & Recommendations: Processes

Evaluation Criteria: Standard of Excellence	Current State Analysis: Observations & Gaps	Leading Practice Standards: Recommendations
<ul style="list-style-type: none"> Clearly defined processes for information exchange between agencies and entities across the Patient Safety Complaint process to improve transparency 	<ul style="list-style-type: none"> UNOS does not have documented criteria to determine when a complaint should become a case, referral, or turnaround Lack of transparency between UNOS and HRSA surrounding timeline of the complaint review process HRSA may become aware of patient safety events later than the guidelines require; 12% of HRSA notifications occurred after the one-day requirement Delays in notification may occur due to: (1) members not reporting incidents to UNOS timely and/or (2) complaints not initially meeting HRSA notification criteria until later in the investigation Risk level changes are not clearly communicated amongst UNOS and HRSA teams Risk level is assigned as an output of the triage form during the intake process; however, a list of defined criteria is only available for Level 1-Exceptional and does not exist for 2-Priority or 3-Common Minimal processes in place to ensure risk level is appropriately assigned; as there is no criteria to validate risk level assignment HRSA does not have its own a triage form to use when complaints are submitted directly to HRSA HRSA lacks an internal tracking mechanism for complaints received through direct notification and subsequent action items 	<ul style="list-style-type: none"> HRSA could define criteria for turn downs, referrals, and cases to be utilized by contractor(s) in their intake process  Contractor(s) can transparently share information around the timeframe required for each step of the case investigation process from start to finish to clarify timeline expectations In the short-term, contractor(s) can develop a HRSA-accessible electronic workflow (at minimum, an Excel tracking spreadsheet) for the case investigation process to increase transparency around timeframes and potentially enable automated bidirectional communications/notifications In the long-term, contractor(s) can develop, maintain, and provide access to a comprehensive dashboard summarizing all complaints (e.g., Tableau, Power BI, etc.), including complaint details and outcomes to ensure HRSA is informed throughout the investigative process HRSA could develop criteria for each risk level to standardize risk assignment across contractors At minimum, the contractor(s) can perform routine inter-rater reliability exercises to determine risk level assignment appropriateness HRSA may develop a simplified triage form to allow consistent risk assessment of complaints directly reported to HRSA HRSA may develop an internal tracker to document patient safety complaints received directly and any relevant next steps





Gap Analysis & Recommendations: Processes

Evaluation Criteria: Standard of Excellence	Current State Analysis: Observations & Gaps	Leading Practice Standards: Recommendations
<ul style="list-style-type: none">Processes exist to monitor performance and compliance to support continuous improvement	<ul style="list-style-type: none">Minimal auditing of UNOS to ensure contractor compliance with relevant regulations, standards, and federal agency requirementsLimited transparency around patient safety complaint outcomes documented by MPSC and UNOS functional areas, hindering the ability for organizations to effectively monitor their performanceHRSA has limited visibility into member compliance or compliance monitoring activities (e.g., volume of site visits, site visit outcomes, etc.) to support continuous improvementReports listing members with a history of repeated non-compliance are currently unavailableUNOS currently performs site surveys every three years; to bridge the three-year gap between surveys, UNOS is considering other monitoring mechanismsOpportunity to address concern that patient safety events may be underreported due to member culture, fear of reporter retaliation, and/or lack of awareness about how to report concerns anonymouslyMinimal processes to provide feedback to the complaint reporter regarding the investigation progress or outcomes	<ul style="list-style-type: none">HRSA could implement audit processes to ensure contractor compliance, inclusive of specific contract requirements, audit schedule, and reporting mechanism Contractor(s) can develop processes to monitor member compliance and address repeated compliance violations Contractor(s) can make the MCL accessible to HRSAUtilize a newly-formed JOC to review complaint outcomes and identify opportunities for continuous improvement and educational opportunitiesConsider utilizing newly-developed KPIs to routinely review reporting and metrics to ensure process adherenceContractor(s) can implement processes to provide continuous education, including flyers/tip sheets, to be posted in OPOs and Transplant Centers providing guidance on when and how to anonymously submit patient safety eventsHRSA and contractor(s) can implement processes to identify opportunities to increase engagement from members and patients/families Contractor(s) can develop processes to provide feedback to complaint reporters with investigation status and outcomes





