OPTN Member Monitoring Processes

Contents

Membership Criteria Reviews

The Organ Procurement and Transplantation Network (OPTN) reviews its members for compliance with OPTN membership requirements on an ad hoc basis. United Network for Organ Sharing (UNOS) Member Quality staff manage the membership application process, and the Membership and Professional Standards Committee (MPSC) and/or the OPTN Board of Directors ultimately approve the applications according to the processes and criteria in the OPTN Bylaws.

Transplant Hospitals

Methodology

The OPTN reviews transplant hospitals for compliance with OPTN membership requirements on an ad hoc basis. A hospital demonstrates compliance with the requirements by submitting data about the hospital, its transplant program(s), and transplant program key personnel (primary transplant surgeon and primary transplant physician) on a membership application. A hospital must submit an application when any of the following events occur:

- A hospital wants to become a transplant hospital member so it can receive organ offers and perform organ transplants
- An existing transplant hospital member wants to begin transplanting a new organ type
- An existing transplant program has a pending change in key personnel, due to either voluntary leadership changes in the program or the pending departure of currently approved key personnel

Any hospital interested in becoming a transplant hospital must contact UNOS Membership to obtain a membership application. When an existing transplant program has a pending change in key personnel, it must notify the OPTN through UNOS Membership in writing of the upcoming change and return the completed application according to the deadline provided by the UNOS membership analyst.

Application Review

Once the hospital returns the application, a membership analyst reviews the entire application to verify that all required questions have been answered and all of the necessary supporting documentation has been submitted. The analyst compares the data submitted in the application to the qualifying criteria from the OPTN bylaws to assess whether or not the application demonstrates compliance with membership criteria. If the application is incomplete, meaning it is missing required data or documentation and/or does not demonstrate compliance with membership criteria, the analyst notifies the hospital by email or phone and provides a due date for submitting the information needed to complete the application. The analyst continues to work with the hospital to obtain the outstanding information until the application is complete. The analyst will not forward an application to the MPSC for review until it is complete.

Once the analyst determines that the application is complete and the hospital has submitted the required information to demonstrate compliance with membership requirements, the analyst notifies the transplant hospital by email or phone that the application is complete and will be forwarded to the MPSC for review.

MPSC Review

Either an ad hoc subcommittee of MPSC members or the full MPSC reviews the complete application. If all subcommittee members vote to approve the application, the new transplant hospital, new transplant program or key personnel change is granted interim approval, pending review by the full MPSC. For a new transplant hospital or program, interim approval means the transplant program(s) can begin to receive organ offers. The membership analyst sends the hospital an interim approval letter via email after the subcommittee's decision. If the subcommittee does not reach consensus, the membership analyst works with the subcommittee and the hospital to obtain any additional information that may resolve the subcommittee's concerns.

At each MPSC meeting, the MPSC reviews applications that have been reviewed by an ad hoc subcommittee since the MPSC's last meeting. If the MPSC votes to approve a new transplant hospital or transplant program application, the new transplant hospital or program is granted interim approval, pending review by the OPTN Board of Directors. If the new hospital or program has not previously received interim approval from an ad hoc subcommittee of the MPSC, then the full MPSC's interim approval means the transplant program(s) can begin to receive organ offers. After the MPSC meeting, the membership analyst sends the hospital an interim approval letter via email that includes the dates of the Board of Directors meeting during which the new hospital or program application will be reviewed by the Board. Only the Board of Directors can give final approval for transplant hospital membership or a designated transplant program. If the MPSC votes to approve a key personnel change application, then the key personnel change is considered approved and the membership analyst sends the hospital an approval letter after the MPSC meeting. Key personnel changes do not have to be reviewed and approved by the Board of Directors.

If the MPSC votes to reject a new transplant hospital, new transplant program, or key personnel change application, the MPSC offers the transplant hospital an interview conducted according to *Appendix L: Reviews and Actions* in the OPTN Bylaws. After the MPSC meeting, the membership analyst sends the hospital an interview offer letter explaining why the MPSC rejected the application and provides the date of the next MPSC meeting when the interview would take place. In addition to participating in an interview with the MPSC, the hospital is encouraged to either provide additional information to demonstrate compliance with the membership requirements that would resolve the MPSC's concerns or to propose different qualified key personnel if the MPSC's concerns are specific to key personnel qualifications.

Histocompatibility Laboratories

Methodology

The OPTN reviews histocompatibility laboratories for compliance with OPTN membership requirements on an ad hoc basis. A laboratory demonstrates compliance with the requirements by submitting data about the laboratory and its key personnel (laboratory director, technical supervisor, general supervisor, and clinical consultant) on a membership application. A laboratory must submit an application when any of the following events occur:

- A laboratory wants to become an OPTN histocompatibility laboratory member

- An existing histocompatibility laboratory member has a pending change in key personnel, due to either voluntary leadership changes or the pending departure of approved key personnel

A laboratory interested in becoming an OPTN histocompatibility member must contact UNOS Membership to obtain an application. When an existing laboratory member has a pending change in key personnel, it must also notify the OPTN in writing of the upcoming change and return the completed application and an updated laboratory coverage plan according to the deadline provided by the membership analyst.

