

# What to Expect: Performance Reviews

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## WHAT TO EXPECT: TRANSPLANT PROGRAM OUTCOMES REVIEW

The Organ Procurement and Transplantation Network (OPTN) Membership and Professional Standards Committee (MPSC) reviews transplant programs for post-transplant and pre-transplant outcomes. If a program performs adult and pediatric transplants, the MPSC analyzes the adult and pediatric outcomes separately. The goal of the MPSC is to work with the program to implement performance improvement measures.

### How does the MPSC identify programs for outcomes review?

The MPSC uses a statistically driven method developed by the Scientific Registry of Transplant Recipients (SRTR) to identify programs for review. The MPSC receives SRTR data twice a year, in the spring and the fall. The MPSC uses the following criteria to identify programs for review (see *Appendix D.12.A: Transplant Program Performance* of the OPTN Management and Membership Policies):

1. The probability that the transplant program meets any of the following criteria is greater than 50% for adult transplants:
  - a. The transplant program's pre-transplant mortality rate ratio is greater than 1.75 during a 2 year period.
  - b. The transplant program's offer acceptance rate ratio is less than 0.30 during a 1 year period.
  - c. The transplant program's 90-day post-transplant graft survival hazard ratio is greater than 2.25 during a 2.5 year period. For pancreas transplant programs, 90-day post-transplant patient survival hazard ratio is greater than 2.25 during a 2.5 year period.
  - d. The transplant program's 1-year post-transplant graft survival conditional on 90-day post-transplant graft survival hazard ratio is greater than 2.25 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 2.25 during a 2.5 year period.
2. The probability that the transplant program meets any of the following criteria is greater than 50% for pediatric transplants:
  - a. The transplant program's pre-transplant mortality rate ratio is greater than 1.75 during a 2 year period.
  - b. The transplant program's offer acceptance rate ratio is less than 0.35 during a 1 year period.
  - c. The transplant program's 90-day post-transplant graft survival hazard ratio is greater than 1.60 during a 2.5 year period.
  - d. 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.

In other words, a hazard ratio of one (1) is the national average. The adult criteria for graft survival as well as the pediatric and adult criteria for pre-transplant mortality are based on the likelihood that the program's performance was at least 75% worse than an average program, accounting for differences in the types of recipients and donor organs transplanted. The pediatric criteria for graft survival is based on the likelihood that the program's performance was at least 60% worse than an average program, accounting for differences in the types of recipients and donor organs transplanted. For offer acceptance, the adult criteria is based on the likelihood that the program's performance was at least 70% worse than average, or 65% for pediatric offers.

Even if a program meets one of the criteria for review, the MPSC may not send the program an inquiry based on various situations, such as recent release from review for outcomes or program membership status.

## What information will the MPSC request?

The initial inquiry from the MPSC includes multiple elements and directions for completion:

- The Transplant Program Outcomes Review Questionnaire gives the program an opportunity to provide information about the overall operation of the transplant program. The questionnaire covers areas such as hospital administration, leadership staff, support staff, and the quality program.
  - Activity Reports give the MPSC a three month outlook of the program's activity, such as the number of patient referrals, evaluations and additions to the waiting list; the number of transplants performed, deaths on the waiting list and active versus inactive patients on the waiting list.
  - A program's transplant log includes a summary of the number of transplants performed and a list containing details and outcomes of each transplant performed. The transplant log is a list generated from the transplant data reported by the program in the Data System for Organ Procurement and Transplantation Network/the OPTN Computer System. The program needs to verify the information contained in the transplant log, make any necessary edits and update the Data System for Organ Procurement and Transplantation Network/the OPTN Computer System, if necessary.
  - The MPSC requests that the program provide a synopsis of each graft failure that occurred within 90 days or one year of transplant, depending on the metric under review, from the beginning of the two and a half year cohort to the present date. An example of a synopsis format is included in the packet.
- Offer acceptance inquiries include a questionnaire, data on additional subgroups analyzed by the SRTR, as well as information about data reports available to help programs analyze their progress.
- Pre-transplant mortality inquiries include a questionnaire and a request for summaries of a sample of patients who died during the observation period.
- All inquiries request a plan for improvement developed following a comprehensive review of the program. The program may also provide any additional information that gives the MPSC a better understanding of what the program is doing to improve their transplant outcomes.

If you are unsure of what you should include on any of the documents, please contact the Performance Analyst associated with your region. The more details you provide with your submission, the better. This gives the MPSC a better understanding of what you are doing to support the program.