Reference Document: Contractor Patient Safety Complaint Notification Form

Contractor Patient Safety Complaint Notification to HRSA

This form is used to notify HRSA of patient safety complaints received or identified by contractor aligned with contract requirements.

Contractor Submitter Contact Information	
Today's Date	Click or tap to enter a date.
Date contractor notified HRSA	Click or tap to enter a date.
Contractor Submitter Name	Click or tap here to enter text.
Contractor Submitter Title	Click or tap here to enter text.
Contractor Submitter Email	Click or tap here to enter text.
Contractor Submitter Phone	Click or tap here to enter text.
Date contractor became aware of patient safety incident	Click or tap to enter a date.
Requires contractor to notify MPSC	<input type="checkbox"/> Yes <input type="checkbox"/> No
Date contractor notified MPSC, if applicable	Click or tap to enter a date.
Patient Safety Complaint Information	
Date patient safety incident occurred	Click or tap to enter a date.
Member code	Click or tap here to enter text.
Hospital number	Click or tap here to enter text.
Member type (OPO, TXC, Lab)	<input type="checkbox"/> OPO <input type="checkbox"/> TXC <input type="checkbox"/> Lab <input type="checkbox"/> Other: Click or tap here to enter text.
Organ Program (select all applicable)	<input type="checkbox"/> Kidney <input type="checkbox"/> Pancreas <input type="checkbox"/> Heart <input type="checkbox"/> Lung <input type="checkbox"/> Liver <input type="checkbox"/> Intestine <input type="checkbox"/> Vascularized allograft (VCA)
Anonymous submission	<input type="checkbox"/> Yes <input type="checkbox"/> No
Complaint receipt mechanism	<input type="checkbox"/> Automated Report <input type="checkbox"/> Disease Transmission Functional Area <input type="checkbox"/> Email <input type="checkbox"/> Fax <input type="checkbox"/> Mail <input type="checkbox"/> Media <input type="checkbox"/> Member Reporting Line <input type="checkbox"/> Other Contractor Staff <input type="checkbox"/> Patient Safety Portal <input type="checkbox"/> Patient Services Functional Area <input type="checkbox"/> Phone <input type="checkbox"/> Other: Click or tap here to enter text.
Complaint primary classification	<input type="checkbox"/> Deceased Donor Organ Procurement <input type="checkbox"/> Candidate Registrations, Modifications and Removals <input type="checkbox"/> Histocompatibility <input type="checkbox"/> Organ Offers, Acceptance, and Verification

