Introduction

Thank you for the opportunity to comment on the Information Collection Request Process Data for Organ Procurement and Transplantation Network, OMB No. 0906-xxxx—New. We are responding as the Organ Procurement and Transplantation Network (OPTN) Board of Directors (BOD), the organization authorized to manage the matching of donated organs with transplant recipients nationwide and to manage the collection of federally required data reported for organ donors, transplant candidates and transplant recipients.

The OPTN thanks HRSA for the opportunity to work with them establishing appropriate data collection principles for this new data collection. We share the common goal of ensuring that meaningful and consistent data is collected regarding the key phases of someone's transplantation journey, from initial referral to registration of individuals either as deceased organ donors or organ transplant candidates. Our response is intended to improve upon the initially proposed forms and processes to maximize their usefulness for meaningful analysis, while also minimizing to the greatest degree possible the additional burden upon organ procurement organizations (OPOs) and organ transplant programs to collect, verify and report the data.

The OPTN BOD is advised by more than 20 OPTN committees, each of which has broad national representation and fulfills a charge to develop or advise on policies within their expertise. The following response, approved by the Executive Committee on the behalf of the OPTN BOD, reflects the comments and recommendations from the Data Advisory Committee (DAC) with input from two cross-functional workgroups (the DAC-sponsored Pre-Waitlist Data Collection workgroup and the MPSC-sponsored OPO Performance Monitoring Enhancement workgroup) with direct stakeholder interest and involvement in the material the data directive addresses. DAC advises the OPTN BOD regarding OPTN data collection and is charged with ensuring that data collection activities are aligned with the OPTN Data Collection Principles.

In general, the response addresses the following themes:

- The data fields should be sufficiently detailed to support careful, reliable and reproducible interpretation based on clearly articulated study design. This will enhance the ability to use these data for describing system performance and opportunities for improvement and the impact of systemic changes on various issues including access to care and variations in care.
- While additional data collection is welcome to increase understanding of key trends, the fields and mechanism of data collection/reporting should first utilize discrete data

elements already available to OPOs and transplant hospitals to the greatest extent possible. This will allow earlier development and implementation of the new data collection forms while reducing the additional data burden on OPTN member institutions and decreasing the time frame needed to develop and implement methods to collect and verify any additional data.

- Some of the comments address data that may be unknown under certain circumstances or present substantial challenges for members to collect. In these cases, we have provided feedback or recommendations for modification.

Data Collection Feedback Summary

As background, on January 31, 2024, the DAC provided early feedback and recommendations to HRSA on the three drafted directive forms. HRSA made this request to the DAC at their November 13, 2023 meeting. Information on how DAC addressed this request, by working with two OPTN workgroups, can be found on the data directive toolkit page of the OPTN website.

The drafted forms released with the Directive, issued on February 5, 2024, did not incorporate the DAC and workgroup recommendations. DAC's pre-waitlist feedback was incorporated into the 60-day federal register notice (FRN) forms issued on November 4, 2024 , however only a small amount of the feedback on the ventilated patient form (VPF) was addressed.

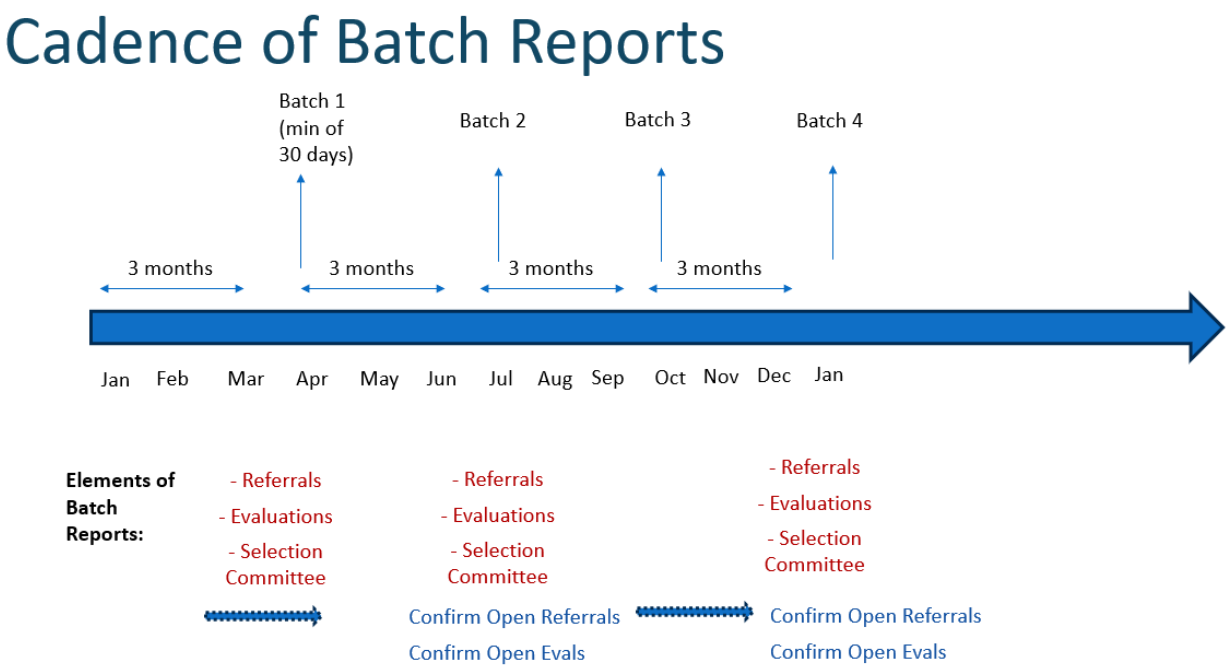
Below is the OPTN's summarized feedback on the proposed data collection. The summary references detailed sections in this document where field level comments and recommendations are provided.

Pre-waitlist Data Collection

The OPTN largely supports the proposed Pre-waitlist Referral and Pre-waitlist Evaluation forms while respectfully requesting additional information and/or context from HRSA. The proposed forms reflect the vast majority of recommendations DAC provided to HRSA on January 31st, 2024 and the OPTN appreciates their acceptance by HRSA. However, there were DAC-recommended data fields removed from the forms, and it would be helpful to understand the concerns that lead to their removal. This question is included in the pre-waitlist field section of this document.

The OPTN also supports the following recommendations DAC provided to HRSA on January 31, 2024 regarding the pre-waitlist data collection cadence and methods:

- Each event (referral and evaluation) has a start and end trigger that mandates sequential data gathering (1st referral event > 2nd evaluation event > 3rd Waitlist registration event)
- Data collection will start at a point in time (TBD by HRSA) for new referrals
- Do not allow transplant programs the ability to edit the data after event closure
- Target a quarterly data collection cycle with the option to submit the data in bulk or manually at predefined intervals
- A batch reporting cadence is recommended, as reflected in the below graphic, because real-time referral and evaluation data is not currently needed for immediate operational purposes of the OPTN. This cadence of data reporting will still facilitate all use cases under consideration while significantly reducing data burden associated with individual patient level real-time forms. Importantly, this cadence is also more likely to yield higher quality data as information is aggregated over time rather than strictly available on the date of the event (e.g. referral).



As the pre-waitlist data collection is implemented, the OPTN will want to know the number of patients 'at-risk' of progressing past referral to evaluation or waitlisting. To fully capture the

outcomes of patients who do not return after referral or evaluation, the OPTN will need to supplement information about patient mortality. Implementing this practice is consistent with the current processes for waiting list candidates and post-transplant recipients. The OPTN recommends partnering with HRSA to prioritize and fund an initiative to augment the OPTN data registry with pre-waitlist patient mortality information. This will also facilitate understanding patient outcomes in this context as centers may be unlikely to acquire mortality data for all patients outside of their healthcare system. Failure to supplement these data will significantly bias estimation of key potential metrics deriving from these data (e.g. time from referral to evaluation) as these estimates will be dependent on understanding the number of patients eligible to progress to a subsequent phase of care.

Ventilated Patient Data Collection

The OPTN strongly supports the stated goal for this data collection of providing "a more objective source of information on procurement practices, the management of donor patients, and how these practices inform the supply of deceased organ donors available for transplant." There is a need for accurate, reproducible data available in a timely manner that can be used to reliably assess OPO performance and for use by OPOs in their own quality assurance and performance improvement efforts. However, the OPTN has significant concerns that the proposed VPF, if implemented without significant improvement on data definitions, logical construct and more granular medical data will not fulfill this stated goal or fulfill the need for accurate, timely assessment of OPO performance.

First, the VPF provides these instructions "The purpose of the Ventilated Patient Form (VPF) is to collect demographic information and OPO process data on ever-ventilated patients with a documented Pronouncement of Death who were referred to the OPO by a hospital or found by the OPO upon death record review as required at 42 CFR 486.348(b)." Understanding the patient population for the VPF and following standardized practices is critical to ensuring consistent and quality data collection. The OPTN requests consideration of the following feedback and recommendation on the form instructions:

- The term 'ever-ventilated' could be interpreted differently across OPOs as currently described, so we request this term be clearly defined, with the appropriate level of detail including reference to timing of ventilation, to ensure consistency in the patient population being captured for reporting.