Application Review

Once the laboratory returns the application to the OPTN, a membership analyst reviews the entire application to verify that all required questions have been answered and all required supporting documentation has been submitted. If the application is incomplete, meaning it is missing required data or documentation and/or does not demonstrate compliance with membership criteria, the analyst notifies the laboratory by email or phone and provides a due date for submitting the information needed to complete the application. The analyst continues to work with the laboratory to obtain the outstanding information until the application is complete. The analyst does not forward an application to the MPSC for review until it is complete.

Once the analyst determines that the application is complete and the laboratory has submitted the required information to demonstrate compliance with membership requirements, the analyst notifies the laboratory by email or phone that the application is complete and will be forwarded to the Membership/Histocompatibility Advisory Subcommittee for review.

MPSC Review

Members of the Membership/Histocompatibility Advisory Subcommittee, which is made up of MPSC histocompatibility representatives and members of the OPTN Histocompatibility Committee, review completed applications. All applications for new histocompatibility laboratories must be reviewed by this subcommittee, as well as any key personnel changes to existing member histocompatibility laboratories. If the reviewers unanimously agree to recommend that the MPSC approve the application, the application is sent to the full MPSC for review, along with the recommendation for approval. If the reviewers do not reach consensus or unanimously recommend the application be rejected, the membership analyst works with the reviewers and the laboratory to obtain additional information to resolve the reviewers' concerns before sending the application to the full MPSC for review.

At each MPSC meeting, the MPSC reviews all histocompatibility laboratory applications that have been reviewed by the Membership/Histocompatibility Advisory Subcommittee and recommended for MPSC consideration since the MPSC's last meeting. If the MPSC votes to approve a new histocompatibility laboratory application, the laboratory is granted interim approval pending review by the OPTN Board of Directors. After the MPSC meeting, the membership analyst sends the laboratory an interim approval letter via email that includes the dates of the Board meeting during which the new histocompatibility laboratory application will be reviewed by the Board. Only the Board can give final approval for histocompatibility laboratory membership. If the MPSC votes to approve a key personnel change application, then the key personnel change is considered approved and the membership analyst sends the laboratory an approval letter after the MPSC meeting. Key personnel changes do not have to be reviewed and approved by the Board of Directors.

If the MPSC votes to reject a new histocompatibility laboratory or key personnel change application, the MPSC offers the laboratory an interview conducted according to *Appendix L: Reviews and Actions* of the OPTN Bylaws. After the MPSC meeting, the membership analyst sends the laboratory an interview offer letter explaining why the MPSC rejected the application and providing the date of the next MPSC meeting when the interview would take place. In addition to participating in an interview with the MPSC, the laboratory is encouraged to either provide additional information to demonstrate compliance with the membership requirements that would resolve the MPSC's concerns or to propose different qualified key personnel if the MPSC's concerns are specific to key personnel qualifications.

Organ Procurement Organizations

Methodology

The OPTN reviews organ procurement organizations (OPOs) for compliance with OPTN membership requirements on an ad hoc basis. An OPO demonstrates compliance with the requirements by submitting data about the OPO and its key personnel (administrative director and medical director) on a membership application. An OPO must submit an application when any of the following events occur:

- An OPO wants to become an OPTN OPO member
- An existing OPO member has a pending change in key personnel, due to either voluntary leadership changes in the OPO or the pending departure of currently approved key personnel

An organization interested in becoming an OPTN OPO member must contact UNOS Membership to obtain a membership application. When an existing OPO member has a pending change in key personnel, it must also notify the OPTN in writing of the upcoming change and return the completed application and the replacement director's curriculum vitae according to the deadline provided by the membership analyst.

Application Review

Once the OPO returns the application, a membership analyst reviews the entire application to verify that all required questions have been answered and all required supporting documentation has been submitted. The analyst also compares the data submitted in the application to the qualifying criteria from the OPTN bylaws to assess whether or not the application demonstrates compliance with membership criteria. If the application is incomplete, meaning it is missing required data or documentation and/or does not demonstrate compliance with membership criteria, the analyst notifies the OPO by email or phone and provides a due date for submitting the information needed to complete the application. The analyst continues to work with the OPO to obtain the outstanding information until the application is complete. The analyst will not forward an application to the MPSC for review until it is complete.

Once the analyst determines that the application is complete and the OPO has submitted the required information to demonstrate compliance with membership requirements, the analyst notifies the OPO by email or phone that the application is complete and will be forwarded to the MPSC for notification and/or review.

MPSC Review

At each MPSC meeting, the MPSC reviews all complete applications that have been received since the MPSC's last meeting. If the MPSC votes to approve a new OPO application, the OPO is granted interim approval pending review by the OPTN Board of Directors. After the MPSC meeting, the membership analyst sends the OPO an interim approval letter via email that includes the dates of the Board of Directors meeting during which the new OPO application will be reviewed by the Board. Only the Board of Directors can give final approval for OPO membership.

If the MPSC votes to reject a new OPO or key personnel change application, the MPSC offers the OPO an interview conducted according to *Appendix L: Reviews and Actions* of the OPTN Bylaws. After the MPSC meeting, the membership analyst sends the OPO an interview offer letter explaining why the MPSC rejected the application and providing the date of the next MPSC meeting when the interview would take place. In addition to participating in an interview with the MPSC, the OPO is encouraged to either provide additional information to demonstrate compliance with the membership requirements that would resolve the MPSC's concerns or to propose different qualified key personnel if the MPSC's concerns are specific to key personnel qualifications.