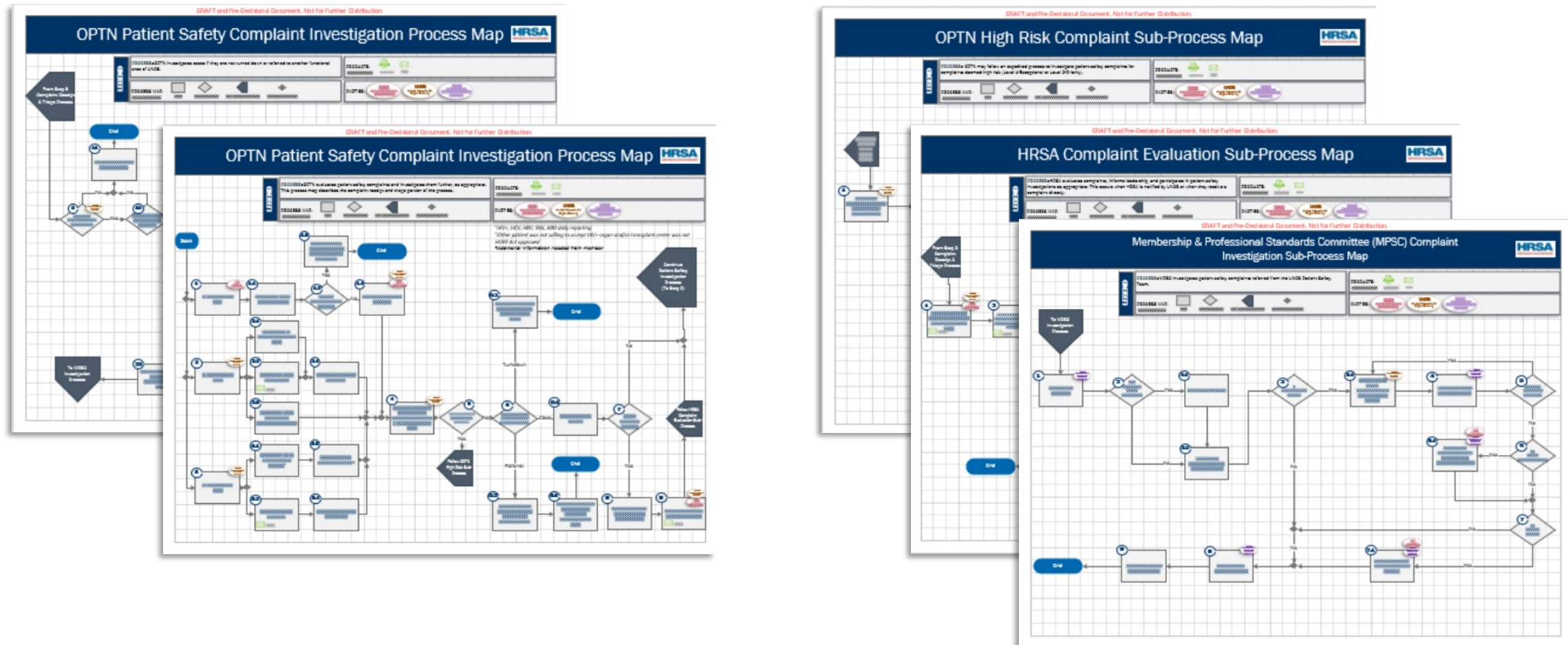
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	<input type="checkbox"/> Allocation <input type="checkbox"/> Living Donation <input type="checkbox"/> Identification of Transmissible Diseases <input type="checkbox"/> Organ and Extra Vessels <input type="checkbox"/> Data Submission Requirements <input type="checkbox"/> Other: Click or tap here to enter text.
Complaint risk level	<input type="checkbox"/> 1 - Exceptional <input type="checkbox"/> 2 - Priority <input type="checkbox"/> 3 - Common
Member Patient Safety History	
Date of Member's most recent site survey	Click or tap to enter a date.
Site survey outcome	Click or tap here to enter text.
If the site survey resulted in a corrective action plan or identification of non-compliance, please provide a link to the site survey outcome documentation	Click or tap here to enter text.
Indicate if the member is currently under any type of compliance monitoring	<input type="checkbox"/> Yes <input type="checkbox"/> No
Indicate if the Member has a history of patient safety events or policy violations in the last three years	<input type="checkbox"/> Yes <input type="checkbox"/> No
If the Member has a history of patient safety events or policy violations, please describe in detail. Please include the organ program being described. Click or tap here to enter text.	
Patient Safety Complaint Summary	
Please describe the complaint in detail: Click or tap here to enter text.	
Patient Safety Complaint Required Actions	
Date Member inquiry (formal or informal) was sent, if applicable	Click or tap to enter a date.
Pending documents from member (please describe which documents are pending and estimated timeline for receipt)	Click or tap here to enter text.
Other next steps	Click or tap here to enter text.