## What is the MPSC looking for when reviewing the program's submission?

The OPTN Management and Membership Policies provide an opportunity for a program to explain the lower-than-expected outcomes based on the following:

- Has the program demonstrated a patient mix, based on factors not adequately adjusted for in the SRTR model?
- Is there a unique clinical aspect of the program (for example, clinical trials being conducted) that explains the lower-than-expected outcomes?

If the program's performance cannot be explained by patient mix or other unique clinical aspects, the MPSC considers the following questions while reviewing the program:

- Has the program evaluated their performance, developed a plan for improvement and implemented the plan for improvement?
- Has the program demonstrated improvement in their outcomes based on recent data?
- Has the program demonstrated an ability to sustain improvement? For example, does the program have the resources needed and processes in place to evaluate their own performance on a regular basis, develop plans for improvement when needed and implement those plans?

### **What actions are available to the MPSC after review of the program's submission?**

The MPSC reviews the submission, as well as additional data on the program available in the SRTR program specific reports (PSRs). Following its review, the MPSC either:

- Releases the program
- Continues to monitor the program

The MPSC may release the program from review if it finds that there is a unique circumstance at the program or that the program has made sufficient progress related to the issues that led to program identification for lower-than-expected outcomes.

If the MPSC decides to continue to monitor the program, the committee reviewers provide feedback and:

- At a minimum for graft survival, the program must complete a new activity report, verify an updated transplant log summary and updated transplant logs, and provide synopses for any graft failures since the last submission.
- The program may need to submit additional information based on the previous submission or the program's data reviewed by the Committee.
  - Examples of common additional requests include: updates to the plan for quality improvement, RCA for the last synopsis, updates to specific protocols, updates on changes in personnel.
- The MPSC may ask questions about specific additional areas associated with the transplant program (facilities, support personnel, ICU, etc.).
- The MPSC may ask the program to participate in an informal discussion. Generally conducted via conference call, informal discussions gather additional information from the program personnel directly including the ongoing efforts to improve outcomes. Informal discussions provide an opportunity for the program to give a presentation and participate in a question-and-answer session with members of the MPSC. The program later receives a summary of the informal discussion.
- In some instances, after review of the program's previous submissions and outcomes data, the MPSC may request that the program participate in an MPSC directed on-site peer visit, as described in *Appendix L.6: Peer Visits* of the OPTN Management and Membership Policies. A panel of transplant peers conduct the on-site visit with at least one OPTN Contractor staff member facilitating. The visit is typically one and a half days of interviews with hospital staff. The program later receives a letter from the MPSC with the peer team's recommendations. The program must then submit a plan for quality improvement addressing the recommendations in the report.
- In very rare instances, the MPSC may ask the program to voluntarily inactivate or cease a component while implementing its improvement efforts, as described in *Appendix D.12.A: Transplant Program Performance* of the OPTN Management and Membership Policies. The

MPSC may request that a program inactivate if the Committee has concerns about patient safety related to lack of progress by the program and a failure to demonstrate improvement in transplant outcomes over a period of time. The MPSC will offer the program an informal discussion prior to requesting voluntary inactivation. If the MPSC recommends that a program inactivate, the program has an opportunity to participate in an interview with the full MPSC.

## Encouraging Process Improvement

In the spirit of process improvement, Performance Analysts will also reach out to members who are not identified for review but are close to the performance monitoring thresholds, providing links to resources for process improvement. 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 implemented metrics are defined as:

For adult transplants:

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

For pediatric transplants:

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

## WHAT TO EXPECT: OPO PERFORMANCE REVIEW

The MPSC notifies Organ Procurement Organizations (OPO) when they are identified for having a lower-than-expected organ yield. The MPSC also reviews many other aspects of the OPO, including: changes to processes and procedures, proactive and introspective reviews of donor yield performance, as well as donor characteristics and placement effort data in determining which OPO’s require further review. The MPSC’s goal is to work with the OPO to implement performance improvement measures.

### How does the MPSC identify OPOs to review?

The SRTR provides the MPSC with OPO organ yield reports twice a year. The SRTR uses a statistically driven method to analyze an OPO’s organ yield with risk adjustment for the mix of donor population.

The MPSC reviews an OPO when actual aggregate and/or specific organ yield falls below expected rates using the following criteria:

- The observed minus the expected yield per 100 donors is less than -10,
- The ratio of observed to expected yield is less than 0.90, and
- The two-sided p-value is less than 0.05.

The SRTR includes donor information over a two year cohort with approximately a 6 month delay from the end of the cohort.