In the case of a key personnel change application, the key personnel change is recorded by UNOS Membership and the OPO is notified when OPTN records have been updated. The membership analyst notifies the MPSC of the key personnel change at the following meeting. Key personnel changes for OPOs do not have to be reviewed and approved by the MPSC or Board of Directors.

Compliance Reviews

UNOS Member Quality staff conduct various ongoing reviews to evaluate OPTN member compliance with OPTN Bylaws and Policies. Reviews include allocation, site surveys, desk reviews, and patient safety investigations. When reviews identify a noncompliance with OPTN Policies or Bylaws, Member Quality staff compile information on the cases for the MPSC to make decisions on the appropriate monitoring or action.

Allocation Reviews

Methodology

The OPTN retrospectively reviews all deceased donor match runs that result in a transplanted organ. UNOS staff review match runs on a two-month delay to allow members the time permitted by policy to complete match runs and report final organ dispositions.

Each month, the UNOS Research Department provides a report identifying match runs for review. The report uses organ acceptances and potential transplant recipient (PTR) refusal or bypass codes entered on donor match runs, as well as the Data System for Organ Procurement and Transplantation Network candidate removal histories.

Compliance Review

Allocation Analysts review PTR refusal and bypass codes entered on the match runs to verify organs are allocated according to the sequence of the match run. They also compare the organ acceptance documented on the match run to the Data System for Organ Procurement and Transplantation Network record of the transplant recipient to verify that the intended recipient received the organ accepted for them. If the analyst does not identify any potential policy violations and does not need clarifying information to complete their review, they close the review with no further action and the member does not receive any correspondence.

However, if further information is required to determine whether a potential policy violation has occurred, the analyst may contact a member via email to request clarification or additional information. In the case of an identified potential policy violation, the analyst sends a notification letter detailing the nature of the violation and applicable policies to the member via secure email. Members receive notification letters on a monthly basis at the conclusion of the review for that month. The MPSC reviews these potential policy violations on a region-by-region basis, annually.

OPO Site Surveys

Methodology

The OPTN performs routine site surveys of OPOs once every three years. The survey includes data validation, donor record reviews, OPO policy and protocol reviews, OPO staff interviews, and educational demonstrations. In order to perform data validation and donor record reviews, site surveyors request a random sample of deceased donors from the UNOS Research Department. Samples are generated from the OPTN Computer System database using the OPO's donor volume to determine the sample size. For non-routine site surveys, the process and timelines may vary based on the areas of focus and urgency of the matter. On rare occasions, these surveys may be unannounced.

Preparation for Review

After determination of the samples, a site surveyor works with the OPO to determine the exact dates of the survey. Once the survey is scheduled, the site surveyor sends a scheduling letter and the survey sample to the OPO. The surveyor also requests copies of the OPO's written protocols that are required by OPTN policy. Prior to the site survey, site surveyors review the OPO's protocols for compliance with OPTN policy.

Compliance Review

Site surveyors spend approximately one to two business days reviewing donor records to verify compliance with general and organ-specific deceased donor OPTN policies, accuracy of data submitted in the Data System for Organ Procurement and Transplantation Network, and compliance with timely data submission requirements. The surveyors review the preliminary survey findings with the OPO staff during the educational meeting day. They also interview OPO staff to confirm their knowledge of the OPO's submitted protocols and the related OPTN policy requirements. Surveyors will provide further education, as needed.

After the Compliance Review

After reviewing findings, a site surveyor sends the OPO a formal written report detailing survey results and requests a corrective action plan for each identified area of potential noncompliance. The OPO is also encouraged to send additional medical record documents that may have been unavailable during the record review to help rectify identified issues of potential noncompliance.

Once the OPO submits its response, the site surveyor reviews the corrective action plan and other medical record documentation and amends the report, as needed. After reviewing the OPO's response, the site surveyor sends a closing letter (and amended report, if applicable) to the OPO with the survey resolution. Based on the overall survey results, the survey may be closed, a focused desk review may be conducted for areas with a high rate of noncompliance, or the survey may be referred to the MPSC.

OPO Desk Reviews

Methodology

The OPTN performs desk reviews of OPOs for one of two reasons: either as follow-up from a routine site survey due to one or more areas of identified noncompliance or as requested by the MPSC due to repeated noncompliance on both a routine site survey and a follow-up desk review. Depending on the previously identified areas of noncompliance, the desk review may consist of any of the following:

- Data validation
- Donor record reviews
- OPO policy and protocol reviews

In order to perform data validation or donor record reviews, site surveyors request a random sample of deceased donors from the UNOS Research Department. Samples are generated from the OPTN Computer System database, using the OPO's donor volume to determine the sample size.

Preparation for Review

After determination of the samples, the site surveyor sends a scheduling letter and the sample of deceased donors to the OPO. When the desk review includes policy and protocol reviews, the surveyor also requests copies of the OPO's written protocols required by OPTN policy.

Compliance Review

Once the site surveyor receives the OPO's requested data and/or policies, they conduct the desk review.