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Reference Document: Current State Patient Safety Complaint Process Map




People & Culture

Evaluation of organizational alignment to ensure clear roles and responsibilities, a culture of safety, and people development.





Gap Analysis & Recommendations: People & Culture

Evaluation Criteria: Standard of Excellence	Current State Analysis: Observations & Gaps	Leading Practice Standards: Recommendations
<ul style="list-style-type: none">• Clear roles and responsibilities across HRSA team members and leadership	<ul style="list-style-type: none">• HRSA Patient Safety team clearly understands program goals and vision• Uncertainty surrounding individual roles, responsibilities, and priorities in supporting program activities• There are minimal materials to orient new members to their roles and responsibilities and those of other team members• Currently, if HRSA members are part of an investigation, they function as a participant or an observer dependent upon the type of investigation	<ul style="list-style-type: none">• Align job descriptions, processes, and policies to goals and vision to strengthen program materials• Provide clarity on individual team member priorities and responsibilities to support program goals and activities• Create standardized orientation and onboarding materials for each role with identified responsible parties as the main POC• Define agency responsibilities (e.g., RACI) and expectations during MPSC Peer Visits• HRSA's investigation role as a participant or an observer could be defined in HRSA-directed vs. MPSC-directed investigations <p> <i>Reference Document: RACI Matrix</i></p>
<ul style="list-style-type: none">• Commitment to a culture of safety, transparency, equity, and continuous improvement	<ul style="list-style-type: none">• Desire to further enhance trust, transparency, quality, and a just culture into the core tenets of the program	<ul style="list-style-type: none">• Identify opportunities for intra- and interagency education promoting patient safety program tenets



Gap Analysis & Recommendations: People & Culture

Evaluation Criteria: Standard of Excellence	Current State Analysis: Observations & Gaps	Leading Practice Standards: Recommendations
<ul style="list-style-type: none">Team members work to the top of their license or skill level to ensure effective and efficient operations	<ul style="list-style-type: none">Currently, there are clinical and non-clinical staff performing a variety of roles for a given investigation that are not consistently aligned to individuals' specialized skills and/or licenses, resulting in potential inefficiencies	<ul style="list-style-type: none">Review current staffing and roles for optimal support and ensure appropriate role delineationAlign tasks to staff skill/license level to ensure the most efficient workflowProvide opportunities for greater autonomy to support decision-making and reduce bottlenecksConsider utilizing the Pathways Program Interns to assist full-time staff with administrative needs and requirements
<ul style="list-style-type: none">Sustainability, succession planning, and people development are integral components of departmental planning and strategy	<ul style="list-style-type: none">A concentration of historical program knowledge lies within a few roles with limited documentation to share historical information across the teamUncertainty around appropriate documentation storage practices	<ul style="list-style-type: none">Provide and leverage resources intentionally to grow individuals within their roles to facilitate department succession planning★ Develop clear guidance for documentation storage and accessibility



Quick Win



Suggested HRSA Oversight Requirement



Reference Document: RACI Matrix

A RACI matrix is a tool used to define and clarify roles and responsibilities within projects or processes. Categorizing tasks as Responsible, Accountable, Consulted, or Informed, ensures a clear understanding and delineation of duties among team members.

RACI Roles	
Role	Description
Responsible (R)	<ul style="list-style-type: none"> Individuals who are accountable for executing and achieving specific tasks or activities Multiple resources can work on a task
Accountable (A)	<ul style="list-style-type: none"> The ultimate decision-maker and responsible party for ensuring tasks are completed correctly and on time Only one accountable person should be assigned per task Group roles should not be the Accountable party The Accountable party can sometimes also be the Responsible party
Consulted (C)	<ul style="list-style-type: none"> Individuals who are not directly involved with carrying out the task but provide insights, guidance, and advice to inform decisions throughout the task's execution May be subject matter experts or stakeholders Bidirectional communication
Informed (I)	<ul style="list-style-type: none"> Individuals or groups who are regularly updated of the progress, decisions, and outcomes of a task Do not actively participate in a task's execution Often one-way communication

RACI Matrix Template			
	Role 1	Role 2	Role 3
Task 1	I	A/R	C
Task 2	C	A	R
Task 3	R	A	I
Task 4	C	I	R
Task 5	C	I	R
Task 6	A	R	I

R Responsible
 A Accountable
 C Consulted
 I Informed



Technology

Evaluation of the existing platforms and methods to efficiently share and retrieve information or communications across HRSA and the contractor(s).