- Since non-donor deaths may not be pronounced in a timely fashion, we recommend relabeling the instructions and the corresponding data field (Date and Time of Pronouncement of Death) to 'Determination of Death'.
- Currently, death record review practices differ across OPOs. In light of this, we request a standard protocol be developed and criteria be defined and implemented for death record reviews. In absence of a standardized process, the data collected from death record reviews will be inconsistent and unlikely to yield objective comparisons between OPOs.
- Today, most OPOs have broad clinical triggers for referrals, and over 80% of the patients referred are not dead at the time of referral. A significant portion of these patients are ruled out for both organ and tissue donation at the time of referral. The OPTN recognizes the criteria for 'ruling out' are not standardized across OPOs and supports working with HRSA to establish a list of absolute contraindications to donation that can be implemented with the VPF data collection to ensure that there is consistent data capture across the system. Additionally, more granular medical and neurological data regarding the patient referral is needed to understand decision making in ruling in or out referrals.
- To achieve the data directive goals, the OPTN recommends HRSA reconsider the scope of the VPF population. The VPF population can include all patient referrals for both living and deceased patients. For those 'ruled out' based upon the absolute contraindications list, OPOs can provide limited data while also being adequate to facilitate an understanding of OPO practices/performance. For those patients who proceed in the donation evaluation process or go on to become a donor, a full VPF can be completed. The standard death record review process would identify any VPFs to submit that were not referred by the hospital.

Secondly, the OPTN notes that the VPF contains many data fields that do not provide sufficient guidance or granularity, thereby creating the risk of subjective interpretation that could inadvertently increase rather than decrease variability in reporting across OPOs. While choice list values are provided within the instructions (e.g., case disposition field), those values do not include definitions to help inform selection of the appropriate choice. The limited guidance and granularity will adversely impact the ability to use the data for comparison of OPO performance and for OPO quality assurance and performance improvement efforts. Importantly, the listed choices are not mutually exclusive outcomes/process and with little guidance a user could select different outcomes for the same fact pattern of a patient's outcome.

As an example, the medical rule-out data element illustrates this concern with the lack of guidance or granularity. Increasing the number of organs procured and transplanted from medically complex donors is one key strategy to make more organs available for transplant. Current OPTN definitions for eligible and imminent neurological death support this strategy through the inclusion of both donor and organ-specific medical exclusionary criteria designed to ensure that patients are not medically ruled out even if only one organ is suitable for transplant. No such exclusionary criteria are provided in the VPF instructions, nor is any additional objective verifiable data requested to support or substantiate a medical rule-out case disposition. The OPTN recommends adding objective, verifiable medical suitability data so that conclusions can be drawn regarding the suitability of specific organs for transplant, making it possible to evaluate and compare OPO performance in maximizing organ utilization.

Thirdly, the OPTN is concerned that the lack of clear definitions or a hierarchical deterministic algorithm in the VPF to select a single case disposition from the options provided will result in widespread variability in reporting. The following two scenarios exemplify how different case dispositions could be selected depending on how an OPO interprets the options provided in the VPF:

> *Scenario 1: A 36-year-old male with gunshot wound referred to the OPO cardiac arrests prior to onsite response or approach.*
>
> Potential dispositions an OPO could select in this case include:
>
> 1) OPO Decline to Pursue Donation (the OPO did not offer the hospital suggestions to support the patient hemodynamically, did not respond on site, did not coordinate uncontrolled DCD)
> 2) Medical Rule Out (since patient had a cardiac arrest, the OPO considers this a medical rule out)
> 3) Cardiac Arrest prior to OR (there is no clear guidance that would indicate that this is an inappropriate choice for outcome)
> 4) Hospital Interference (patient was not called with sufficient time for OPO to get on site and coordinate a different outcome so could be considered a referral made to OPO outside of timely requirement)
>
> *Scenario 2: A 36-year-old brain-dead potential organ donor referred to the OPO has a living will opposing donation.*
>
> There is no case outcome explicitly available for this scenario, so the OPO could choose:

1) OPO Decline to Pursue Donation
2) Cardiac Arrest Prior to OR
3) Medical Rule Out

These two scenarios are not meant to encompass all possible points of variation, but rather to demonstrate the need for a clear algorithm that precludes variation in reporting. Additional comments on case disposition options are provided in the VPF field section of this document.

The OPTN has studied this situation and in 2023, the Membership and Professional Standards Committee (MPSC) developed a concept paper titled *Concepts for OPOs Referral Evaluation Data Collection Process.* The concept paper acknowledged that OPOs collect a large amount of data on referrals, but there is inconsistency in their processes and in how the data points are defined. The paper proposes a new approach to OPTN data collection by focusing on developing a module that can be incorporated into Electronic Donor Records (EDRs) that includes standardized documentation of referral findings and logic to drive responses by frontline staff to questions during the referral evaluation process. The module would include algorithms that would define outcomes. The standardized data captured through this EDR module would then electronically transfer this data to the OPTN Computer System. This proposed approach also aligns with the OPTN's recommendation on reconsidering the patient population for the VPF. The OPTN requests HRSA evaluate the MPSC's work product, attached, alongside this VPF feedback.

Finally, the VPF is intended to collect data on OPO processes. The OPTN believes that the blending together of process and outcome data fields in one data collection form undermines the ability to accurately measure the incidence and prevalence of process deviations from evidence-based best practices. Process deviations do not necessarily result in failed donation outcomes but preventing the documentation of process deviations for organ donors, or when other case disposition is selected, will result in the underreporting of process deviations and undermine the ability to have meaningful comparisons of OPO performance in managing process deviations. The inclusion of Hospital Interference as a case disposition option is the most notable example of the problematic blending of process and outcome measures in the VPF. Clearer definitions describing what constitutes Hospital Interference in addition to specific guidance related to OPO provision of process deviation reports or remediation plans to hospitals or hospital acceptance of process deviation reports or remediation plans provided by the OPO is needed.

The proposed VPF is too subjective to be meaningful and too limited in its specificity to be useful for purposes of OPO performance assessment and OPO quality assurance and performance improvement efforts. Major changes are required as described above and further documented in the VPF field level section to meet the stated goals.

Additional Comments

In addition to the data collection feedback, the OPTN is providing additional comments for HRSA's consideration

1. Communicate OPTN policy changes as the result of the Directive

   As the steward of OPTN Policy 18: Data Submission Requirements, the DAC and the OPTN BOD need to understand the impacts of the directive on this OPTN policy. Based on the proposed data collection, policy changes are expected. Since these changes are not following the normal OPTN policy development process, the OPTN requests HRSA communicate these policy changes prior to submitting this data collection package to the Office of Management and Budget (OMB) for final approval. For members to adequately prepare for this change in data collection, it is imperative they understand the submission timelines and start dates for this new data collection.

2. Set implementation plans and timelines in collaboration with vendor stakeholders

   The implementation of the directive has dependencies on member systems, third-party systems development efforts and testing. The VPF form implementation is expected to bring significant change to OPO processes and systems. Since the member systems are where the data originates, proactive coordination and collaboration is essential for the OPTN to manage its limited financial and human resources. To support a successful roll-out, the DAC members have offered to be part of a pre-waitlist pilot roll-out. The OPO community also supports a pilot approach to rolling out the new data collection.

3. Provide resources needed to support benchmark reporting

   Assist members in improving their practices by developing benchmark reporting for the new data collection. Making such benchmarks publicly available can also improve system transparency for patients, donor families, and other patient-centric entities.

4. Support the OPTN further improving this data collection

HRSA shared their goal with this directive is to have the OPTN start collecting the appropriate data required to understand referral and evaluation activity. The OPTN Board encourages HRSA to communicate broadly their support for future committee projects that will further enrich this data. For example, the OPTN should take up projects to add social determinants of health factors so leadership can gain a deeper understanding of the population of potential donors and patients being referred and evaluated.

Closing

Pre-waitlist data collection

In closing, DAC generally endorses and the OPTN Executive Committee supports the pre-waitlist data collection requirements as proposed in the 60-day FRN. Additional comments and recommendations are included in this response to assist HRSA in finalizing the specific data requirements and planning for the development and implementation phases.

Ventilated Patient data collection

In closing, DAC advised the OPTN Executive Committee that the VPF data collection requirements need additional work prior to their endorsement. To support improving the VPF, this response contains comments and recommendations for HRSA's consideration. DAC and the MPSC workgroup chair shared much of this feedback on January 31, 2024, and offer again to assist HRSA in making the necessary adjustments to the VPF. In summary, the DAC has the following concerns: The VPF data collection in its current form

- is unlikely to meet HRSA's stated goals, as some of the data collection lacks the granularity needed for its intended use, for example medical rule-out reasons.
- requires further definition of terms, choice list values and a logical data flow to collect consistent and complete data.
- is likely to have fields reported as "Unknown" for patients that are ruled out early in the donor evaluation process prior to OPO going on-site or accessing medical record.
- does not have a clear target population; several items require clarification and standardization to achieve the goals.
    - The OPTN strongly recommends HRSA partner with the MPSC workgroup to layout a holistic approach for this data collection so it can be standardized in the EDR systems to ultimately source the appropriate data fields downstream to the OPTN Computer System.