After the Compliance Review

The site surveyor sends the OPO a formal written report detailing review findings and requests a corrective action plan for each identified area of potential noncompliance. The OPO is also encouraged to send additional medical record documents that they may not have provided with the initial record submission that could help rectify identified issues of potential noncompliance.

Once the OPO submits its response, the site surveyor reviews the corrective action plans and other medical record documentation and amends the report, as needed. After reviewing the OPO's response, the site surveyor sends a closing letter (and amended report, if applicable) to the OPO with the desk review resolution. If the MPSC requested the desk review, or if the desk review identifies continued

potential noncompliance with OPTN policy, then the desk review results are referred to the MPSC. If the MPSC did not request the desk review and the review did not identify potential noncompliance with OPTN policy, then the review is closed.

Transplant Hospital Site Surveys

Methodology

The OPTN performs routine site surveys of transplant hospitals once every three years. The survey includes data validation, medical record reviews, transplant hospital policy and protocol reviews, hospital staff interviews, and educational demonstrations. In order to perform data validation and medical record reviews, site surveyors request a random sample of the hospital's patients and living donors from the UNOS Research Department. Samples are generated from the OPTN Computer System database using the program's waitlist volume to determine the sample size. For non-routine site surveys, the process and timelines vary based on the areas of focus and the urgency of the matter. On rare occasions, these surveys may be unannounced.

Preparation for Review

After determination of the samples, the site surveyor works with the transplant hospital to determine the exact dates of the survey. Once the survey is scheduled, the site surveyor sends a scheduling letter and the survey sample to the hospital. The surveyor also requests copies of the transplant hospital's written protocols that are required by OPTN policy. Prior to the site survey, site surveyors review the transplant center's protocols for compliance with OPTN policy. Site surveyors also run reports in the Data System for Organ Procurement and Transplantation Network to determine the transplant hospital's compliance with vessel storage requirements, if applicable.

Compliance Review

Site surveyors spend roughly two to three business days reviewing medical records to verify compliance with general, organ-specific, and living donor OPTN policies, accuracy of data submitted in the Data System for Organ Procurement and Transplantation Network, and compliance with timely data submission requirements. The surveyors review the preliminary survey findings with the transplant hospital staff during the educational meeting day. They also interview transplant hospital staff to confirm their knowledge of the hospital's submitted protocols and the related OPTN policy requirements. Surveyors will provide further education, as needed.

After the Compliance Review

After reviewing findings, a site surveyor sends the transplant hospital a formal written report detailing survey results and requests a corrective action plan for each identified area of potential noncompliance. The transplant hospital is encouraged to send additional medical record documents that may have been unavailable during the record review to help rectify identified issues of potential noncompliance.

Once the transplant hospital submits its response, the site surveyor reviews the corrective action plan and other medical record documentation and amends the report, as needed. After reviewing the transplant hospital's response, the site surveyor sends a closing letter (and amended report, if applicable) to the transplant hospital with the survey resolution. Based on the overall survey results, the

survey may be closed, a focused desk review may be conducted for areas with a high rate of noncompliance, or the survey may be referred to the MPSC.

Transplant Hospital Desk Reviews

Methodology

The OPTN performs desk reviews of transplant hospitals for one of two reasons: either as follow-up from a routine site survey due to one or more areas of identified noncompliance or as requested by the MPSC due to repeated noncompliance on both a routine site survey and a follow-up desk review. Depending on the previously identified areas of noncompliance, the desk review may consist of any of the following:

- Data validation
- Medical record reviews
- Transplant hospital policy and protocol reviews

In order to perform data validation or medical record reviews, site surveyors request a random sample of patients and living donors from the UNOS Research Department. Samples are generated from the OPTN Computer System database, using the program's waitlist volume to determine the sample size.

Preparation for Review

After determination of the samples, the site surveyor sends a scheduling letter and the sample to the transplant hospital. When the desk review includes policy and protocol reviews, the surveyor also requests copies of the transplant hospital's written protocols that are required by OPTN policy.

Compliance Review

Once the site surveyor receives the transplant hospital's requested data and/or policies, they conduct the desk review. If the review includes the transplant hospital's compliance with vessel storage requirements, the surveyor runs reports in the Data System for Organ Procurement and Transplantation Network and reviews the results to determine compliance.

After the Compliance Review

The site surveyor sends the transplant hospital a formal written report detailing review findings and requests a corrective action plan for each identified area of potential noncompliance. The hospital is also encouraged to send additional medical record documents that they may not have provided with the initial record submission that could help rectify identified issues of potential noncompliance.

Once the transplant hospital submits its response, the site surveyor reviews the corrective action plans and other medical record documentation and amends the report, as needed. After reviewing the transplant hospital's response, the site surveyor sends a closing letter (and amended report, if applicable) to the transplant hospital with the desk review resolution. If the MPSC requested the desk review, or if the desk review identifies continued noncompliance with OPTN policy, the reviews are referred to the MPSC. If the MPSC did not request the desk review and the review did not identify any potential noncompliance, then the review may be closed.

