

**Presentation to Investigative Staff of
the Senate Finance Committee –
UNOS Process for Reviewing OPOs**

April 26, 2021

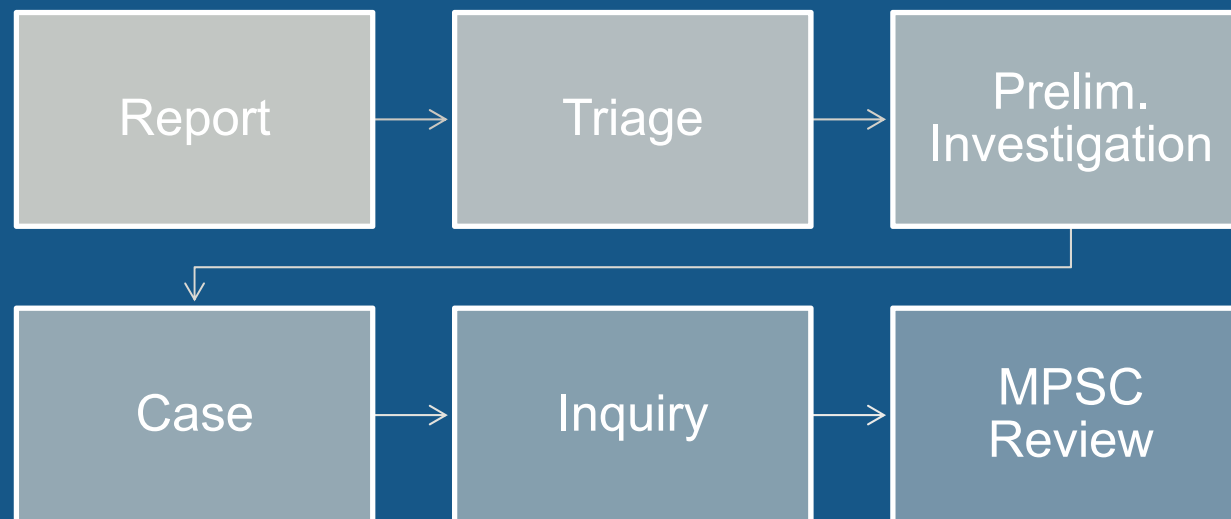
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Overview of OPO Review Process



Reports – Where They Come From

- All reviewed by Incident Handling but from multiple sources:

Member OPOs

*Improving Patient Safety Portal (UNet)
Reporting Hotline (886-787-4909)*

Internal UNOS Referrals

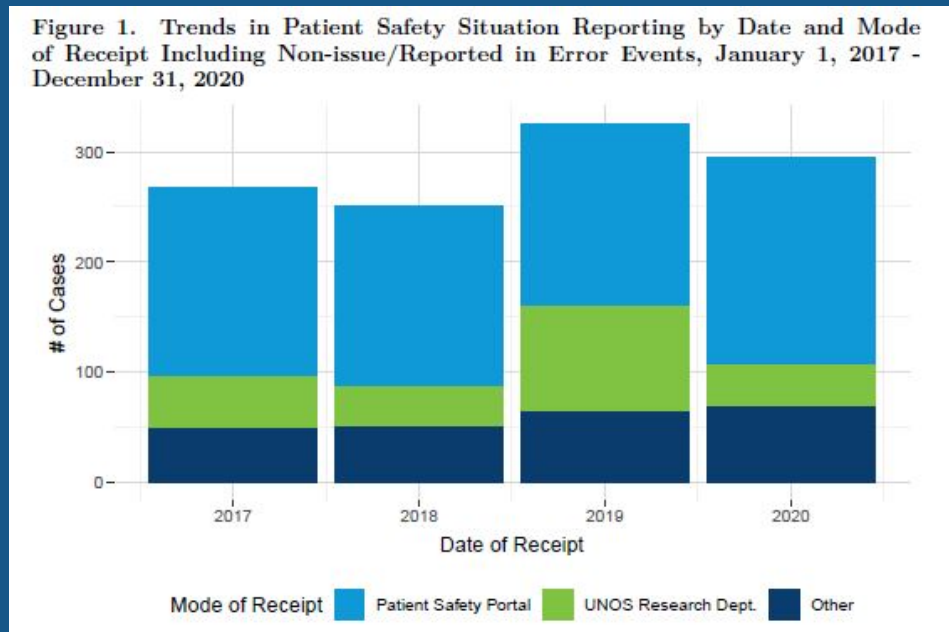
*Member Quality (e.g., site surveys)
Patient Services | Research*

Other Stakeholders

Letters, Faxes, Emails, etc.