- blends together two types of data collection on one form
  - Combining patient demographic, clinical and terminal step data alongside process data and hospital interference is problematic.
  - Hospital interference data fields require further information to achieve a higher level of data quality and consistency in the responses.
  - Data submission timelines are unclear however it is unlikely all this data would be available in the same timeframe for timely submission. HRSA should consider this data being captured on separate forms.

As a partner in managing the OPTN data registry, the OPTN wants to partner with HRSA to improve this new data collection quickly so that it can proceed to the next step in the approval process. The OPTN welcomes the earliest opportunity to discuss this feedback with HRSA and identify next steps.

Pre-waitlist Referral Form – Field and Instructions Feedback

The OPTN recommends including the definition of referral, including guidance on the beginning and end points of the referral in a short paragraph at the beginning of the form and form instructions. This would mirror current forms that define the timing of the data collection for said form in an instruction paragraph located at the top of the form. Proposed Referral definition: The organ transplant referral phase begins with the first medical record notification to the transplant team of the following: Minimum of three patient identifiers (name, birth date, birth sex) and patient contact information. The organ transplant referral phase ends with the medical record notification to the transplant team of any of the following: Initial visit with the patient (in-person or virtual encounter) or Tx team orders tests. At this time, the referral closure and reasons are documented.

Field Label	Feedback
Organ	Recommend clarifying how to report multi-organ patients or patients referred for single organ but become multi-organ candidates.
Source of payment/secondary	Options are TBD, could utilize options in primary insurance
Referring provider NPI	• Recommend including an option for self-referral. • Recommend including how to report referrals from dialysis center social workers in instructions.
Referral status	Recommend adding more information to the definition/instructions to include information about the process to report a patient that moved to the Evaluation Phase.

Category	Feedback
Missing Fields	• Consider adding - Evaluated and declined by another center for transplant: yes/no
Additional Feedback	• Patients referred but not seen would not be able to complete all the required fields. • DAC's Pre-waitlist Workgroup can support reviewing the final choice list values for code fields during the solutioning of this data collection.
Functionality/ Solutioning	• Cascade patient demographic data from Referral to Evaluation form to reduce burden. • Data collection must be a periodic upload or API due to volume.

Category	Feedback
Fields without feedback	• Transplant center • Transplant center code • Patient MRN • First name • Middle name • Last name • DOB • Birth sex • SSN • Race • Ethnicity • Primary phone number • Permanent street address • City of permanent residence • State of permanent residence • Zip code of permanent residence • Country of permanent residence • Referral date • Death date • Referral status/Referral closure reason

Pre-waitlist Evaluation Form – Field and Instructions Feedback

The OPTN recommends including the definition of evaluation, including guidance on the beginning and end points of the evaluation in a short paragraph at the beginning of the form and form instructions. This would mirror current forms that define the timing of the data collection for said form in an instruction paragraph located at the top of the form. Proposed Evaluation definition: In the evaluation phase, medical and non-medical information is gathered about the patient so that the multidisciplinary selection committee can determine whether the patient is suitable to be registered to the national waitlist for an organ. The evaluation phase begins at the initial visit with the patient's agreement to complete the review process. The evaluation phase ends when the patient's case is presented during the committee review meeting.

Field Label	Feedback
Initial Evaluation Appointment Completion Date	This field was removed from DAC's original submission. What was the intent to remove this data field? The OPTN recommends this field be retained.
Evaluation Status/Evaluation Cancelation Reason	This field was removed from DAC's original submission. What was the intent to remove this data field? The OPTN would like to understand how a canceled evaluation (reported in error by the member) would be managed.
Organ	OPTN suggests multi-select functionality to account for more than one organ transplant
Source of Payment/Secondary	Recommend choice list options match the new source of payment options DAC recently approved
Working for Income	Clarify the definition of part-time to include "casual employment"
Height	• Add a "not available" option (if patient drops out or is declined prior to measurements being collected) • Include better clarification on what height to use, such as the most recent or at initial evaluation time
Weight	• Add a "not available" option (if patient drops out or is declined prior to measurements being collected)

Field Label	Feedback
	• Include better clarification on what weight to use, such as the most recent or at initial evaluation time
Primary Diagnosis	Recommend choice list options match diagnosis options used in other OPTN Computer System

Category	Feedback
Additional Feedback	DAC's Pre-waitlist Workgroup can support reviewing the final choice list values for code fields during the solutioning of this data collection.
Fields without feedback	• Transplant Center • Transplant Center Code • Patient MRN • First Name • Last Name • DOB • Birth Sex • SSN • Race • Ethnicity • City of Permanent Residence • State of Permanent Residence • Zip Code of Permanent Residence • Country of Permanent Residence • BMI (Read only) • Evaluation Status • Selection Committee Decision • Selection Committee Date • Selection Committee Decision/Death Date • Selection Committee Decision/Declined Reason

Ventilated Patient Form – Field and Instructions Feedback

Many of the data elements on the VPF would not be available for all patient referrals due to how far the patient progressed in the donor evaluation process resulting in submission of 'unknown' values. Limited data is gathered when there is a clear reason to rule out a patient early in the process versus a more complete VPF submission for a patient where the OPO goes on-site or accesses the patient's medical record remotely.

Field Label	Feedback
Home Zip Code	• Recommend that the instructions include a note to not report the hospital zip code in this field and choose "Unknown" if the patient's home zip code is not known. • Include an instruction of what to enter if patient does not live in the United States. • Likely that the data will be reported as "Unknown" for patients that are ruled out early in the donor evaluation process prior to OPO going on-site or accessing medical record.
Race	• Recommend assessing the priority of updating race data collection to the recently issued OMB standard. Concerns about current data collection not addressing bi-racial and multi-racial categories. • Likely that the data will be reported as "Race Not Reported" for patients that are ruled out early in the donor evaluation process prior to OPO going on-site or accessing medical record.
Gender Identity	• Recommend removal of this data element as it is o Inconsistent with the pre-waitlist forms and other OPTN data collections. o This information is not consistently collected by donor hospitals. o Gender identity has no clinical relevance to organ donation and transplantation. • Likely that the data will be reported as "Unknown" for patients that are ruled out early in the donor evaluation process prior to OPO gathering information from legal next of kin.
Height	• Likely that the data for majority of patients will be reported as "Unknown" as most patients are ruled out early in the donor evaluation process prior to OPO going on-site.
Weight	• Likely that the data for majority of patients will be reported as "Unknown" as most patients are ruled out early in the donor evaluation process prior to OPO going on-site.

Field Label	Feedback
	• Requiring gathering of weight for these patients will pose significant time and financial cost burden.
Age	• Recommend consistency with other OPTN data collection that includes date of birth, if available, that will calculate age and age be collected only if date of birth is unknown. • Recommend inclusion of option for unknown for patients that have not been identified.
HIV Status	• Requests clarification for why HIV status is being collected and no other relevant serologies, especially when HIV positive status is no longer an absolute rule out. • Suggest removal of this field and only collect for donors given the sensitivity of this information and that HIV is not an absolute rule out for donation.
Did patient legally document their decision to be an organ donor?	• Request clarifying the instructions regarding cascade to the Date and Time of Pronouncement of Death in the event of a No response to this question. • Most responses will likely be reported as "Unknown" as most patients are ruled out early in the donor evaluation process prior to OPO accessing registries or DMV records.
First Person Authorization Restrictions	• Request clarification on what should be the definitive sources for these restrictions. • Suggest removing tissue as an option as tissue authorization is not relevant to the organ donation process and not within OPTN scope.
Date and Time of Pronouncement of Death	• As noted in feedback for population definition, suggest completion of form and collection of this data element only when patient died within a set time after extubation where there was a potential for donation. Over 80% of referrals are not dead at time of referral and a large portion of those are ruled out for both organ and tissue donation. These patients may not die for days, weeks or even months later or potentially not die. Requiring date and time of death for all these patients is a significant cost burden that provides little value for improvement of the donation process. • Date and time for death of a referred patient that was ruled out for both organ and tissue donation early in patient evaluation will be unknown. • Suggest replacing "pronouncement" with "determination" because official pronouncement of death sometimes is done much later.

Field Label	Feedback
	• Suggest inclusion of additional question to gather whether the patient experienced a neurologic death or a circulatory death
KDPI (not required field)	• Recommend removal of this field for the following reasons: o Optional data collection o The raw data needed to calculate the KDPI would not be available for non-donors since much of the data needed to accurately calculate KDPI comes from a medical/social history collected from the legal next of kin and testing which is conducted on a small fraction of patients. o The calculation of KDPI is done by the OPTN Computer System and not by OPOs for donors. The KDPI for registered donors can be provided by the OPTN. o The KDPI changes as additional patient information is collected. • If this field is retained, recommend changing it to KDRI rather than KDPI given that the KDPI is calculated based on a reference to all recovered donors from the prior year.
Primary Insurance (not required)	• Since this field is not required, recommend that it be removed. • This information is not captured by OPOs for ventilated patient referrals or donors. • Concern that collecting this information from the donor hospital could impact the relationship between hospital personnel and OPOs as it is highly sensitive information and it has no effect on the donation process or OPO performance. • For these reasons, it is likely to be reported as "Unknown" for most patients.
Date of Death Record Review	• Suggest moving the "Date of Death Record Review" and the "Date and Time of Hospital Referral" fields to follow the "How did the OPO learn of this patient" field for better flow of the form. • Recommend that the scope of death record review be defined and standardized to produce consistent, quality data as there is variability in how death record reviews are performed.
Was the patient referred by the hospital to the OPO?	• Recommend removal of this field as it is duplicate of the "How did the OPO learn of this patient?" field.