Patient Safety and Non-routine Compliance Reviews

Methodology

When the OPTN becomes aware of a member's potential noncompliance with OPTN obligations or a potential threat to patient health, public safety, or the integrity of the OPTN, UNOS Compliance and Safety Investigators conduct an investigation. A patient safety or potential noncompliance review is initiated when:

- An OPTN member submits a report through the Improving Patient Safety Portal in the OPTN Computer System
- A concerned individual calls the member reporting telephone line
- A concerned individual emails, faxes, or mails a correspondence
- A UNOS department refers a case or concern
- An automated safety monitoring report signals a potential safety incident
- Concerns are identified through publicly available information such as media reports, news articles, etc.

Site Surveyors also receive automated monitoring reports and will request information from members to determine if there is a potential noncompliance. Their process is designed to mirror the process that the Compliance and Safety Investigators follow.

Intake, Triage, and Containment

When an event is reported by an individual outside of UNOS and the reporter's email or mailing address is known, patient safety staff send an acknowledgment of the report. The acknowledgment explains that UNOS will not disclose the reporter's identity to the subject of the report and will not disclose the outcome of the investigation to the reporter.

Patient safety staff then review and triage the report to determine whether:

- Readily available information suggests the report is accurate
- The potential incident meets any of the criteria requiring it to be reported to HRSA according to OPTN contract requirements (see "HRSA-required event reporting" below)
- The potential incident involves issues such as actual, or the potential for, direct harm to patients, a risk to patient health or public safety, or a risk to the integrity of the OPTN

If the incident appears to involve any of these risks, staff notify HRSA, MPSC leadership, and/or UNOS leadership and work with the member to implement an immediate containment plan as needed.

Incident Investigation

Once any necessary containment plans have been implemented, patient safety staff send inquiry letters to all relevant parties involved to gather complete information about the incident. At a minimum, patient safety staff request:

- A detailed explanation of what occurred and why it happened
- Findings of any root cause analyses or post-case reviews
- A description of any corrective actions developed as a result of the incident

- Copies of policies, procedures, medical records, and other supporting documentation, as needed

Parties may receive additional inquiries requesting clarifying or supporting documentation as needed to supplement information obtained through the initial inquiries. A potential OPTN policy noncompliance does not have to be present for staff to request information or documentation related to an event.

Post-investigation Assessment

At the conclusion of the investigation, staff present findings to a multi-disciplinary team that determines whether a potential policy or bylaw noncompliance occurred, or if there is an ongoing risk to patient safety or public health. If a potential noncompliance does not exist, there is no threat to patient safety or public health, and the reported event is not a living donor event as defined by OPTN policy, staff close the case and the member(s) receives a closure letter. If the team identifies a potential noncompliance threat to patient safety or public health, or a threat to the integrity of the transplant system, the member receives a notification letter explaining the potential policy or bylaw noncompliance and staff refer the case to the MPSC for review. The MPSC may review any event, even without a specific OPTN policy citation. If the reported event is a living donor event as defined by OPTN policy, staff refers the case to the MPSC for review according to *Policy 18.6: Reporting of Living Donor Events*.

HRSA-Required Event Reporting

Since 2011, HRSA and the OPTN have identified certain events that could pose a serious risk to patient health, public safety, or the integrity of the transplant system. When the OPTN receives one of these reports, the OPTN must notify the HRSA Contract Officer Representative (COR) within specified timeframes. UNOS Member Quality staff notify the COR within 24 hours of receiving a report of the following events:

- A transplant or "near miss" of the wrong organ into an organ recipient
  - "Wrong organ" is defined as the wrong organ type or the correct organ from the incorrect donor
  - "A transplant of the wrong organ" also means the action was unintentional and not identified prior to transplant
  - Consistent with OPTN policy, "transplant" is defined as after anastomosis
  - "Near miss" means the program's established safety checks, including but not limited to those required by OPTN policy, do not identify the wrong organ, and the program identifies the wrong organ after the induction of general anesthesia
- A transplant or "near miss" into the wrong organ recipient
  - "Wrong organ recipient" means a candidate other than the candidate for whom a transplant program accepted the organ
  - "A transplant into the wrong organ recipient" also means the action was unintentional and not identified prior to transplant
  - Consistent with OPTN policy, "transplant" is defined as after anastomosis
  - "Near miss" means the program's established safety checks, including but not limited to those required by OPTN policy, do not identify the wrong organ, and the program identifies the wrong organ after the induction of general anesthesia
- A suspected or confirmed human immunodeficiency virus (HIV) transmission from a donor (deceased or living) to a transplant recipient