Gap Analysis & Recommendations: Technology

Evaluation Criteria: Standard of Excellence	Current State Analysis: Observations & Gaps	Leading Practice Standards: Recommendations
<ul style="list-style-type: none">Centralized, secure digital platforms to track information including status of patient safety incidents, investigations, and KPIs	<ul style="list-style-type: none">Lack of comprehensive digital platforms to track complaints, store member-specific files, and access key metricsInformation related to patient safety complaints are documented across multiple platforms; complaints are tracked by the contractor in a contractor-owned spreadsheet (i.e., the MCL), as well as specific member filesCurrent patient safety tracking platform(s) are only UNOS-accessible; HRSA must request information on an ad-hoc basisLack of a single platform creates challenges for UNOS in completing data requests due to the fragmented nature of the data/documentation storage	<ul style="list-style-type: none"> Contractor(s) can develop a single complaint tracker, a single repository for member-specific files, and a single dashboard for KPIs that are HRSA-accessible, <i>as referenced in the first standard of excellence in the Data-driven Decisions domain</i>
<ul style="list-style-type: none">A single, secure electronic communication system is utilized to allow asynchronous communication between organizations	<ul style="list-style-type: none">HRSA and UNOS communicate via a UNOS-owned secure email systemThe current secure email system has limitations, including (1) the inability for HRSA to initiate secure email communications, and (2) the inability for HRSA to “reply all” once a secure email string has been initiated	<ul style="list-style-type: none"> In the short-term, HRSA could research and identify solutions to address the limitations with the existing secure email system with UNOSIn the long-term, HRSA can implement a secure email system to be used with all contractors



Communication

Evaluation of current communication within and across HRSA and the contractor regarding Patient Safety.





Gap Analysis & Recommendations: Communication

Evaluation Criteria: Standard of Excellence	Current State Analysis: Observations & Gaps	Leading Practice Standards: Recommendations
<ul style="list-style-type: none">• Clear understanding of organizational goals, processes, and standards around OPTN Modernization and its impact on Patient Safety activities	<ul style="list-style-type: none">• HRSA Patient Safety team is dedicated to the overall mission and modernization initiatives and has a desire to enhance overall communication	<ul style="list-style-type: none">★ Enhance bidirectional communications (top-down and bottom-up) through regular touchpoints to enhance internal processes, set and meet clear expectations, and streamline deliverables
<ul style="list-style-type: none">• Patient safety information is transparently communicated across HRSA staff, contractors, and leadership	<ul style="list-style-type: none">• No routine communication between UNOS and HRSA regarding patient safety complaints & investigation status; updates are provided via ad-hoc requests• Complaint investigation next steps are not consistently shared between UNOS and HRSA patient safety teams	<ul style="list-style-type: none">• Utilize a newly-formed JOC to establish routine communication regarding patient safety complaint and investigation status and next steps, <i>as referenced in the second standard of excellence in the Structured Governance domain</i>• Establish routine touchpoints between HRSA staff and leadership to prepare for JOCs and enhance intraorganizational communication• Implement routine bidirectional communication between the HRSA patient safety team and the contractor(s) patient safety team(s) before, during, and after JOCs to ensure alignment around initiatives, investigations, role expectations, and role delineation
<ul style="list-style-type: none">• Provide a dedicated mechanism for members to provide feedback	<ul style="list-style-type: none">• Member feedback is currently provided ad hoc via multiple communication channels	<ul style="list-style-type: none">📋 Contractor(s) can implement a dedicated mechanism (e.g., annual member survey) to collect member feedback such as contractor management of patient safety complaints, patient safety educational opportunities, and general questions or concerns