If an OPO meets the criteria above, the MPSC will NOT send an initial inquiry if the OPO:

- Is currently under MPSC review for lower-than-expected organ yield, or
- Was released from actively reporting to the MPSC for lower-than-expected organ yield in the past two SRTR cycles.

### **What information will the MPSC request?**

The MPSC will request that the OPO complete and submit the following documentation. Instructions for completion of these documents are included in the packet sent to an OPO.

- The OPO Performance Questionnaire gives the OPO an opportunity to provide information about the overall operation of the OPO and about donors during the cohort period. The questionnaire covers areas such as general OPO facilities, administrative support, and the donation process of the OPO.
- The MPSC sends the OPO a donor yield spreadsheet that includes a select list of donors where the organ for which the OPO was identified was not transplanted. The list includes donors that meet the following criteria:
  - Kidneys:
    - Any donor under age 70 with 1.2 or more kidneys expected than transplanted, and
    - A random sample of 25% of the donors under age 70 with a gap between yields between 0.7 and 1.2.
  - Liver, Heart or Lung:
    - Any donor under the age of 70 for liver and 60 for thoracic organs with a gap greater than 50% between the expected yield and observed yield for the organ under review, and
    - A random sample of 25% of the donors under the age of 70 for liver/60 for thoracic organs with a gap between yields less than 50%.
- The OPO may also provide any additional information that may provide the MPSC a better understanding of what the OPO is doing to improve organ yield.

### **What is the MPSC looking for when reviewing the OPO's submission?**

The OPTN Management and Membership Policies provide an opportunity for an OPO to explain the lower-than-expected organ donor yield based on the following:

- Has the OPO demonstrated a donor mix, based on factors not adequately adjusted for in the SRTR model?
- Is there a unique donor characteristic or demographic aspect that explains the lower-than-expected donor yield?

If the OPO's performance cannot be explained by donor mix or some other unique aspect, the MPSC considers the following questions while reviewing the OPO:

- Has the OPO evaluated their organ yield performance, developed a plan for improvement and implemented the plan for improvement?
- Has the OPO demonstrated improvement based on recent data?
- Has the OPO demonstrated an ability to sustain improvement? For example, does the OPO have the resources needed and processes in place to evaluate their own performance on a regular basis, develop plans for improvement when needed and implement those plans?

### **What actions are available to the MPSC after review of the OPO's submission?**

The MPSC reviews the submission as well as additional data on the OPO. Following its review, the MPSC either:

- Releases the OPO or
- Continues to monitor the OPO

The MPSC may release the OPO from review if it finds that there is a unique circumstance at the OPO or that the OPO has made sufficient progress related to the issues that led to OPO identification for lower-than-expected organ yield.

If the MPSC decides to continue to monitor the OPO:

- At a minimum, the OPO must provide information on donors since the previous submission.
- The OPO may need to submit additional information based on the previous submission or the organ donor data reviewed by the Committee.
  - Examples of common additional requests: Policies and procedures or specific questions relating to the review including updates on personnel recruitment or explanations of placement efforts for organs not transplanted.
- The MPSC may ask the OPO to participate in an informal discussion. Generally conducted via conference call, informal discussions gather additional information from the OPO personnel directly including the ongoing efforts to increase and improve organ utilization. Informal discussions provide an opportunity for the OPO to give a presentation and participate in a question-and-answer session with members of the MPSC. The OPO later receives a summary of the informal discussion from the MPSC.
- The MPSC may request that the OPO participate in an MPSC directed on-site Peer Visit, as described in *Appendix B.2: OPO Performance Requirements* of the OPTN Management and Membership Policies. A panel of OPO peers conduct the on-site visit with at least one OPTN Contractor staff member facilitating. The visit is typically one and a half days of interviews with OPO staff. The OPO later receives a letter from the MPSC with the peer team's recommendations. The OPO must then submit a plan for quality improvement addressing the recommendations in the report.

If you are unsure of what you should include on any of the documents, please contact the Performance Analyst associated with your region. The more details you provide with your submission, the better. This gives the MPSC a better understanding of what you are doing to improve.



## WHAT TO EXPECT: MPSC FUNCTIONAL INACTIVITY REVIEW – KIDNEY, LIVER, HEART, LUNG, AND STAND-ALONE PEDIATRIC PROGRAMS

The MPSC notifies transplant programs for functional inactivity reviews when a transplant has not been performed during a specified time period, depending on the program type.