    - Staff will report all instances of a potential donor-derived HIV transmission when confirmatory testing determines a recipient has HIV
    - If confirmatory testing is not planned or will not be completed within 72 hours, staff will report the potential transmission if the amount of time in the following factors suggest there is a high likelihood of HIV transmission from the donor:
        - The time between transplant and the suspected transmission
        - The donor serologies and risk factors
        - The recipient's pre-transplant serologies and risk factors
- Any complaint, issue, or concern that may post a serious or time-sensitive threat to patient health or public 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
    - Staff will notify HRSA if the preliminary investigation determines that a reported issue under review is both credible and represents a serious or time-sensitive threat to patient health or public safety
    - Staff will report any case where there is a credible threat of imminent media involvement associated with a complaint alleging a serious or time-sensitive threat to patient health or public safety, even if the preliminary investigation has not yet determined whether the report is credible
- A living donor death, regardless of the time period after surgery and regardless of cause of death
    - As UNOS receives reports external to OPTN data that supplement the OPTN data set, UNOS will notify the COR within 24 hours of identification of events not already reported to the OPTN, and will work with the member to submit required information to the OPTN Patient Safety Reporting Portal
- Failure of a native organ in a living organ donor
    - "Failure of a native organ" means:
        - A living liver donor is added to the liver waiting list within 2 years of donation
        - A living kidney donor is added to the kidney waiting list within 2 years of donation
        - A living kidney donor begins chronic dialysis within 2 years of donation
    - As UNOS receives reports external to OPTN data that supplement the OPTN data set, UNOS will notify the COR within 24 hours of identification of events not already reported to the OPTN, and will work with the member to submit required information to the OPTN Patient Safety Reporting Portal
- Evidence of an attempt to deceive the OPTN or the United States Department of Health and Human Services (e.g., falsifying medical records)
- Use of a device for a condition, diagnosis, or procedure that is contraindicated by the United States Food and Drug Administration (FDA)
- Any "never event," as included in the Centers for Medicare and Medicaid Services' (CMS) policies for selected hospital-acquired conditions (HACs), in an OPTN member hospital that impacts transplant patients or living organ donors (including those under evaluation for living organ donation)

UNOS Member Quality staff notify the COR within one business day of receiving a report of the following events:

- Any sanction taken by a state medical board or other professional body against a transplant professional working for an OPTN member

MPSC Compliance Review

Methodology

The MPSC compliance review process involves compiling information on current cases from UNOS Member Quality staff for the MPSC to make decisions on the appropriate monitoring or action for noncompliance with OPTN Policies or Bylaws.

UNOS Compliance Operations Analysts receive cases from Member Quality staff and add documentation of member compliance history, transplant program or OPO volumes, and the MPSC's historical response to similar compliance issues to the case information. Ad hoc subcommittees of the MPSC continuously review cases and make recommendations for action. The full MPSC approves these recommendations at an in-person meeting or on a conference call.

To assist in the MPSC's compliance review, the MPSC develops operational rules. These operational rules streamline the MPSC's workflow and allow them to have a manageable caseload for review. Operational rules also standardize the review of like cases that have a low impact on patient safety. The MPSC reviews operational rules annually, or earlier if needed, and are decided on primarily during open session meetings. MPSC Review Process

The MPSC determines the appropriate action based on the case type and member response:

- If the MPSC has no concerns based on the member's response, they may issue a final action or close the review with no further action required.
- If the MPSC has concerns, they may request that the member submit additional information or take additional action.
- The MPSC may continue to request information until the member has addressed all the concerns.

In instances where reviewing documents is inefficient or the MPSC is considering recommending that the Board of Directors take additional action, the member may be offered additional interactions with the MPSC, such as:

- An informal discussion:
  - Used to gather additional information and provide the MPSC and member an opportunity to discuss the review and seek feedback
  - A conference call with at least four members of the MPSC
  - Recommendations from the call must be taken to the full MPSC for approval
- An interview:
  - Used to discuss an ongoing review; allows the member to present corrective actions and allows the MPSC to determine an appropriate action

    - Can be held in-person or by conference call with the full MPSC
    - Recommendations from an interview are final
- A hearing:
    - Used only when the MPSC is recommending that the Board of Directors take an adverse action
    - A formal process with the full MPSC where the member may be represented by an attorney
    - Recommendations from a hearing involve additional monitoring or Board review

If the MPSC requests an informal discussion, interview, or hearing as part of a case review, a compliance operations analyst contacts the member to schedule the event, gather any additional information the MPSC requests, and provide the member with information about the logistics of the event and the MPSC's concerns. The MPSC makes recommendations and decisions as outlined in *Appendix L: Reviews and Actions* of the OPTN Bylaws.

After the MPSC Review

After the MPSC meeting, the member receives a letter from a compliance operations analyst on behalf of the MPSC with the Committee's recommendations. If the MPSC requests additional monitoring, the analyst provides a list of expected items and due dates. The analyst also answers questions about the MPSC's concerns and the content of the submissions. The analyst sends all information to a subcommittee or the full MPSC for review until the MPSC releases the member from monitoring. The analyst then sends the member a letter informing them that the review process has ended.

Performance Reviews

The OPTN reviews both OPO and transplant hospital performance. The MPSC's goal is to work with members identified through these reviews to implement performance improvement measures. The criteria used to identify members for performance review serve as triggers to request information from members so the MPSC can look at the member's performance more closely.

OPO Yield

Methodology

The OPTN reviews OPO aggregate organ yield, as well as kidney, liver, heart, and lung yield, on an ongoing basis. To assist the OPTN in identifying OPOs for review, the Scientific Registry of Transplant Recipients (SRTR) creates reports twice a year using a statistically driven method that includes risk adjustment for the makeup of an OPO's donor population. Each report includes donors over a 24-month period, with an approximately six-month delay between the end of the report period and the time the report is generated. Each time the reports are generated, the reporting period moves forward six months. The MPSC identifies OPOs for review according to the criteria outlined in *Appendix B.2 OPO Performance Requirements* of the OPTN Bylaws.