Field Label	Feedback
Date and Time of Hospital Referral	• Suggest moving the "Date of Death Record Review" and the "Date and Time of Hospital Referral" fields to follow the "How did the OPO learn of this patient" field for better flow of the form. • Recommend clarifying instructions to provide guidance on how to document patients referred by one hospital and transferred to another, including patients that were referred and closed and then referred again by the same hospital or a different hospital.
Remote EMR Access	• Clarification requested on what this field is intending to collect - did the OPO have remote access to the hospital EMR or did the OPO accessed the hospital EMR remotely for this patient? • Remote access to hospital EMRs is determined at the hospital level or by OPO staff user, not on a patient level. • There are also varying levels of remote EMR access granted by hospitals. • Clarification of the instructions is requested as to whether this is a child question when the OPO responds "No" to the "Did the OPO respond onsite at the hospital to the patient referral" or is to be entered for all referred patients.
Advance Directive	• Clarification is requested as to whether this would be collected only as the source of first-person authorization or objection to donation, used in determining the appropriate LNOK decisionmaker, or if an advanced directive on end-of-life care such as withdrawal of care exists.
Patient Record Type	• Clarification is requested in the instructions to provide guidance on at what point in the evaluation this should be determined – at time of referral or at time of case disposition since eligibility changes as more patient information becomes known about the patient or the patient's condition changes • Suggestion that the field label be changed to "Donation pathway" or "Pathways being considered for donation"

Field Label	Feedback
Was the patient medically ruled out by the OPO prior to approach?	• Recommend a standardized definition of the criteria for a medical rule out and more granular data be collected on the reason a patient is medically ruled out for use here and for the case disposition of "Medical Rule Out." • Clarification requested of the meaning of the term "prior to approach" and what is expected if the patient is ruled out after the legal next of kin is approached, either before or after legal donation authorization is obtained.
Family Objection	• Clarification of how this field should be completed when there is first person authorization and an objection from legal next of kin. • Recommend that "family" be replaced with "legal next of kin" in the field name.
Date and Time of First OPO Hierarchy Approach for Authorization	• Request for definition of "first" in the instructions. • Request that instructions be revised to request "time of approach" rather than "time of OPO onsite response" which could be via telephone or onsite.
Authorization	• The options provided in the instructions require clarification. Regardless of whether the hospital discusses donation with the legal next of kin, the OPO will discuss with legal next of kin and get legal authorization. • Clarify whether response to this question is dependent on documentation of authorization. • Suggest adding an option of "Undecided" as authorization may have been requested at time of case disposition but the legal next of kin may not have decided whether to authorize.
Tissue Authorization	• Suggest removing this field as it is not relevant to the organ donation process and not within OPTN scope. • If the field is retained, an additional option for ruled out for tissue donation should be added and clarification on what would be included in tissue, for example eye dispositions, and categories of tissue since may get authorization for some types of tissue and not others.
Case Disposition	• Request definitions for each of the disposition options be included in the instructions. • Clarification if the disposition options are mutually exclusive and if so, define when each option should be used to the exclusion of others. For example, hospital interference can occur at same time as other dispositions on the option list.

Field Label	Feedback
	• Suggest adding “wardens” in addition to ME and Coroner, since the warden can decline when the patient is in custody at time of death. • Request clarification for appropriate case dispositions to use for ventilated patients found on death record review. The only disposition that appears to apply is Hospital Interference so should this be the default?
Describe Hospital Interference	• Suggest replacing the term “interference” with a less harsh term as use of interference could damage relationship with donor hospitals • Concern that reporting hospital interference to OPTN and CMS could damage OPO relationship with donor hospitals. • Clarification requested as to when a response to this question is needed – only when the interference is an outcome that was the cause for no donation or anytime there is hospital interference reflecting opportunities for improvement in hospital process. • Request specific definitions and clarifications of the options. o Referral made outside timely requirement – Should this be completed for every non-timely referral or only those that result in inhibition of donation. OPO definitions of timely referral vary so will limit the use of the data for comparison purposes o Ventilated Patient Not Referred to the OPO – there is no medical or age criteria defined for use by OPOs to identify ventilated patients with donation potential on death record review. o Unplanned Extubation After Referral Made to OPO – hospital may have planned extubation but not communicated it to the OPO or hospital may not have planned the extubation and not communicated it to the OPO. o Hospital Blocked OPO Approach for Authorization – clear definition is needed here. • Suggest Ventilated Patient Not Referred to the OPO autofill for ventilated patients identified on death record review. • Suggest additional options: o Hospital approached, family declined, OPO unable to talk with family

Field Label	Feedback
	o Hospital declined to medically treat o Patient appeared brain dead but testing not completed o Patient Transitioned to Comfort Care Before Referral Made to OPO – family may transition to comfort care only but not extubated
Report Provided to Hospital and Report to Hospital Accepted	• Concern these fields carry a significant burden by individual case and require a change in process since OPOs generally formally document reports on a monthly or longer cadence and not by individual case. • Clarification requested for if reports are required only for those cases where it inhibited donation; what constitutes a report, verbal or written; who at hospital specifically should receive report for it to be considered provided to the hospital; what constitutes acceptance by the hospital; how the hospital will demonstrate or document acceptance or rejection of the report. • Clarification is needed for the expected time frame for reporting of these fields as may not be available in the same time frame as other data requested on the form.
Remediation Plan Provided to Hospital and Remediation Plan for Hospital Accepted	• Concern these fields carry a significant burden by individual case and require a change in process since OPOs generally formally document improvement plans on a monthly or longer cadence. • Suggest replacing “remediation” with less harsh term such as “Improvement Plan” • Clarification requested of definition of "remediation plan;" if plan is required only for those cases where it inhibited donation; what constitutes a remediation plan, verbal or written; who at hospital specifically should receive report for it to be considered provided to the hospital; what constitutes acceptance by the hospital; how the hospital will demonstrate or document acceptance or rejection of the remediation plan.
Date and Time Case Close	• Clarification required of the definition of “case close.” A case has many end points depending on the disposition and the regulatory requirements governing it. For example, would the case close date and time be when the OPO has ceased external contact in the

Field Label	Feedback
	case (hospital partners, legal next of kin, etc.), when the last necessary field is completed in the OPO EMR, or when the case is required to be reported to the OPTN. How is this determined for patients identified on death record reviews?
Fields for which no field-specific feedback is provided	• Status • DonorNet Donor ID • OPO Record ID • Case detail/How did the OPO learn of this patient? (remove "Case detail/" from field name • OPO • Patient Hospital • Last Name • First Name • Middle Initial • Birth Sex • Ethnicity (comment in Additional Feedback) • Cause of Death (comment in Additional Feedback) • Mechanism of Death (comment in Additional Feedback) • Circumstance of Death (comment in Additional Feedback) • OPO Onsite Response • Date and Time of OPO Onsite Response • Method of Authorization Used by OPO • Approaches • Modality of First Approach • Language of First Approach • Interpreter for Approach • Date and Time of Authorization Obtained

OPTN

Concept Paper

Concepts for Organ Procurement Organization Referral Evaluation Process Data Collection

OPTN Membership and Professional Standards Committee

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UNOS Member Quality

Contents

Concepts for Organ Procurement Organization Referral Evaluation Process Data Collection

Sponsoring Committee: *Membership and Professional Standards Committee*
Approved on: *December 6, 2023*

Executive Summary

The Organ Procurement and Transplant Network (OPTN) Membership and Professional Standards Committee (MPSC) began evaluating organ procurement organization (OPO) performance using a single metric, organ yield, for identifying underperforming OPOs in 2012. Organ yield is a risk-adjusted metric that measures organs transplanted per donor.[1,2] The organ yield metric measures only one aspect of OPO performance once a patient becomes a deceased donor, defined as an individual from whom at least one organ is recovered for purposes of transplantation. The MPSC recognizes the need to incorporate metrics that evaluate multiple phases of donation, to create a more holistic approach to evaluation of OPO performance. However, the OPTN collects limited data through the Death Notification Registration (DNR) form on aspects of the donation process that precede registration as a donor on the Death Notification Registration (DNR) form. Additionally, the DNR is completed only for deaths that meet the definitions for eligible death or imminent neurological death contained in *OPTN Policy 1.1 Definitions,*[3] which do not reflect the potential donor pool. OPOs collect a large amount of data on referrals but there is inconsistency in processes and how the data points are defined. Therefore, before consideration can be given to appropriate metrics, the OPTN needs to develop new, high quality data collection that incorporates consistent processes and data definitions.