- The format of reporting records varies by source

Reports – Where They Come From



Source: OPTN Operations & Safety Committee, *Trends and Patterns in Patient Safety Cases Report to the OPTN: January 1, 2017 – December 31, 2020* (April 1, 2021)

Reports – Broad Array

- Anyone can refer anything for investigation
 - Investigation must confirm substantiated noncompliance
 - Reporter will not receive any information on investigation or outcome due to confidential medical peer review protections
- MPSC does not see or take action on every noncompliance; primarily concerned with patient safety or systemic issues
- Board and HRSA have directed the MPSC to focus on
 - Helping members improve; identifying and referring educational opportunities; encouraging self-reporting; improving perception of MPSC within the transplant community

Reports – Broad Array

Figure 6. Trends in Patient Safety Cases by Event Types (High-Level Category), January 1, 2019 - June 30, 2020

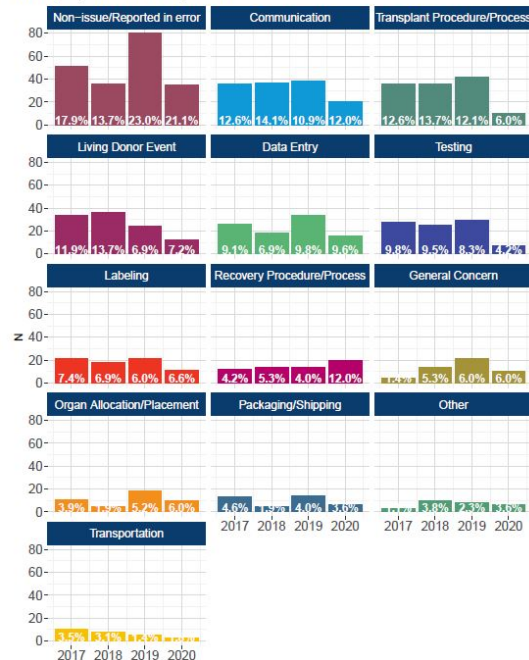


Table 6. Patient Safety Cases by Event Type (High-Level Category)

Event Category	2017	2018	2019	2020	Total
Non-issue/Reported in error	51 (17.9%)	36 (13.7%)	80 (23.0%)	35 (21.1%)	202 (19.0%)
Communication	36 (12.6%)	37 (14.1%)	38 (10.9%)	20 (12.0%)	131 (12.3%)
Recovery Procedure/Process	12 (4.2%)	14 (5.3%)	14 (4.0%)	20 (12.0%)	60 (5.7%)
Data Entry	26 (9.1%)	18 (6.9%)	34 (9.8%)	16 (9.6%)	94 (8.9%)
Living Donor Event	34 (11.9%)	36 (13.7%)	24 (6.9%)	12 (7.2%)	106 (10.0%)
Labeling	21 (7.4%)	18 (6.9%)	21 (6.0%)	11 (6.6%)	71 (6.7%)
General Concern	4 (1.4%)	14 (5.3%)	21 (6.0%)	10 (6.0%)	49 (4.6%)
Organ Allocation/Placement	11 (3.9%)	5 (1.9%)	18 (5.2%)	10 (6.0%)	44 (4.1%)
Transplant Procedure/Process	36 (12.6%)	36 (13.7%)	42 (12.1%)	10 (6.0%)	124 (11.7%)
Testing	28 (9.8%)	25 (9.5%)	29 (8.3%)	7 (4.2%)	89 (8.4%)
Other	3 (1.1%)	10 (3.8%)	8 (2.3%)	6 (3.6%)	27 (2.5%)
Packaging/Shipping	13 (4.6%)	5 (1.9%)	14 (4.0%)	6 (3.6%)	38 (3.6%)
Transportation	10 (3.5%)	8 (3.1%)	5 (1.4%)	3 (1.8%)	26 (2.5%)
Overall	268 (100.0%)	251 (100.0%)	325 (100.0%)	146 (100.0%)	990 (100.0%)

Source: OPTN Operations & Safety Committee, *Trends and Patterns in Patient Safety Cases Report to the OPTN: January 1, 2017 – December 31, 2020* (April 1, 2021)

Triage – Immediate Evaluation of Reports

- Reports immediately reviewed (w/in 2 hours, 7 AM to 10 PM)
- Incident Handling makes an assessment:



- OPOs supply additional information, as needed, e.g., explanatory narratives, medical records, policies, corrective actions, under the protection of the medical peer review privilege

Triage – Potential Outcomes

No Action

Closing Letter

Preliminary Investigation

Expedited Case

Triage – Early Reporting Criteria

- Some factors trigger early reporting to HRSA / MPSC leadership
 - Direct/specific harm to patient(s) or high potential for harm
 - Member action or inaction that resulted in such harm
 - Concern that harm may occur again soon
 - Threat to integrity in or trust of the OPTN
 - Situation requiring IH/MPSC/UNOS/OPTN involvement to resolve in timely manner

Preliminary Investigation

- If an ongoing risk exists, preliminary investigation focuses on:
 - Assessing what happened and whether member's containment plan should appropriately prevent the issue from happening again
 - If staff have concerns about member containment plan, will take to MPSC leadership and/or reviewers for feedback
- If no ongoing risk, preliminary investigation focuses on:
 - Using readily available information (details from the report, UNet, etc.) to assess whether the report is verifiable and whether the report suggests a potential patient safety issue or policy violation

Opening a “Case”

- A report will become a “case” if any potential patient safety or policy or bylaw noncompliance may exist
- A report will not become a case if there is no identified patient safety risk and at least one of the following:
 - Event already evaluated through a different monitoring process
 - Insufficient information to conduct an evaluation
 - No policy noncompliance
- A report will also not become a case if it solely pertains to something outside the OPTN’s authority

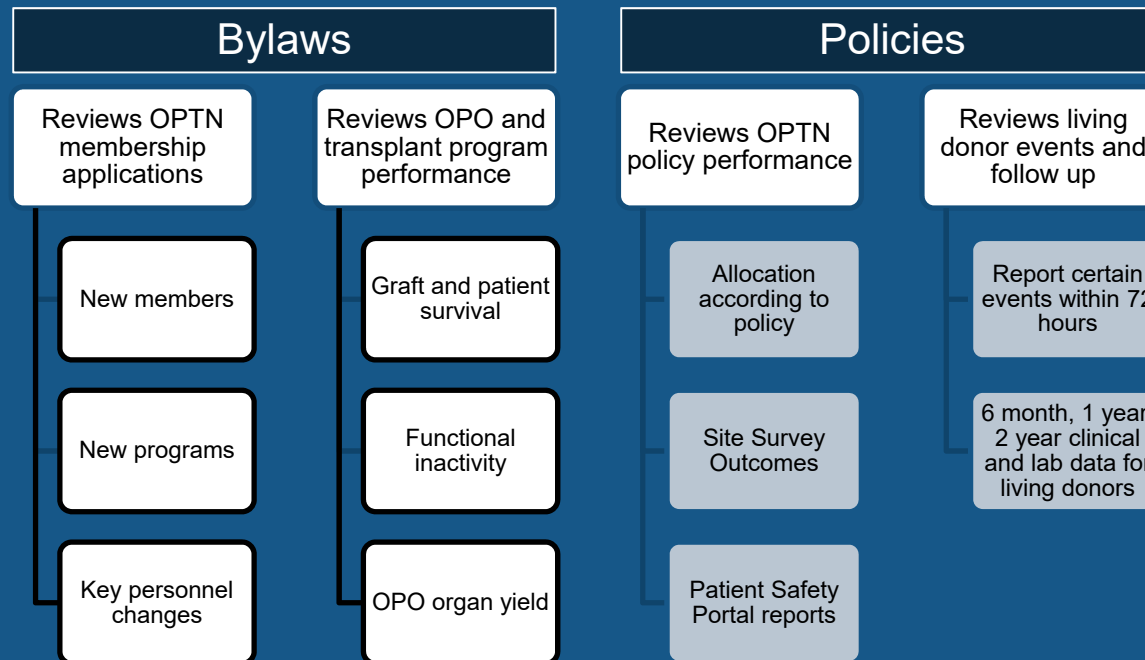
Case Inquiries

- Staff thoroughly investigates any report that becomes a case
 - Send inquiry to member for detailed information
 - Gather any other relevant information, internal and external
 - Analyze all information to determine any potential noncompliance
 - Notify member of referral to MPSC or case closure
- IH staff present cases to cross-functional Member Quality staff during routine and ad hoc meetings throughout the case process
 - Representatives from MQ leadership, MPSC Operations, Allocations, Site Survey and Performance Monitoring teams, plus Chief Medical Officer
 - Intent is to help identify potential risks, lines of inquiry and applicable policy or bylaws, and to promote consistent decision-making