Request for Information

Performance Analysts send each OPO identified for review a questionnaire to complete. The questionnaire allows the OPO to provide information about its operations and donors during the review

period. The OPO also receives a donor yield spreadsheet that lists select donors from whom the organ(s) for which the OPO was identified was not transplanted. The OPO must provide information on the placement efforts, factors affecting placement, and organ details for the identified donors; it may also provide information about opportunities identified and steps taken to improve organ yield.

Once an OPO returns its questionnaire and supporting documentation to the OPTN, a performance analyst reviews the submission to verify that all of the requested documents have been submitted. If some of the requested documentation is missing, the analyst notifies the OPO and provides a due date for submitting the documentation. When the member's submission is determined to be complete, the information is prepared for MPSC review.

Transplant Program Outcomes

Methodology

The OPTN reviews pre- and post-transplant outcomes to identify potential risks to patient health or public safety. To assist the OPTN in identifying programs for review, the Scientific Registry of Transplant Recipients (SRTR) obtains data from the OPTN Computer System, risk adjusts the data based on a program's patient population, and statistically models the data using a Bayesian approach to create reports for the OPTN twice a year. Data on graft survival includes the transplants performed by a program over a 30-month period, with approximately a one-year delay between the end of the report period and the time the report is generated. Data on offer acceptance includes data for a one-year period. Data on pre-transplant mortality includes a two-year period. Each time the reports are generated, the reporting period moves forward six months. The MPSC identifies transplant programs for outcomes review according to the criteria in *Appendix D.12.A Transplant Program Performance* of the OPTN Bylaws, which are:

- The probability that the transplant program meets any of the following criteria is greater than 50% for adult transplants:
  - The transplant program's pre-transplant mortality rate ratio is greater than 1.75 during a two year period.
  - The transplant program's offer acceptance rate ratio is less than 0.30 during a 1 year period.
  - The transplant program's 90-day post-transplant graft survival hazard ratio is greater than 1.75 during a 2.5 year time period. For pancreas transplant programs, 90-day post-transplant patient survival hazard ratio is greater than 1.75 during a 2.5 year period.
  - The transplant program's 1-year post-transplant graft survival conditional on 90-day post-transplant graft survival hazard ratio is greater than 1.75 during a 2.5 year period. For pancreas transplant programs, 1-year post-transplant patient survival conditional on 90-day post-transplant patient survival hazard ratio is greater than 1.75 during a 2.5 year period.
- The probability that the transplant program meets any of the following criteria is greater than 50% for pediatric transplants:
  - The transplant program's pre-transplant mortality rate ratio is greater than 1.75 during a two year period.
  - The transplant program's offer acceptance rate ratio is less than 0.35 during a 1 year period.
  - The transplant program's 90-day post-transplant graft survival hazard ratio is greater than 1.60 during a 2.5 year period.

- The transplant program's 1-year post-transplant graft survival conditional on 90 day post-transplant graft survival hazard ratio is greater than 1.60 during a 2.5 year period.

Request for Information

Performance analysis staff send each transplant program identified for review a questionnaire to complete. The questionnaire allows the program to provide information about program operations, as well as:

- Performance improvement efforts the program has implemented
- Program activity, such as the number of patients the program evaluated for listing during a designated time period or the program's method of evaluating organ offers
- Unique clinical aspects that may have influenced the observed performance rates

If identified for graft survival, the program must also validate transplant data submitted in the OPTN Computer System and provide a synopsis of the recipient graft failures that occurred within the appropriate time periods from the beginning of the review period to the present date.

Once a transplant program returns its questionnaire and supporting documentation to the OPTN, a performance analyst reviews the submission to verify that all of the requested documents have been submitted. If some of the requested documentation is missing, the analyst notifies the transplant program and provides a due date for submitting the documentation. When the member's submission is determined to be complete, the information is prepared for MPSC review.

Performance Improvement

In the spirit of process improvement, performance analysis staff also reach out to members who are not identified for review but are close to the performance monitoring thresholds. The MPSC has defined a "performance improvement zone" in addition to the requirements for official MPSC review. Programs that fall within the performance improvement zone are not obligated to interact with the OPTN but are encouraged to monitor their own performance and implement process improvements in hopes of avoiding future MPSC review.

The performance improvement zones for the metrics implemented in July 2022 and July 2023 are defined as:

- Adult and Pediatric Pre-transplant Mortality Rate Ratio – Greater than 50% probability that the program's pre-transplant mortality rate ratio is greater than 1.5, but less than 1.75.
- Adult Offer Acceptance Rate Ratio – Greater than 50% probability that the program's offer acceptance rate is less than 0.40, but greater than 0.30.
- Pediatric Offer Acceptance Rate Ratio – Greater than 50% probability that the program's offer acceptance rate is less than 0.45, but greater than 0.35.
- Adult 90-Day Graft Survival – Greater than 50% probability that the program's 90-day graft failure rate is greater than 1.5, 50% higher than expected, but below 1.75.
- Pediatric 90-Day Graft Survival –Greater than 50% probability that the program's 90-day graft failure rate is greater than 1.35, 35% higher than expected, but below 1.60.
- Adult 1-Year Conditional Graft Survival – Greater than 50% probability that the program's conditional 1-year graft failure rate is greater than 1.5, 50% higher than expected, but below 1.75.