### For different program types, what are the correlating inactivity periods?

Kidney, Liver, or Heart Programs:

- Failure to perform at least 1 transplant in 3 consecutive months

Lung Programs:

- Failure to perform at least 1 transplant in 6 consecutive months

Pediatric Stand-alone Programs:

- Failure to perform at least 1 transplant in 12 consecutive months

Islet, Intestinal, and VCA Programs:

- No functional inactivity definitions have been established

Please note: Islet, Intestine, and VCA programs are not currently monitored. Multi-organ transplants are not factored into these inactive time periods.

Although the inactive periods are used to identify programs for review, the MPSC considers many aspects of the program to determine further needs for evaluation, including:

- Changes in key personnel
- Changes to processes and procedures within the transplant program
- Proactive measures to increase transplant volume
- Geographical locations

The goal of the MPSC is to partner with programs and support the implementation of performance improvement measures to ultimately increase the number of transplants.

### How does the MPSC identify programs that have not performed a transplant?

The OPTN Contractor's Research department provides the MPSC with reports identifying programs that have not performed a transplant during the specified time period. The report notes the program's approval date, the number of active and inactive patients on their waiting list, and a list of organs offered to the program that they declined and were eventually accepted and transplanted elsewhere.

The MPSC will NOT send an inquiry if the program meets one of the following:

- Is already under review
- Has been released from actively reporting in the last two MPSC reporting cycles
- Is inactive or withdrawn
- Has been in active membership status for less than one year, or
- Has not received organ offers (applies to an initial identification, if a program is identified a second time with no offers, it will enter the performance review process)

### What information will the MPSC request?

All programs must complete and submit the following documentation in response to an initial inquiry from the MPSC. Instructions for completion of these documents are included in the packet.

- The Transplant Program Expanded Inactivity Questionnaire gives you an opportunity to provide information about the overall operation of the transplant program. The questionnaire covers areas such as hospital administration, facilities, support personnel, Quality Assurance and Performance Improvement (QAPI), patient referral and evaluation, etc.
- The Activity Report gives the MPSC a three month outlook of your program's activity, such as the number of patient referrals, evaluations, and additions to the waiting list; the number of transplants performed, deaths on the waiting list and active versus inactive patients on the waiting list.
- A program's transplant log summary and transplant logs are included with the correspondence from the MPSC. The transplant log is a list generated from the transplant data reported by the program in the Data System for Organ Procurement and Transplantation Network/the OPTN Computer System. The dates of the logs are determined using SRTR cohort dates that show data from the date of the program's initial inquiry through the most current date. Remember, even though the transplant log dates include transplants performed to the present, transplants performed after the last day of the program's initial cohort are not included in the data analysis that identified the program for MPSC review. The additional logs are supplemental information to show the number of transplants the program performed since the end of the cohort, including the outcomes within one year post-transplant.
  - The MPSC requests that you verify that all of the information on the transplant logs is correct. If there are any edits, please note them and include any additional transplants, including patient deaths/graft failures.
  - Common edits to the transplant logs: Updating/adding a surgeon/physician who last saw the patient, cause of organ failure, cause of death and/or graft failure.
- Analysis of Organ Offer/Turndown Report provided to the program in the initial correspondence
- Patient notification requirements- If a transplant program is notified by the MPSC that the program has been identified as functionally inactive, written notice must be provided within 30 days of the date of the MPSC notification to:
  - Potential candidates
  - All candidates registered on the waiting list
- Program should provide a sample of the patient notification letter and the list of candidates or potential candidates that were sent the letter.

Information to be included in the patient notification letters include:

1. The dates identified in the MPSC notification during which no transplants were performed.
2. The reason no transplants were performed.
3. The options available to the candidates, including multiple listing or transfer of accrued waiting time to another transplant hospital.
4. A copy of the OPTN Contractor's Patient Information Letter.

If you are unsure of what you should include on any of the documents, please contact the Performance Analyst associated with your region. The more details you provide with your submission, the better. This gives the ad hoc subcommittee of the MPSC a better understanding of what you are doing to support the program and increase the number of transplants.

### **What recommendations could the MPSC make after review of my submission?**

- Release from actively reporting: The MPSC is satisfied with the progress your program has made related to the issues that led it to be identified as functionally inactive.