The MPSC proposes a new approach to OPTN data collection by focusing on developing a module that can be incorporated into Electronic Donor Records (EDRs) that includes standardized documentation of referral findings and logic to guide the user in documenting the pertinent information. The data captured upstream through this EDR module can then be transferred electronically to the OPTN Computer System as part of a new potential donor registry. This concept paper provides information and requests feedback about the proposed approach to standardizing data capture, the potential data to be captured, the use of logic and algorithms, and potential data collection of in-hospital deaths from transplant hospitals.

Background

The MPSC conducts OPO performance reviews under the authority of the OPTN Final Rule §121.10 (b)(1)(iii) that requires that the OPTN establish plans and procedures for conducting ongoing and periodic reviews and evaluations of OPOs for compliance with the Final Rule and OPTN bylaws and

[1] Briefing Paper Proposed Model for Assessing the Effectiveness of Individual OPOs in Key Measures of Organ Recovery and Utilization, June 2011. Available upon request.
[2] OPTN Bylaws, Appendix B.2 *OPO Performance Requirements*. Available at https://optn.transplant.hrsa.gov/media/lgbbmahi/optn_bylaws.pdf
[3] OPTN Policy 1.1 *Definitions*. Available at https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.

policies. This responsibility is further defined by the OPTN contract with the Health Resources & Services Administration (HRSA), which requires the contractor to "monitor OPTN member performance, including threats to patient health and public safety, maintain and develop efforts to improve OPTN member performance, and impose sanctions when warranted.

The OPTN Contractor shall develop processes to:
• monitor and review OPTN member performance, including threats to patient health and public safety;
• evaluate, assess, and monitor over time all OPTN members for compliance with the requirements of National Organ Transplantation Act (NOTA), the OPTN final rule, OPTN Bylaws and policies;
• educate and encourage OPTN member compliance with the requirements of NOTA, the OPTN final rule, OPTN Bylaws, and OPTN policies; and
• promote member performance improvement to meet OPTN strategic planning goals as identified in Task 3.2.7."[4]

The MPSC began evaluating organ procurement organization (OPO) performance using a single metric, organ yield, for identifying underperforming OPOs in 2012. Organ yield is a risk-adjusted metric that measures organs transplanted per donor. The organ yield metric measures only one aspect of OPO performance once a patient becomes a donor. The MPSC recognizes the need to incorporate metrics that evaluate multiple phases of donation, to create a more holistic approach to evaluation of OPO performance.

The OPTN Ad Hoc Systems Performance Committee (SPC), established by the OPTN President in 2018, was charged with considering metrics and elements that could be universally accepted as performance standards, not only for transplant programs, but also for organ procurement organizations (OPOs) and the transplant system as a whole.[5] The SPC also considered ways the OPTN could support system performance. In its report to the OPTN Board of Directors in June 2019, the SPC provided recommendations across four areas, including performance monitoring enhancements.[6] The SPC suggested developing additional measures of OPO performance that focus on "maximizing utilization of potential donors rather than simply maximizing utilization of recovered organs." The SPC acknowledged the need for additional data collection regarding donation potential, OPO referral activity, and rule-outs, noting that most if not all OPOs have this data but that it is not currently centrally or standardly collected. The SPC noted the need for more input and work to identify and define appropriate metrics. In July 2019, the Centers for Medicare and Medicaid Services (CMS) began work on new OPO outcomes measures pursuant to an Executive Order issued on July 10, 2019.[7] The MPSC deferred consideration of new OPO performance metrics while CMS was considering and developing new OPO outcomes measures. CMS finalized new OPO outcomes measures in March 2021 with an implementation date of August 1, 2022.[8] At its October 2022 meeting, the MPSC considered recommendations from the National Academies of Science, Engineering and Medicine's *Realizing the Promise of Equity in the Organ*

[4] Organ Procurement and Transplantation Network; HHSH250201900001C. April 1, 2019.
[5] Ad Hoc Systems Performance Committee. Available at https://optn.transplant.hrsa.gov/members/committees/ad-hoc-systems-performance-committee/
[6] Neil H, Overacre B, Rabold M, Haynes CR. Briefing paper ad hoc systems performance committee report. Available at https://optn.transplant.hrsa.gov/media/3015/201906_spc_boardreport.pdf.
[7] *Executive Order on Advancing American Kidney Health* issued July 10, 2019. Available at https://trumpwhitehouse.archives.gov/presidential-actions/executive-order-advancing-american-kidney-health/.
[8] Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Public Comment Period; Delay of Effective Date, Federal Register February 2, 2021. Available at https://www.federalregister.gov/documents/2021/02/02/2021-02180/medicare-and-medicaid-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to.

Transplantation System report. In addition to other potential initiatives, the MPSC suggested beginning work on a more holistic evaluation of OPO performance.[9]

The MPSC received updates on the current state of OPO performance monitoring from the Scientific Registry of Transplant Recipients (SRTR), including suggestions to consider. Representatives from CMS provided an overview of CMS' oversight of OPOs; the new CMS OPO outcome measures and the data CMS uses for the outcome measures including how it is obtained and analyzed; and an update on the implementation process, particularly for OPOs that fall within Tier 2 and Tier 3 during the interim assessment years and the recertification cycle. Consideration of this information, in addition to blue sky discussions on the characteristics of well-performing OPOs, helped the MPSC define the scope of this project.[10] Additionally, the OPTN Board of Directors provided feedback to the MPSC on the scope and prioritization of areas of this OPO performance monitoring enhancement work.[11]

With regard to eventual performance metric development, the MPSC believes the OPTN needs separate metrics from CMS but acknowledges the metrics should be complimentary. Specifically, the MPSC supports the development of more focused measures that evaluate portions of the donation process included in the CMS donation and transplantation rates. In developing new metrics, the MPSC has endorsed incorporating the majority of the principles the MPSC developed as part of the transplant program performance monitoring enhancement project.[12] These principles include that OPTN performance monitoring should include metrics that:

- measure OPO activities that are clearly within OPTN authority.
- the OPO can impact.
- the OPO is responsible for.
- have a clearly desired outcome.
- are risk adjusted.

For the transplant program performance monitoring project, the MPSC also endorsed a principle of not requiring collection of new data or development of a new metric, but that cannot be applied to OPO performance metrics because new data collection is clearly needed. The OPTN collects numerous data points across most aspects of transplant program performance and there were many already existing transplant program metrics to evaluate. The OPTN collects limited data through the Death Notification Registration (DNR) form on aspects of the donation process that precede registration as a donor. Additionally, the DNR is completed only for deaths that meet the definitions for eligible death or imminent neurological death which do not reflect the entire potential donor pool. OPOs collect a significant amount of data on referrals but as noted by the SPC, there is inconsistency in data collection completion and how the data points are defined. Therefore, before consideration can be given to appropriate metrics, the OPTN needs to develop new, high quality data collection that incorporates consistent processes and data definitions. New data collection will eventually support the development of performance metric(s) and any needed risk adjustment.

[9] OPTN Membership and Professional Standards Committee, Meeting Summary, October 26-27, 2022. Available at https://optn.transplant.hrsa.gov/media/dwpj5j5b/20221026_mpsc_meeting_minutes_public.pdf.
[10] OPTN Membership and Professional Standards Committee, Meeting Summary, May 4, 2023. Available at https://optn.transplant.hrsa.gov/media/d5sf1py4/20230504_mpsc_meeting_minutes_public.pdf

[11] OPTN Board of Directors, Executive Summary, June 9, 2023. Available at https://optn.transplant.hrsa.gov/media/vyhj4zw2/20230609_board-of-directors_meeting-summary.pdf
[12] Briefing Paper Enhance Transplant Program Performance Monitoring System, December 2021. Available at https://optn.transplant.hrsa.gov/media/yctffgt2/20211206-bp-mpsc-enhnc-tx-prgrm-prfrmnc-mntrng-syst.pdf

Project Plan

In light of the unavailability of quality and timely data on OPO performance during the phases that precede the registration of a donor, the MPSC's process for eventual development of holistic evaluation of OPO performance encompasses several phases.

Phase 1 focuses on developing the ability to collect data for the referral to authorization phases of the donation process that result from standard processes and consistent definitions for data points across all OPOs. The MPSC cannot evaluate the appropriateness of potential OPO outcome measures without a process to ensure data integrity. To develop this project, the MPSC is sponsoring a workgroup that includes representatives from the OPTN MPSC, OPO, Data Advisory, Patient Affairs, and Transplant Coordinators Committees. The OPO Performance Monitoring Enhancement Workgroup (Workgroup) contains equal numbers of OPO and transplant hospital representation, as well as a patient representative and epidemiologist, that represent all but one OPTN region. OPO representatives reflect six OPTN regions and OPOs of varying donor volume.