Next Steps



Next Steps



1

Readiness Exercise: Perform a readiness exercise to identify preparedness to undertake each recommended initiative



2

Prioritization: Prioritize initiatives based on level of effort and value proposition



Reference Document: 2 x 2 Prioritization Matrix



3

Project Plan: Develop project plan to execute prioritized initiatives



4

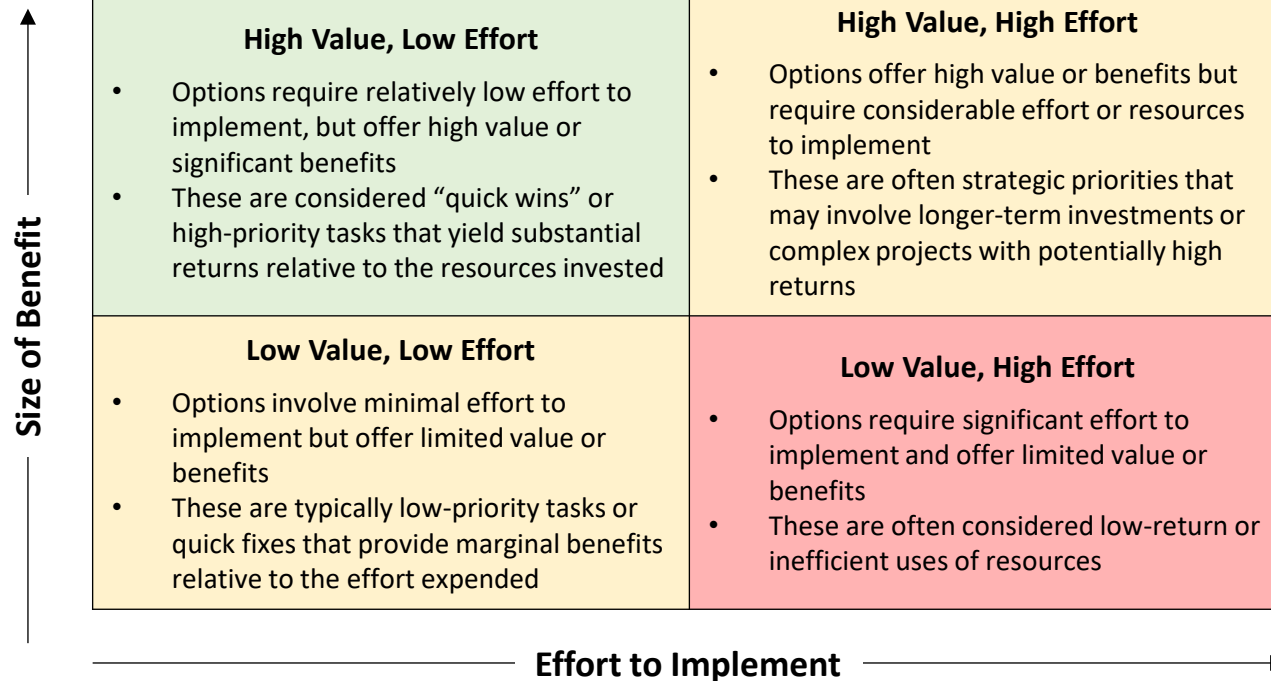
Future Oversight Requirements: Consider incorporating findings into future internal and external oversight and tracking efforts