- Continue to monitor: Your program will continue to actively report to the MPSC.
  - At a minimum, you will be asked to complete a new activity report, verify an updated transplant log summary and updated transplant logs, (the transplant log timeframe will begin from when you were first identified – present date), and
  - You may need to submit additional information based on the previous submission or the program’s data reviewed by the Committee.
    - Examples of common additional requests: Updates to the plan for quality improvement, plans to increase outreach and the number of referrals, plans to increase the patients on the waiting list, updates to specific protocols, updates on changes in personnel.
- The MPSC may ask the program participate in an informal discussion. Generally conducted via conference call, informal discussions gather additional information from the program personnel directly including the ongoing efforts to improve outcomes. Informal discussions provide an opportunity for the program to give a presentation and participate in a question and answer session with members of the MPSC. The program later receives a summary of the informal discussion.
- In very rare instances, the MPSC may ask the program to voluntarily inactivate while implementing its efforts to increase transplant volume, as described in *Appendix D.11 Review of Transplant Program Functional Inactivity* of the OPTN Management and Membership Policies. The MPSC will request that a program inactivate if the Committee has concerns about patient safety generally related to lack of progress by the program and a failure to increase referrals, patients on the waiting list, and ultimately not actively performing transplants. The MPSC will offer the program an informal discussion prior to requesting voluntary inactivation. If the MPSC recommends that a program inactivate, the program has an opportunity to participate in an interview with the full MPSC.

## MEMBER GUIDE: MPSC FUNCTIONAL INACTIVITY REVIEW – PANCREAS PROGRAMS

Programs that do not perform a transplant during a specified time period are considered functionally inactive. For pancreas programs, functional inactivity occurs if both of the following are true:

1. Failure to perform at least 2 transplants in 12 consecutive months.
2. Either of the following in 12 consecutive months:
  - a. A median waiting time of the program’s kidney-pancreas and pancreas candidates that is above the 67th percentile of the national waiting time.
  - b. The program had no kidney-pancreas or pancreas candidates registered at the program.

Although the inactive periods are used to identify programs for review, the MPSC considers many aspects of the program to determine further needs for evaluation, including:

- Changes in key personnel
- Changes to processes and procedures within the transplant program
- Proactive measures to increase transplant volume
- Geographical locations

The goal of the MPSC is to partner with programs and support the implementation of performance improvement measures to ultimately increase the number of transplants.

## How does the MPSC identify programs that have not performed a transplant?

The OPTN Contractor's Research department provides the MPSC with reports identifying programs that have not performed a transplant during the specified time period, and provides their median waiting time compared to the national median waiting time. The report notes the program's approval date, the number of active and inactive patients on the waiting list, and a list of organs offered to the program that they declined and were ultimately accepted and transplanted elsewhere.

The MPSC will NOT send an inquiry if the program:

- Is already under review
- Has been released from actively reporting in the last two MPSC meeting reporting cycles
- Is inactive or withdrawn
- Has been in active membership status for less than one year
- Has not received organ offers (applies to an initial identification, if a program is identified a second time with no offers, it will enter the performance review process)

## What information will the MPSC request?

All pancreas (including kidney/pancreas) programs identified as functionally inactive must complete and submit the following documentation in response to an initial inquiry from the MPSC. Instructions for completion of these documents are included in the packet.

- The Transplant Program Expanded Inactivity Questionnaire gives the program an opportunity to provide information about the overall operation of the transplant program. The questionnaire covers areas such as hospital administration, facilities, support personnel, QAPI, patient referral and evaluation, etc.
- The Activity Report is designed to give the MPSC a three month outlook of the program's activity, such as the number of patient referrals, evaluations, and additions to the waiting list; the number of transplants performed, deaths on the waiting list and active versus inactive patients on the waiting list.
- A program's transplant log summary and transplant logs are included with the correspondence from the MPSC. The transplant log is a list generated from the transplant data reported by the program in the Data System for Organ Procurement and Transplantation Network/the OPTN Computer System. The dates of the logs are determined using SRTR cohort dates that show data from the date of the program's initial inquiry through the most current date. Remember: even though the transplant log dates will include transplants performed to the present, transplants performed after the last day of the program's initial cohort are not included in the data analysis that identified the program for review. The additional logs are supplemental information to show the number of transplants the program performed since the end of the cohort, including the outcomes within one year post-transplant.
  - The MPSC requests that the program verify all of the information on the transplant logs is correct. If there are any edits, please note them and update the Data System for Organ Procurement and Transplantation Network/the OPTN Computer System accordingly. Include any additional transplants, including patient deaths/graft failures.
  - Common edits to the transplant logs include: updating/adding a surgeon/physician who last saw the patient, cause of organ failure, cause of death and/or graft failure.
- Analysis of Organ Offer/Turndown Report provided to the program.