The MPSC has asked the OPO Performance Monitoring Enhancement Workgroup, as part of phase 1, to focus on defining standard processes and consistent definitions for essential data points for the referral to authorization phases of the donation process and develop a proposal for a standardized OPTN data collection tool. The new data collection is intended to assist in defining the donation potential and to identify when and why potential donors do not proceed to donation.[13] Phase 1 will consist of collection of feedback through this concept paper on the proposed process for data capture, the potential data to be captured and eventual electronic data transfer to the OPTN Computer System. The feedback will inform the development of a data collection proposal that is targeted for release for public comment in Summer 2024. Additional planning with EDR vendors must occur to finalize the data collection requirements and design within the EDR systems and the electronic methods to transfer the data into the OPTN Computer System.

Phase 2 will involve the MPSC's determination of appropriate metrics and criteria for evaluation of OPO performance. This phase will not commence until there is sufficient available data to develop metrics that include adequate risk adjustment to isolate OPO performance, namely things that an OPO is responsible for and can impact.

Progress So Far

Approach to Data Capture

The Workgroup and the MPSC are proposing a new approach to OPTN data collection by focusing on the development of a standardized module that incorporates consistent definitions, use of yes or no question logic, and algorithms that can be incorporated into OPOs' electronic donor records as a first step. The data captured through this module can then be transferred electronically to the OPTN Computer System. Based on discussions by the MPSC and a review of the 2019 AOPO-SRTR Region 8 Pilot Project, it was clear that there is substantial variation in OPO practice, definition of terms, and data completeness during the donation phases that precede registration of a donor. Currently, very little data is collected by the OPTN on individual referrals and ventilated referrals. The OPTN collects aggregated

[13] OPTN Membership and Professional Standards Committee, Meeting Summary, July 25-17, 2023. Available at: https://optn.transplant.hrsa.gov/media/safg1di3/20230725_mpsc_meeting_minutes_public-2.pdf

data on the number of referrals and limited data fields on deaths that meet the definitions of eligible or imminent neurological death on the OPTN Death Notification Registration form. The MPSC and the Workgroup recognized the need to introduce standardization of processes and data entry practices in order to promote integrity of the data to be collected, and to increase the scope of data recovered on all referrals.

The 2019 AOPO-SRTR Region 8 Pilot Project was an effort to determine the data needed to define donation potential. The Workgroup reviewed the development process and documentation used during the Region 8 pilot and heard from representatives of two of the Region 8 pilot participants who noted that the big takeaways from the effort were standardization of processes and how data points are defined.[14] The biggest lesson from the pilot was that each OPO had different data system rules and definitions and efforts to retrospectively fit OPO collected data into common definitions was difficult and yielded data that could not be adequately evaluated. The creation of a set of standards on data documentation and collection was critical to the ultimate success of the Region 8 pilot project. The SRTR, who worked with the Region 8 OPOs on this pilot, reviewed the process flow for data capture and the data capture documentation developed for the pilot. The Workgroup also reviewed an existing donor tracking tool that is incorporated in an OPO's EDR that uses logic to drive required responses to yes/no questions which relieves the frontline staff from making judgement calls and promotes consistency in data capture. The user does not select the outcome. Alternatively, the logic ensures data collection completeness and the user collects raw data on what occurred during the referral evaluation process and the algorithms in the background define the outcomes. The tool utilizes several periodic quality control checks using algorithms that identify if the data provided does not logically match the outcome. The Workgroup also reviewed data dashboards that are populated by the data captured by the donor tracking tool.[15]

The Workgroup supported the development of a standardized module that can be incorporated into OPOs' EDRs that will support standardization of processes and data definitions through the use of logic that drives responses by frontline staff to questions during the referral evaluation process. The module would include algorithms in the background that would define outcomes. The module would also incorporate data capture for missed referrals during OPO monthly death record reviews. OPOs would be required to capture data on the referral process using the OPTN specifications and the OPTN would work with the OPOs and available EDR vendors to develop modules within their systems that meet these specifications. In this concept paper, "standardized module or module" is used to refer to an EDR offering that includes standardized raw data capture, logic using questions, and algorithms that define outcomes. References to the "draft data capture tool" are used to identify the document contained in Appendix A that provides detail on the questions and all possible data to be collected for different phases of the referral evaluation process. The Workgroup has developed a draft data capture tool that details the data to be captured in each phase of the donation process and incorporates questions and logic that are used to direct the user to the appropriate next set of questions. The standardized module would replace current OPO data capture processes changing the manner in which this data is collected. The draft data capture tool includes data elements that some OPOs may currently capture in notes rather than in data fields in their EDRs but the Workgroup believed it necessary to have clear, consistent defined fields in order to adequately capture donation potential and the reasons why referrals do not proceed to donation. The draft data capture tool describes the data that would be captured by an OPO

[14] OPTN OPO Performance Monitoring Enhancement Workgroup, Meeting Summary, August 17, 2023. Available at https://optn.transplant.hrsa.gov/media/4hmp40fj/20230817_mpsc-opo-performance-monitoring-enhancement-wg_meeting-summary.pdf
[15] OPTN OPO Performance Monitoring Enhancement Workgroup, Meeting Summary, August 17, 2023. Available at https://optn.transplant.hrsa.gov/media/4hmp40fj/20230817_mpsc-opo-performance-monitoring-enhancement-wg_meeting-summary.pdf

in its own systems. The Workgroup anticipates the development of OPTN data collection based on this data capture tool in a future proposal targeted for summer 2024 public comment that will provide for electronic transfer of the data from the OPOs' EDRs to the OPTN Computer System. Although the draft data capture tool may appear quite long at first glance, the logic incorporated into the proposed standardized module will drive the user to the appropriate sections and data to be completed based on the circumstances for that individual referral so not all sections will be completed for all referrals. A similar tool used by the Workgroup Chair results in frontline staff completing two screens in their EDR. Therefore, although the use of the EDR standardized module will change the way OPOs capture data about referrals, ventilated referrals, and potential donors, most OPOs collect similar data in some form or fashion so it should not result in a significant increase in OPOs' data collection burden.

The Workgroup has also developed algorithms that would be incorporated into the background of the module for different referral outcomes that can be used for quality control and for creation of quality improvement reports. Algorithm maps that incorporate all potential outcomes and timely notification of the OPO can be found in Appendix B.

The Workgroup identified a number of benefits to this approach for an eventual OPTN data collection proposal. The incorporation of standardized responses and logic that directs the user through predetermined questions based on the users' responses to simple yes/no questions drive consistent processes and data documentation, addresses concerns about the quality of self-reported OPO data, and increases the reliability and integrity of the data collected. The use of standardized processes and logic will not only decrease variation between OPOs but also between individual frontline staff by decreasing the need for individual frontline staff to make potentially inconsistent judgement calls when evaluating referrals and potential donors. The use of a standard module incorporated into all OPOs' EDRs promotes a shared understanding of the definition of data points and resulting process and outcomes measures derived from that data. Additionally, the OPO capture and OPTN collection of broader data on the characteristics of referred patients and the referral evaluation process will support the ability to create risk adjustment models for metrics that isolate the performance of the OPO which is currently not available in national donation outcome metrics. Finally, use of the EDR standardized module will provide OPOs with a large number of data reports in their systems for use in their process improvement efforts and improvement efforts in collaboration with donor hospitals such as:

- Total number of referrals
- Total number of ventilated referrals
- Onsite rate for ventilated referrals and for potential donors
- Number of ventilated referrals that were determined to be not medically suitable with number that fall under each reason for unsuitability
- Rates of medical suitability rule outs
- Potential for donation, including numbers for potential donors after brain death (DBD) and potential donation after circulatory death (DCD) donors
- Proportion of overall referral and ventilated referrals for non-donation or donation outcomes
- Authorization rate
- Donation rate
- Number of organ donors
- Number of DCD and DBD donors

- Rates for potential donors that were not pursued because did not meet DBD and DCD requirements
- Number of organs recovered for transplant
- Numbers that fell within each reason a potential donor may not have moved forward to donation such as next of kin declined, patient arrested, medical examiner declined
- For DCD donors specifically,
    - Number of not DBD referrals
    - Number not considered a DCD candidate and why
    - Number where next of kin was not approached and why including patient arrests where the hospital withdrew support or limited therapies
    - Recoveries not attempted because patient arrested including where hospital withdrew support or limited therapies
    - Recoveries attempted
    - Number of withdrawals of support that were attempted but patient did not die
- Hospital Process Data on referrals for use in giving feedback to donor hospitals which associates authorization rates, conversion rates, potential donor numbers and organ donor numbers with whether the referral was:
    - Timely and planned
    - Timely only
    - Planned only
    - Neither timely or planned
    - Missed

The Workgroup noted that this data would be invaluable in OPO and donor hospital improvement efforts. Both OPO members and transplant hospital members on the Workgroup felt that having this data and reports available would be extremely useful for OPOs and donor hospitals in efforts to maximize identification of potential donors and increase deceased donation and transplants. Additionally, once the OPTN is collecting this data, it will provide quality reliable data not only to produce potential OPO outcomes metrics for use by the MPSC in its evaluation of OPO performance but also for the development of benchmark reports in the Data Services Portal for use by OPOs. Benchmark reports on these data points can help OPOs identify opportunities for improvement.[16]