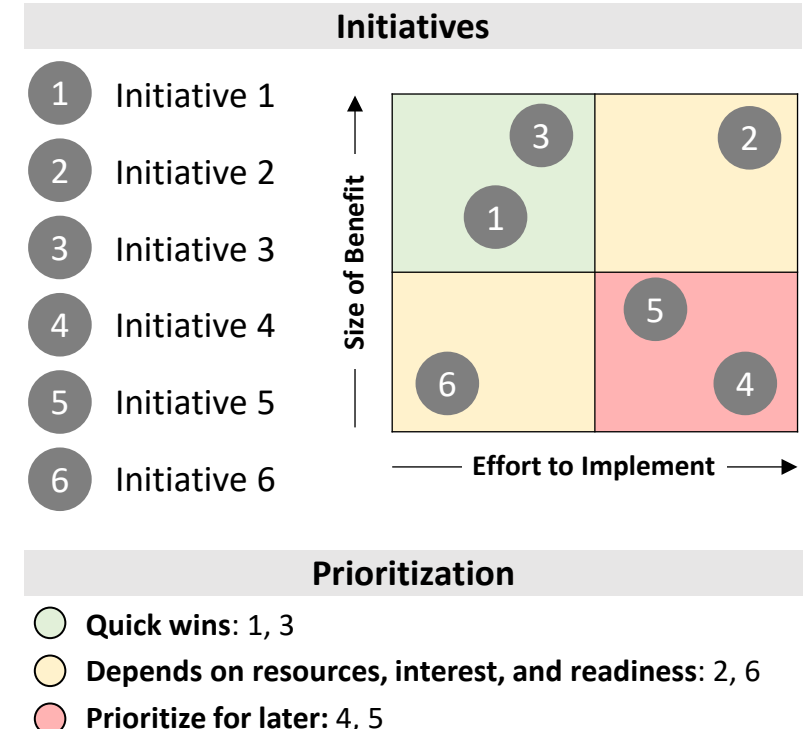
Reference Document: 2 x 2 Prioritization Matrix

A 2 x 2 prioritization matrix is a decision-making tool that categorizes options based on their level of effort required and the value they provide. Options are plotted on a four-quadrant grid based on their relative scores for effort and value. The matrix prioritizes actions by visually identifying options that offer high value with minimal effort.

Prioritization Framework



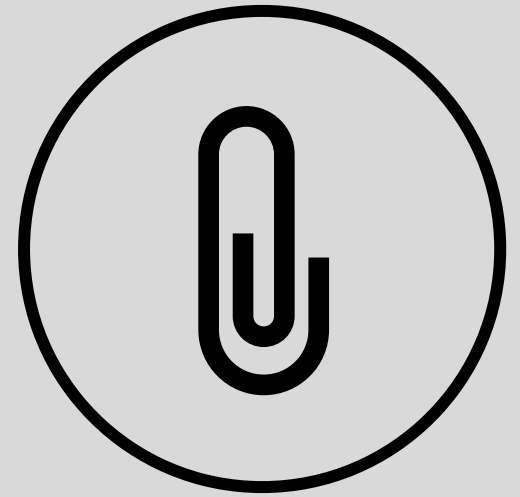
Prioritization Example



Questions



Appendix



Quick Wins & Future Contract Requirements

Quick wins are initiatives that deliver immediate positive results but may not necessarily be the most impactful or highest priority initiative; these are generally initiatives that can be implemented quickly and with relatively low effort. Suggested HRSA oversight requirements are items and initiatives that could be required of future vendor(s) but are not intended as an exhaustive list. The project support team identified initiatives that could qualify as quick wins and indicated these with a star icon (★) and future contract requirements with a contract icon (📄). Initiatives that are both quick wins and suggested future contract requirements are indicated with both a star and contract icon (★📄).