- Patient notification requirements include written notice provided within 30 days of the date of the MPSC notification to:
  - Potential candidates and
  - All candidates registered on the waiting list

The written notification must include:

- The dates identified in the letter of inquiry during which no transplants were performed.
- The program's median waiting time in the consecutive 12 month period for kidney/pancreas and pancreas candidates compared to the 67th percentile of the national waiting time.
- The reason no transplants were performed.
- The options available to the candidates and potential candidates, including:
  - The opportunity to be multiple listed;
  - The ability to transfer accrued waiting time to another transplant hospital;
  - And a list of other pancreas transplant programs within 125 nautical miles, in-state or in-commonwealth.
- A copy of the OPTN Contractor's Patient Information Letter.

The program must provide a representative copy of the written notification distributed to potential candidates and candidates on the waiting list and a list of all patients that received the written notice.

If you are unsure of what you should include on any of the documents, please contact the Performance Analyst associated with your region. The more details you provide with your submission, the better. This gives the ad hoc subcommittee of the MPSC a better understanding of what you are doing to support the program and increase the number of transplants.

### **What recommendations could the MPSC make after review of my submission?**

- Release from actively reporting: The MPSC is satisfied with the progress the program has made related to the issues that led to the identification of the program as functionally inactive.
- Continue to monitor: The program continues to actively report to the MPSC.
  - At a minimum, the program must complete a new activity report, verify an updated transplant log summary and updated transplant logs, (the transplant log timeframe will begin from when the program was first identified – present date), and
  - The program may also need to submit additional information based on the previous submission or the program's data reviewed by the Committee.
    - Examples of common additional requests include: updates to the plan for quality improvement, plans to increase outreach and the number of referrals, plans to increase the patients on the waiting list, updates to specific protocols, updates on changes in personnel.
- The MPSC may ask the program participate in an informal discussion. Generally conducted via conference call, informal discussions gather additional information from the program personnel directly including the ongoing efforts to improve outcomes. Informal discussions provide an opportunity for the program to give a presentation and participate in a question and answer session with members of the MPSC. The program later receives a summary of the informal discussion from the MPSC.
- In very rare instances, the MPSC may ask the program to voluntarily inactivate while implementing its efforts to increase transplant volume, as described in *Appendix D.11 Review of Transplant Program Functional Inactivity* of the OPTN Management and Membership Policies.

The MPSC will request that a program inactivate if the Committee has concerns about patient safety generally related to lack of progress by the program and a failure to increase referrals, patients on the waiting list, and ultimately not actively performing transplants over a period of time. The MPSC will offer the program an informal discussion prior to requesting voluntary inactivation. If the MPSC recommends that a program inactivate, the program has an opportunity to participate in an interview with the full MPSC.

## **WHAT TO EXPECT: TRANSPLANT PROGRAM PEER VISITS**

The MPSC may recommend that your program participate in a peer visit.

### **What is a peer visit?**

Peer visits are a tool used by the MPSC to obtain an objective evaluation of the transplant program by experienced transplant professionals. Peer visits are conducted on behalf of the MPSC and under confidential medical peer review.

The peers review the program's policies and procedures and information associated with the MPSC's review of the program prior to the on-site visit. During the visit, the peers conduct interviews and typically tour the hospital's transplant facilities, including but not limited to the OR suite, ICU and other post-operative areas, and clinic facilities. After the visit, the peer team prepares a report outlining the program's strengths and opportunities for improvement. The MPSC reviews and approves the report and asks the member to prepare a plan for quality improvement that addresses the team's findings.

### **Who participates in a peer visit?**

The MPSC determines what types of transplant professionals should participate in the visit. OPTN Contractor staff identify potential peer team members and present recommendations to the MPSC Chair for approval. Peer teams typically include a transplant surgeon, transplant physician and primary program administrator and may also include other professionals such as a transplant quality administrator or a transplant anesthesiologist. At least one OPTN Contractor staff member is present to help facilitate the on-site visit.

The team will likely schedule interviews with hospital administration, transplant program staff, and any ancillary hospital staff involved in the program. It is essential that key transplant program personnel be available during the visit.

### **When will the peer visit take place?**

OPTN Contractor staff contacts you, shortly after you receive the letter, to begin planning the visit. Peer teams are typically on site for two days, typically either Tuesday and Wednesday or Wednesday and Thursday.

Staff makes every effort to provide at least one month's advance notice of the visit and works with the transplant program to find dates that are mutually agreeable. If mutually agreeable dates are not available, the MPSC Chair makes the final decision.

### **How should we prepare for the peer visit?**

- Review the OPTN Policies, Bylaws, and Management and Membership Policies referenced in the letter.