Summary of Potential Data Capture in OPO Electronic Donor Record (EDR) Systems

The tables below provide a summary of the proposed data that would be captured for various phases of the referral evaluation process and in-hospital ventilated deaths of patients seventy-five and younger that are identified through OPO death record reviews. Limiting the documentation to patients seventy-five or younger is based on both a definition of potential donor developed as part of the 2019 AOPO-SRTR Region 8 Pilot Project and the “donor potential” definition used by CMS.[17] A referral is defined as a notification received by an OPO from a donor hospital of an imminent death or death. Ventilated

[16] OPTN OPO Performance Monitoring Enhancement Workgroup, Meeting Summary, November 9, 2023. Available at https://optn.transplant.hrsa.gov/media/vupfeyqi/20231109_mpsc-opo-pme-work-group_meeting-summary.pdf
[17] 42 CFR §486.302 Definitions. Available at https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-486/subpart-G

referral is defined as any patient referred that is on a ventilator or other mechanical support. As the summary indicates, the user would complete data fields and periodically respond to yes/no questions that will determine the next section of data capture the user will need to complete. For example, when a referral is received, certain hospital and patient demographic information is captured followed by a question of whether the patient is on a ventilator or other mechanical support device. Based on whether the answer to that question is yes or no, the user will be directed to collection of cause of death information to close out the referral or to questions relevant to further evaluation of ventilated referrals. The reasons why a referral did not proceed to donation are captured as the user moves through the referral evaluation process. The tables describe every data capture section. However, based on the logic that will drive completion of the data capture module, not all sections will be completed for every referral and some sections will be completed at different points in the referral/potential donor evaluation process based on the circumstances of the individual referral. Separate tables are provided for all referrals (Table 1), all ventilated referrals (Table 2), ventilated referrals evaluated onsite (Table 3), and organ recovery (Table 4). Table 5 Hospital Death Record Review (Ventilated Patient <= 75 Years Old) provides information on the data capture expected for in-hospital deaths of ventilated patients aged 75 or younger that were not referred to the OPO and are identified during monthly OPO death record reviews of donor hospitals.

Although a summary is provided below to give an idea of how a referral would flow through the module from initial referral to organ recovery, the details of all potential data that would be captured by the standardized module, as well as examples of the logic that would be incorporated to steer the user through the referral process and data capture, are included in draft data capture tool in Appendix A.

Table 1: Potential Data Capture for All Referrals

Section	Summary of Data Capture	Rationale
Record Source	• Choose Donor Hospital Referral	Collects whether the source is a donor hospital referral or hospital death record review where a missed referral, defined as a ventilated patient who is 75 years old or younger, is identified
Hospital Information	• Hospital name • Unit at time of referral • Date/time of referral • Date/time of admission • If patient transferred to another hospital following initial referral	These sections capture data about all referrals, regardless of whether the patient is ventilated. This data can be used to evaluate donor hospital performance and capture data about causes of death for non-ventilated referrals for purposes of understanding the population and for future risk adjustment.
Patient Demographic Information	• Patient Name • Date of birth or age if date of birth unknown at time of referral • Birth Sex • Race • Ethnicity	
Was the patient on ventilator or other mechanical support (e.g., ECMO, LVAD) at time of referral?	• If yes, move to **Hospital Referral Process** Section • If no, donor evaluation stops and user will complete **Classification of Cause of Death for Non-Ventilated Referrals** and: ○ If patient is not ventilated due to cardiac arrest prior to referral, either due to extubation or while on ventilator, **Circumstances of Cardiac Arrest**	

Classification of Cause of Death of Non-Ventilated Referrals	• User selects one from an extensive list of categories and causes of death	Use of this list will create a consistent capture of causes of death across all OPOs. As part of the SRTR Region 8 pilot, a review of referral data that was entered over one year in the classification of death data fields and text fields was used to develop this list. Consistent classification of cause of death is essential to developing future metrics and risk adjustment.
Circumstances of Cardiac Arrest	• Date/time of cardiac arrest • Primary circumstances of the arrest	This section will be completed anytime during the referral to organ recovery phases when the patient is no longer pursued as a potential donor due to cardiac arrest. This data will provide a better understanding of missed opportunities for donation and support OPO efforts to work with donor hospitals on improvement efforts.

Table 2: Potential Data Capture for Ventilated Referrals

Section	Summary of Data Capture	Rationale
Hospital Referral Process	• Referral made in time to go onsite or approach family in person? • Mean Arterial Pressure (MAP) at referral • Neurological status at referral • Family approaches regarding donation or limitation or withdrawal of life-sustaining therapies made by healthcare team prior to referral	This section provides insight into the hospital referral process that can be used in evaluating donor hospital performance and the ventilated patient's status at time of referral.
Cause/Mechanism/ Manner of Death	• OPTN classified causes, mechanism, and manner of death • Contributing causes of/factors to patient's death including: ○ Multiple cancers ○ Multiple cardiovascular conditions ○ Multiple infections ○ Multiple liver diseases ○ Kidney Disease ○ Multiple Lung diseases ○ Pediatric specific causes of death	This section includes the OPTN causes, mechanism and manner of death categories but also includes some contributing causes to better understand the clinical status of referrals. The OPTN currently collects a lot of clinical data on actual donors but not on referrals so the contributing causes/factors will provide additional data for evaluation and for risk adjustment. The OPTN Data Advisory Committee has plans to review and revise OPTN donor cause of death, mechanism of injury, and circumstance of death data fields.
Medical Examiner Communication Process	• Did OPO notify the medical examiner/coroner? • Did the medical examiner/coroner accept the case? • Did medical examiner/coroner decline donation for all organs?	Completion of this section provides data to help identify improvements in the medical examiner/coroner process.
Did OPO staff evaluate the patient onsite at the referring hospital?	• If yes, provide continue through evaluation of referral • If no, user will complete: ○ **Medical Suitability Evaluation** if there is a medical contraindication to donation	This question is a point at which an OPO decides whether it is appropriate to continue to pursue the referral by going onsite. If the OPO does not evaluate the patient onsite, data is captured to understand why which supports goal of tool to identify when and why a potential donor does not proceed to donation.

	○ **Circumstances of Cardiac Arrest** if arrested prior to OPO arrival or ○ **Final Neurological Assessment at Case Disposition** if patient not brain dead and determined not to be a potential DCD candidate	
Medical Suitability Evaluation	• Was the patient medically suitable? ○ If, no select either General Donor Exclusion or Organ Function ○ If General Donor Exclusion, select all of the reasons why not medically suitable ○ If medically unsuitable due to Organ Function, select one exclusion for every organ.	The question regarding medical suitability will be answered for all ventilated referrals. The remainder of this section would be completed at any point in the referral evaluation process if a patient is determined to be not medically suitable to be a donor. The exclusion criteria listed are based on the OPTN definitions for eligible death. The information is being collected to determine why a potential donor does not proceed to donation.
Final Neurological Assessment at Case Disposition	• Any brainstem reflexes present ○ If yes, go to DCD Evaluation ○ If no, was the patient pronounced brain dead? ▪ if yes date & time ▪ if no, reason why with drop down • DCD Evaluation if not brain dead ○ Review of each brainstem reflex ○ Primary non-neurological injury? If yes, drop down ○ Supportive device in place? If yes, type of device ○ Down time? ○ Cardiac compressions? ○ Time since injury ○ Respiratory drive assessment, if yes, results; if no why (dropdown) ○ Is patient considered a DCD Candidate? If no, checklist for why	This would be completed for all ventilated referrals but always would reflect the last neurological assessment and DCD evaluation prior to the disposition of the case. The earliest would be the decision not to go onsite and the latest would be the last assessment before organ recovery. Captures the last neurological assessment for all ventilated referrals and DCD evaluation data if patient is not brain dead. With the increase in the number of DCD donors, this data will help OPOs understand DCD potential, where there are opportunities, characteristics that may be associated with a potential DCD donor that does not die and DCD evaluation effective practices.
Next of Kin (NOK) Authorization Process: Advanced Directives	• Registry accessed? And if so which ones and was there a donor designation • Donor designation on another form of Advanced Directive? If yes, select from drop down list • Written evidence of opposition to donation by decedent? If yes, select from drop down list	Captures data about donor designation status, why the OPO did not approach the next of kin, timing of family conversations, who the OPO spoke to, and the results of the conversation. These sections capture process information around authorization that can be used to determine opportunities for improvement. If donor does not proceed to donation at this phase, collection of reasons why supports goal of tool to identify when and why a potential donor does not proceed to donation. These sections can be accessed prior to going onsite or while onsite to accommodate individual potential donors and OPO circumstances.
Was NOK approached regarding donation or notified of patient's donor designation?	• If yes, continue with **NOK Approach** questions. • If no, available responses ○ Complete **Medical Suitability Evaluation** if medical contraindication identified prior to approach ○ Complete **Circumstances of Cardiac Arrest** if arrested prior to NOK Approach ○ Complete **Final Neurological Assessment at Case Disposition** if patient not brain dead, not a DCD candidate ○ Medical Examiner Restriction	