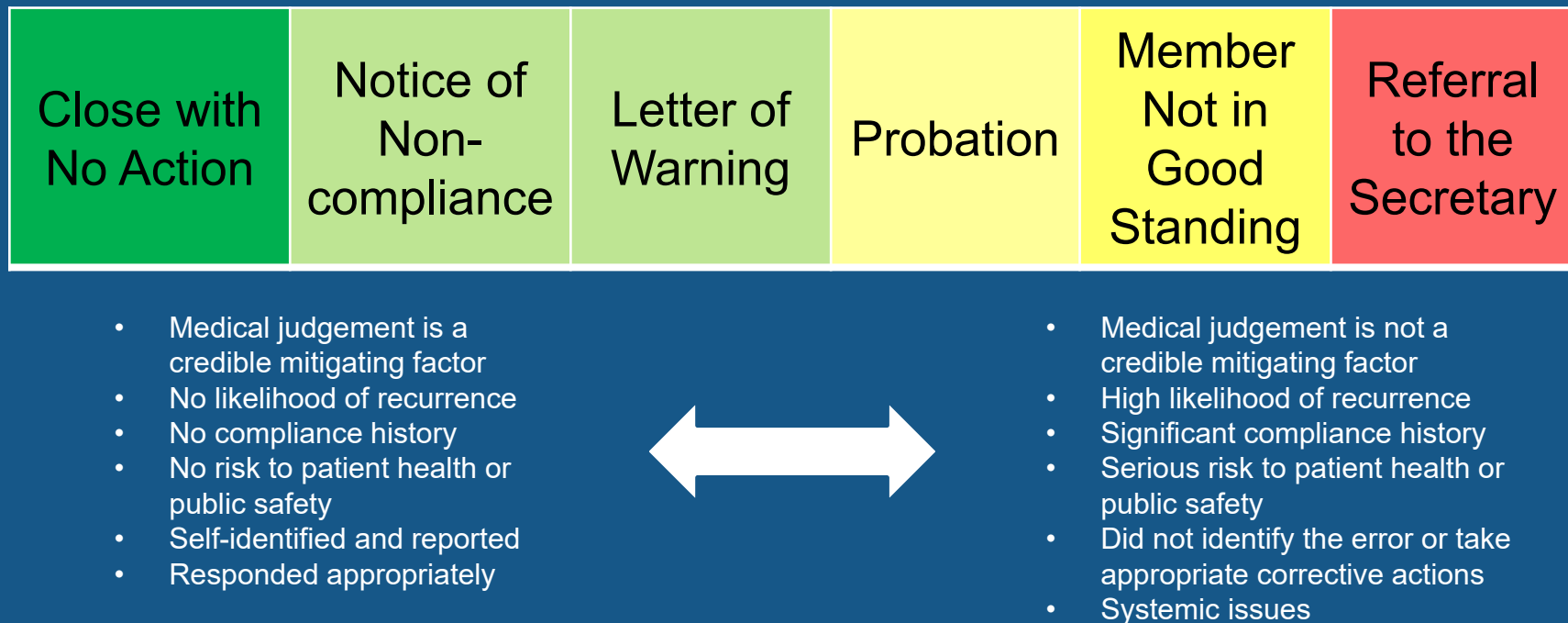
MPSC Review – Scope of Authority

- Must follow the Bylaws and Policies as written
 - No authority to enforce the “spirit” of policy; must stick to the actual language
- Cannot grant exceptions to policies or bylaws, unless explicitly authorized by policy or bylaw
- Can review potential noncompliance with any policy; does not need to state that the MPSC will review noncompliance
- Can review any issue that presents a risk to patient health or public safety, even if no other policy violation exists (OPTN Bylaws, Art. I, § E.)