- Provide all information requested in the letter by the specified due date. The peer team may identify additional information that helps them prepare for the peer visit. OPTN Contractor staff communicates any additional requests for information to the member.
- Assign a designated contact to work with OPTN Contractor staff to plan the visit. Provide staff with the designated contact's name, email, office and cell phone numbers as soon as possible. The designated contact should:
  - Ensure key hospital and program personnel are available during the peer visit.
  - Work with staff to finalize the agenda.
  - Work with staff to arrange the peer team's lodging.
  - Work with staff to arrange the peer team's travel between the hotel and hospital during the visit and between the hospital and the airport/train station after the visit (OPTN Contractor staff will arrange the peer team's air/train travel).
  - Reserve a conference room large enough to accommodate the peer team and the largest group of interviewees for the duration of the visit. The room should have Wi-Fi access and sufficient power outlets for the team's laptops.
  - Arrange for a light breakfast and lunch for the peer team in the conference room on both days of the visit.
  - If requested, ensure any requested patient records or other documents are in the conference room prior to the peer team's arrival.

### What should we do or expect during the peer visit?

- The primary contact should greet the team upon their arrival to the hospital on the first day.
- Have a contact person near the conference room or easily accessible to answer questions or provide assistance as needed throughout the visit.
- Have a hospital staff member available to quickly address any IT issues or help in providing access to electronic medical records, if needed.
- Be prepared to provide quickly any additional information the peer team may request, such as patient charts, protocols or policies, and QAPI meeting minutes.
- OPTN Contractor staff makes every effort to stick to the schedule but may need to adjust in order to accommodate the peer team's requests. For example, the peer team may cancel a scheduled interview if they feel it is not necessary based on earlier interviews or documentation they reviewed. Alternatively, the team may request that an interviewee return to answer additional questions, or may ask to spend additional time reviewing patient records.
- Expect the peer team to ask direct and probing questions. Such questions help the peer team obtain the necessary information as quickly as possible. All inquiries are intended to help the program, the peer team, and the MPSC identify potential areas for improvement.
- On the second day, after the last interview, the team begins to draft their report based on their findings.
- For advisory peer visits, before leaving the hospital, the team conducts an informal exit interview with the interviewees and provides an overview of their findings. OPTN Contractor staff give a closing statement outlining the next steps.
- For investigative peer visits, the peer team does not conduct exit interviews or provide information regarding their findings while on site. OPTN Contractor staff answers any questions regarding next steps while on-site.



## What happens after the peer visit?

- The peer team finalizes its report and submits it to the MPSC for review and approval.
- Peer team members are not permitted to interact with the program until the MPSC's review is complete. Please direct any questions or concerns to OPTN Contractor staff. Do not attempt to contact the peer team.
- Staff provides the program with a copy of the final report and any additional MPSC requests or recommendations. Staff works with the MPSC to provide this information to the program as quickly as possible, but the timing is dependent on the MPSC meeting schedule and agendas. Staff provides an estimated timeline for your receipt of the report after the peer visit.
- The MPSC will request that the program submit a plan for quality improvement that addresses all of the recommendations within the report. The MPSC typically requests that the program submit a response plan within 4 weeks, though actual due dates may vary based on the MPSC's meeting cycles.
- As a part of continuous improvement efforts, staff sends a survey regarding the peer visit process shortly after you receive the peer report. Staff also send you a survey approximately six months after the visit to assess the visit's impact on your program. Participation in the survey is completely optional, but we appreciate any feedback you are willing to provide and will use the information to identify areas for improvement in future peer visits.
- Expenses relating to the peer visit, including but not limited to travel and lodging for the peer team and at least one OPTN Contractor staff member and honoraria for the peer team, are charged to the hospital.

## WHAT TO EXPECT: OPO PEER VISITS

The MPSC may recommend that your OPO participate in a peer visit.

### What is a peer visit?

Peer visits are a tool used by the MPSC to obtain an objective evaluation of the OPO by experienced OPO professionals. Peer visits are conducted on behalf of the MPSC and under confidential medical peer review.

The peers review the OPO's policies and procedures and information associated with the MPSC's review of the issue prior to the on-site visit. During the visit, the peers conduct interviews and may tour the OPO's facilities. After the visit, the peer team prepares a report outlining the OPO's strengths and opportunities for improvement. The MPSC reviews and approves the report, and asks the member to prepare a plan for quality improvement that addresses the team's findings.