- Pediatric 1-Year Conditional Graft Survival – Greater than 50% probability that the program's conditional 1-year graft failure rate is greater than 1.35, 35% higher than expected, but below 1.60.

Transplant Program Activity

Methodology

The OPTN reviews kidney, liver, pancreas, heart, and lung transplant programs on an ongoing basis to verify that the programs remain functionally active by performing transplants at frequencies specified in *Appendix D.11.A Functional Inactivity* of the OPTN Bylaws.

Three times a year, the UNOS Research Department provides Performance Analysts with a report identifying each program that has not performed a transplant at the required frequency and that is therefore considered functionally inactive. The report includes the program approval date, the number of active and inactive patients on the program's waiting list, and a list of deceased donor organs that were not accepted by the program but were accepted and transplanted by another transplant hospital.

Request for Information

Performance Analysis staff send each transplant program identified for functional inactivity review a request for information that includes:

- A questionnaire to provide information about the overall operation of the transplant program
- Program activity, such as the number of patients the program evaluated for listing during a designated time period
- A log of transplants performed by the program and reported in the OPTN Computer System that the program must validate for data accuracy
- A copy of the program's organ offer/turndown report. This report lists all deceased donor organs offered to the program since the program's last performed transplant that the program refused and another transplant program accepted and transplanted. The program must verify the accuracy of the data on the report and provide details about each organ refusal.
- A request for a sample copy of the letter sent to potential candidates and candidates on the waiting list notifying them of the program's inactivity, as well as a list of the patients who received the letter

Once a transplant program returns its questionnaire and supporting documentation to the OPTN, a performance analyst reviews the submission to verify that all of the requested documents have been submitted. If some of the requested documentation is missing, the analyst notifies the transplant program and provides a due date for submitting the documentation. When the member's submission is determined to be complete, the information is prepared for MPSC review.

MPSC Performance Review

After a transplant program or OPO identified for MPSC performance review returns its questionnaire and supplemental documentation, the documents are blinded to de-identify patient data and then sent

to an ad hoc subcommittee of three MPSC members for review. The subcommittee makes a recommendation for action, which is then presented to the MPSC at its next in-person meeting.

During each of its three annual multi-day meetings, the MPSC reviews the members' submissions, related SRTR data such as OPO- and program-specific reports, and the recommendations of the ad hoc subcommittees and recommends an action for each member under review. These actions include requesting further information, continuing to monitor the program/OPO, or releasing the program/OPO from actively reporting. After the MPSC meeting, a performance analyst sends a letter to the member on behalf of the MPSC communicating the MPSC's recommendation.

Peer Visits

Methodology

The MPSC may recommend that a member participate in an on-site peer visit. Peer visits give the MPSC an objective evaluation of the member by experienced transplant professionals. Member Quality staff identify potential peer team members and present recommendations to the MPSC Chair for approval. Peer teams typically include individuals from like organizations and at least one UNOS staff member who helps facilitate the visit. UNOS bills the member participating in the peer visit for all expenses related to the visit, including travel expenses and peer team member honorariums.

Preparation for Review and Peer Team Review

A member recommended for a peer visit must provide organizational information to the peers as requested. The peer team may identify additional information that will help the member prepare for the peer visit, and Member Quality staff communicate any additional requests for information.

Once on site, the peer team interviews key staff, institutional leadership, and support services personnel. Interviews help the member, the peer team, and the MPSC identify potential areas for improvement. The peer team also reviews pertinent information specific to the identified areas of evaluation.

MPSC Review of Peer Team Report

After the visit, the peer team prepares a report outlining the member's strengths and opportunities for improvement. The MPSC reviews the peer team's report and supporting documentation, if any.

Following the MPSC's review of the peer team report, an analyst sends the member a letter that includes the final report and any additional MPSC requests or recommendations. The member must submit a plan for quality improvement that addresses all of the recommendations within the report.

HRSA-Directed Special Reviews

The UNOS Member Quality department conducts special reviews of OPTN members at the request of HRSA when concerns over compliance with OPTN Obligations and/or risks to patient health or public safety exist.

Upon receipt of the initial written directive from HRSA, Member Quality staff begin planning for the investigation. These investigations may take the form of peer visits, focused on-site surveys and/or desk reviews, increased monitoring of specific member actions, or process improvement support. Using a standard planning template, staff analyze the needs for an on-site review and the types of tools appropriate for the issue. If the investigation involves on-site reviews with practicing transplant professionals (peer visits), staff initiate the recruitment. Staff also facilitate communication between UNOS, MPSC leadership and HRSA representatives to identify areas of focus, specific questions to be addressed, and expected outcomes and deliverables. Member Quality staff provide HRSA representatives updates based on an agreed-upon timeline. Unless otherwise specified, if the investigation includes an on-site visit, staff provide an update to the Contract Officer Representative (COR) at the end of the first day of the visit.

After returning from the member institution, staff verbally present preliminary findings during the next standing MPSC leadership call on which HRSA representation is present. For reviews that do not include an on-site portion, UNOS delivers a written high-level summary of findings to the COR upon completion of the investigation. All final reports are delivered to the COR in the timeframe specified by the HRSA directive.