Domain	Quick Wins	Minimum Suggested HRSA Oversight Requirements
Defined Program	<ul style="list-style-type: none"> Contractor(s) can offer documentation of all processes, criteria, forms, glossary of terms/definitions, etc. for HRSA review; HRSA can then thoroughly review and align to the leading practice standard 	<ul style="list-style-type: none"> Contractor(s) can offer documentation of all processes, criteria, forms, glossary of terms/definitions, etc. for HRSA review; HRSA can then thoroughly review and align to the leading practice standard
Data-Driven Decisions	<ul style="list-style-type: none"> Contractor(s) can develop a single complaint tracker that fully captures the narrative of the case, case status, dates for each step of the investigative process, and outcomes; this can be used to see high-level case statuses and member complaint history Contractor can develop a HRSA-accessible member directory with all identifiers Contractor can assign unique identifiers to all complaints, ensuring the identifier remains associated with the respective complaint throughout the investigative process Versioning can be documented by the contractor(s) to help track changes to data elements over time 	<ul style="list-style-type: none"> Contractor(s) can develop a comprehensive dashboard of key metrics populated by the contractor that HRSA staff can passively access to track and trend patient safety data Contractor(s) can develop a single complaint tracker that fully captures the narrative of the case, case status, dates for each step of the investigative process, and outcomes; this can be used to see high-level case statuses and member complaint history Contractor(s) can develop a single repository for member-specific files that encapsulates medical records, case notes, correspondence, member-provided reports, etc.; this can be used to access case- and member-specific documentation Minimum standards for reporting and data quality can be developed by HRSA and subsequently met by contractor(s)
Structured Governance	<ul style="list-style-type: none"> Consider leveraging a bi-monthly leadership/staff JOC to begin standardized program enhancements 	<ul style="list-style-type: none"> Contractor(s) can succinctly track and trend member compliance and non-compliance over time to properly monitor and manage members systematically and electronically Recommend contractor(s) use standardized templates and reporting requirements for ease of oversight by HRSA (e.g., complaint tracking fields, risk criteria, complaint classification definition, etc.)

Quick Wins & Future Contract Requirements, cont.

Quick wins are initiatives that deliver immediate positive results but may not necessarily be the most impactful or highest priority initiative; these are generally initiatives that can be implemented quickly and with relatively low effort. Suggested HRSA oversight requirements are items and initiatives that could be required of future vendor(s) but are not intended as an exhaustive list. The project support team identified initiatives that could qualify as quick wins and indicated these with a star icon (★) and future contract requirements with a contract icon (📄). Initiatives that are both quick wins and suggested future contract requirements are indicated with both a star and contract icon (★📄).

Domain	Quick Wins	Minimum Suggested HRSA Oversight Requirements
Processes	<ul style="list-style-type: none"> Contractor(s) can utilize the newly-developed “Contractor Patient Safety Complaint Notification Form” to effectively communicate all relevant information succinctly Contractor(s) can make the MCL accessible to HRSA 	<ul style="list-style-type: none"> Contractor(s) can utilize the newly-developed “Contractor Patient Safety Complaint Notification Form” to effectively communicate all relevant information succinctly Contractor(s) can transparently share information around the timeframe required for each step of the case investigation process from start to finish to clarify timeline expectations Contractor(s) can develop processes to monitor member compliance and address repeated compliance violations Contractor(s) can develop processes to provide feedback to complaint reporters with investigation status and outcomes
People & Culture	<ul style="list-style-type: none"> Develop clear guidance for documentation storage and accessibility 	N/A
Technology	<ul style="list-style-type: none"> In the short-term, HRSA could research and identify solutions to address the limitations with the existing secure email system with UNOS 	<ul style="list-style-type: none"> Contractor(s) can develop a single complaint tracker, a single repository for member-specific files, and a single dashboard for KPIs that are HRSA-accessible, as referenced in the first standard of excellence in the Data-driven Decisions domain
Communication	<ul style="list-style-type: none"> Enhance bidirectional communications (top-down and bottom-up) through regular touchpoints to enhance internal processes, set and meet clear expectations, and streamline deliverables 	<ul style="list-style-type: none"> Contractor(s) can implement a dedicated mechanism (e.g., annual member survey) to collect member feedback such as contractor management of patient safety complaints, patient safety educational opportunities, and general questions or concerns