### Who participates in the peer visit?

The MPSC determines which types of OPO professionals should participate in the visit. OPTN Contractor staff identify potential peer team members and present recommendations to the MPSC Chair for approval. Peer teams typically include a CEO, COO, Quality Director, and may also include other professionals such as a Clinical Director, Family Services Expert or a CMO. At least one OPTN Contractor staff member is present to help facilitate the on-site visit.

The team typically schedules interviews with the OPO Medical Director, OPO Board of Directors, and Medical Advisory Board. It is essential that key personnel be available during the visit.



## When will the peer visit take place?

OPTN Contractor staff contacts you, shortly after you receive the letter, to begin planning the visit. Peer teams are normally on-site for two days, typically either Tuesday and Wednesday or Wednesday and Thursday.

Staff makes every effort to provide at least one month's advance notice of the visit and works with the OPO to find dates that are mutually agreeable. If mutually agreeable dates are not available, the MPSC Chair makes the final decision.

## How should we prepare for a peer visit?

- Review the OPTN Policies, Bylaws, and Management and Membership Policies referenced in the letter.
- Provide all information requested in letter by the specified due date. The peer team may identify additional information that helps them prepare for the peer visit. OPTN Contractor staff communicates any additional requests for information to the member.
- Assign a designated contact to work with OPTN Contractor staff to plan the visit. Provide staff with the designated contact's name, email, office and cell phone numbers as soon as possible. The designated contact should:
  - Ensure key OPO personnel are available during the peer visit.
  - Work with staff to finalize the agenda.
  - Work with staff to arrange the peer team's lodging.
  - Work with staff to arrange the peer team's travel between the hotel and OPO during the visit and between the OPO and the airport/train station after the visit (OPTN Contractor staff will arrange the peer team's air/train travel).
  - Reserve a conference room large enough to accommodate the peer team and the largest group of interviewees for the duration of the visit. The room should have Wi-Fi access and sufficient power outlets for the team's laptops.
  - Arrange for a light breakfast and lunch for the peer team in the conference room on both days of the visit.
  - If requested, ensure any requested donor records or other documents are in the conference room prior to the peer team's arrival.

## What should we do or expect during the peer visit?

- The primary contact should greet the team upon their arrival to the OPO on the first day.
- Have a contact person near the conference room or easily accessible to answer questions or provide assistance as needed throughout the visit.
- Have an OPO staff person available to quickly address any IT issues or help in providing access to electronic medical records, if needed.
- Be prepared to provide quickly any additional information the peer team may request, such as donor records, protocols or policies, and QAPI meeting minutes.
- OPTN Contractor staff makes every effort to stick to the schedule but may need to adjust in order to accommodate the peer team's requests. For example, the peer team may cancel a scheduled interview if they feel it is not necessary based on earlier interviews or documentation they reviewed. Alternatively, the team may request that an interviewee return to answer additional questions, or may ask to spend additional time reviewing donor records.

- Expect the peer team to ask direct and probing questions. Such questions are necessary to obtain the needed information as quickly as possible. All inquiries are intended to help the OPO, the peer team, and the MPSC identify potential areas for improvement.
- On the second day, after the last interview, the team begins to draft their report based on their findings.
- For investigative peer visits, the peer team does not conduct an exit interview or provide any information regarding their findings while on site. OPTN Contractor staff answers any questions regarding next steps while on site.

### **What happens after the peer visit?**

- The peer team finalizes its report and submits the report to the MPSC for review and approval.
- Peer team members are not permitted to interact with the OPO until the MPSC's review is complete. Please direct any questions or concerns to OPTN Contractor staff. Do not attempt to contact the peer team.
- Staff provides the OPO with a copy of the final report and any additional MPSC requests or recommendations. Staff works with the MPSC to provide this information to the OPO as quickly as possible, but the timing is dependent on the MPSC meeting schedule and agendas. Staff provides an estimated timeline for your receipt of the report after the peer visit.
- The MPSC will request that the OPO submit a plan for quality improvement that addresses all of the recommendations within the report. The MPSC typically requests that the OPO submit a response plan within 4 weeks, though actual due dates may vary based on the MPSC's meeting cycles.
- As a part of continuous improvement efforts, staff sends a survey regarding the peer visit process shortly after you receive the peer report. Staff also sends a survey approximately six months after the visit to assess the visit's impact on your OPO. Participation in the survey is completely optional, but we appreciate any feedback you are willing to provide and will use the information to identify areas for improvement in future peer visits.
- Expenses relating to the peer visit, including but not limited to travel and lodging for the peer team and at least one staff member and honoraria for the peer team, are charged to the OPO.