MPSC Review – Scope of Authority



MPSC Review – Disciplinary Options



MPSC Review – Levels of Review / Interaction

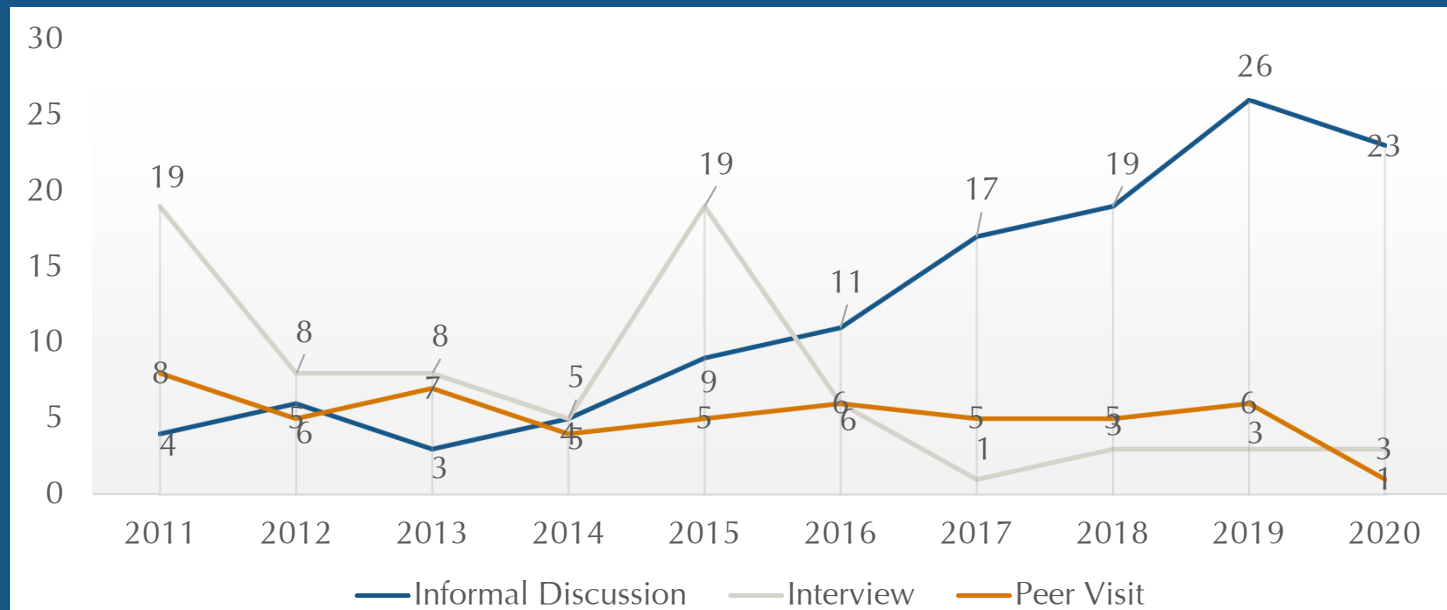
Step	When is it used?	Format
Peer Visit	<ul style="list-style-type: none"> Assist members in addressing issues affecting performance, program operations Deeper investigation of issues/concerns 	<ul style="list-style-type: none"> 3-5 Transplant professionals visit member site Interviews and record review over 2 days Formal report with recommendations issued by MPSC
Informal Discussion	<ul style="list-style-type: none"> Any time MPSC needs to speak directly a member Required in some instances by the OPTN Bylaws 	<ul style="list-style-type: none"> 4-6 MPSC members participate Via teleconference 10 minute member presentation 15 minute Q&A
Interview	<ul style="list-style-type: none"> MPSC needs to speak to a member to determine action Rejected membership applications If the MPSC is considering Probation, or MNGS 	<ul style="list-style-type: none"> Full MPSC may participate, must have at least 10 MPSC members present Teleconference or at in-person meetings 15 minute presentation 30 minute Q&A

MPSC Review – Levels of Review / Interaction

Step	When is it used?	Format
Hearing	<ul style="list-style-type: none"> After interview If the MPSC is considering Probation or MNGS 	<ul style="list-style-type: none"> Approx. six hours, scheduled as needed Member, OPTN represented by counsel Detailed presentations and Q&A discussing all aspects of member org.
OPTN Board of Directors Review	<ul style="list-style-type: none"> After hearing If the MPSC recommends Probation or MNGS 	<ul style="list-style-type: none"> Member presentation and Q&A MPSC Chair presentation and Q&A

- HRSA participates throughout the MPSC Review process
- A member may also be referred to the HHS Secretary for Secretarial Actions (OPTN Bylaws, App. L. § 13)

MPSC Review – More Informal Discussions



Source: MPSC Report to Board, December 2020

MPSC – Increased Use of Informal Discussions

- Useful mechanism
 - Opportunity for member to provide information to MPSC
 - Short call with a small subcommittee of MPSC members
 - Intended to ask questions not obvious from document submission
 - Decision of subcommittee reported to full MPSC for approval
- Benefits Over Alternatives
 - Information gathering
 - Can help quickly identify and resolve issues
 - Opportunity for dialogue between member and subcommittee
 - Less threatening format

Questions or Comments?

Next Steps

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