	○ No NOK identified – choose gift document, hospital administrator, court order, other and skip rest of NOK Authorization Process questions	
Next of Kin (NOK) Authorization Process: NOK Approach	• Who approached NOK first regarding organ donation? OPO staff or Hospital staff • NOK relationship to patient • Date/Time of OPO NOK donation conversation • Timing of NOK donation conversation? ○ Before pronouncement of brain death or discontinuation of ventilator or other mechanical support and why – choose from drop down list ○ After pronouncement of death • Did NOK authorize organ donation or assent to patient's donor designation ○ If yes, was authorization obtained for BD, DCD or both ○ If no and patient donor designated, did OPO move forward in opposition of NOK	

Table 3: Potential Data Capture for Ventilated Referrals Evaluated Onsite

Section	Summary of Data Capture	Rationale
Hospital Referral Process	• OPO Onsite Response Times – accommodates multiple onsite responses • Patient height and weight	Collects OPO process information for evaluation of opportunities for improvement and clinical data on height and weight.
Organ Allocation	• Was organ allocation attempted? ○ If no, provide reason why ▪ Complete **Medical Suitability Evaluation** if medical contraindication identified prior to allocation ▪ Complete **Circumstances of Cardiac Arrest** if arrested prior to allocation ▪ Medical Examiner restriction ○ If yes, answer whether each organ is allocated ○ If organ is not allocated, note reason why from drop down list: ▪ Complete organ specific exclusions in **Medical Suitability Evaluation** ▪ Medical examiner restriction ▪ NOK declined ○ If organ is allocated, answer yes/no whether accepted	Collects process data on why allocation was not attempted for a potential donor or for a specific organ in order to identify opportunities for improvement. Supports goal of tool to identify when and why a potential donor does not proceed to donation.

Table 4: Potential Data Capture for Organ Recovery

Section	Summary of Data Capture	Rationale

Organ Recovery: Ventilated referrals for which any organs accepted or patient taken to OR for recovery	• Was the patient taken to the OR for organ recovery or was DCD recovery attempted?
	  ○ If no, select why
	  ▪ Complete **Circumstances of Cardiac Arrest** if arrested prior to recovery
	  ▪ No recipients identified
	• If DCD recovery attempted, location of discontinuation of ventilator or other mechanical support? Drop Down
	• Recovery location – hospital OR or OPO Recovery Center
	• Method of Recovery – DBD, Controlled DCD, Maastricht Category II DCD or Maastricht Category IV DCD (Cardiac arrest while brain dead)
	• Date/Time of Cross Clamp or N/A, DCD attempted, did not die
		Collects process data on why organ recovery was not attempted or why no organs were recovered if potential donor was taken to the operating room supporting goal of tool to identify when and why a potential donor does not proceed to donation.
		
		Currently unavailable data would be collected around the circumstances of attempted DCD recovery that could provide information about the characteristics that may be associated with a potential DCD donor that does not die and DCD evaluation effective practices.

Organ Recovery: Ventilated Referrals for which there is a Date/Time of Cross Clamp entered	• Was at least one organ recovered for transplant
	  ○ Complete **Medical Suitability Evaluation** if medical contraindication identified in OR
	  ○ Organs ruled out in OR
	  ○ Organs refused, lists not exhausted
	  ○ Organs refused, lists exhausted	

Table 5: Potential Data Capture from Death Record Review at Donor Hospitals

Section	Summary of Data Capture	Rationale
Hospital Information	• Hospital name • Date/time of admission	These are the data elements included in the data capture tool that would need to be completed for ventilated patients aged seventy-five or younger that are identified during death record reviews at donor hospitals that were not reported to the OPO at time of death. The data will be used to determine donation potential, risk adjustment and opportunities for donor hospital improvements.
Patient Demographic Information	• Patient name • Date of birth or age if date of birth unknown • Birth Sex • Race • Ethnicity	

Cause/Mechanism/ Manner of Death	• OPTN classified causes, mechanism, and manner of death
	• Contributing causes of/factors to patient's death including:
	  ○ Multiple cancers
	  ○ Multiple cardiovascular conditions
	  ○ Multiple infections
	  ○ Multiple liver diseases
	  ○ Kidney Disease
	  ○ Multiple Lung diseases
	  ○ Pediatric specific causes of death	

Next of Kin (NOK) Authorization Process: Advanced Directives	• Registry accessed? And if so which ones and was there a donor designation • Donor designation on another form of Advanced Directive? If yes, select from drop down list	

	• Written evidence of opposition to donation by decedent? If yes, select from drop down list	

Was NOK approached regarding donation or notified of patient's donor designation?	• If yes, continue with **NOK Approach** questions.
	• If no, available responses
	  ○ Complete **Medical Suitability Evaluation** if medical contraindication identified prior to approach
	  ○ Complete **Circumstances of Cardiac Arrest** if arrested prior to NOK Approach
	  ○ Complete **Final Neurological Assessment at Case Disposition** if patient not brain dead, not a DCD candidate
	  ○ Medical Examiner Restriction
	  ○ No NOK identified – choose gift document, hospital administrator, court order, other and skip rest of NOK Authorization Process questions	

Next of Kin (NOK) Authorization Process: NOK Approach	• Who approached NOK first regarding organ donation? OPO staff or Hospital staff
	• NOK relationship to patient
	• Date/Time of OPO NOK donation conversation
	• Timing of NOK donation conversation?
	  ○ Before pronouncement of brain death or discontinuation of ventilator or other mechanical support and why – choose from drop down list
	  ○ After pronouncement of death
	• Did NOK authorize organ donation or assent to patient's donor designation?
	  ○ If yes, was authorization obtained for BD, DCD or both
	• If no and patient donor designated, did OPO move forward in opposition of NOK	

Final Neurological Assessment at Case Disposition	• At time of case disposition, did the patient have any brainstem reflexes present?
	  ○ If yes, go to DCD Evaluation
	  ○ If no, was the patient pronounced brain dead?
	  ○ if yes date & time
	  ○ if no, reason why with drop down
	• DCD Evaluation if not brain dead
	  ○ Review of each brainstem reflex
	  ○ Primary non-neurological injury? If yes, drop down
	  ○ Supportive device in place? If yes, type of device
	  ○ Down time?	

	○ Cardiac compressions? ○ Time since injury ○ Respiratory drive assessment, if yes, results; if no why (dropdown) ○ Is patient considered a DCD Candidate? If no, checklist for why	
Medical Suitability Evaluation	• Was the patient medically suitable? ○ If, no select either General Donor Exclusion or Organ Function ○ If medically unsuitable due to a General Donor Exclusion, select all of the reasons why not medically suitable ○ If medically unsuitable due to Organ Function, select one exclusion for every organ.	
Circumstances of Cardiac Arrest	• Date/time of cardiac arrest • Primary circumstances of the arrest	

Potential Collection of In-hospital Death Data from Transplant Hospitals

To cross-check the validity of the data collected from OPOs and address concerns about the quality of OPO self-reported data, the Workgroup is considering the development of a separate data collection proposal that would require transplant hospitals to report in-hospital death data that includes ventilatory status and International Classification of Diseases, 10th Revision (ICD-10) diagnosis codes.[18] Transplant hospitals would not be required to report additional clinical data other than the death and ICD-10 diagnosis and procedure codes regarding ventilator status. Hospitals routinely report this data to other agencies, including OPOs, so the Workgroup does not believe this would require a significant additional data burden for transplant hospitals. The in-hospital death data collected from transplant hospitals could be used to further validate OPO submitted data and could also serve as a demonstration project for a potential future collection of data from all donor hospitals. The OPTN does not have authority to collect in-hospital death data from all donor hospitals since donor hospitals are not OPTN members but does have the authority to collect this data from OPTN member transplant hospitals under *OPTN Final Rule 121.11 Record maintenance and reporting requirements*. Although the OPTN has not previously collected data on in-hospital deaths from member transplant hospitals, the OPTN Bylaws include requirements for transplant hospital referral of potential donors as reflected in the *OPTN Bylaws, Appendix D.12.C. Routine Referral Procedures*.

HRSA Request for Additional Feedback

In mid-November 2023, HRSA requested the OPTN Data Advisory Committee (DAC) provide feedback on a drafted data collection form for ventilated referrals that will help inform an upcoming HHS Secretarial Directive for the OPTN to collect this data. The OPTN Final Rule provides that OPOs or transplant hospitals shall, as specified from time to time by the Secretary, submit to the OPTN . . . information regarding transplantation candidates, transplant recipients, donors of organs, transplant program costs and performance, and other information that the Secretary deems appropriate" and requires the OPTN

[18] OPTN OPO Performance Monitoring Enhancement Workgroup, Meeting Summary, August 17, 2023. Available at https://optn.transplant.hrsa.gov/media/4hmp40fj/20230817_mpsc-opo-performance-monitoring-enhancement-wg_meeting-summary.pdf

to "provide to the Secretary any data that the Secretary requests."[19] Although this request is not directly part of the MPSC's Enhance OPO Performance Monitoring System project, the OPO Performance Monitoring Enhancement Workgroup and the DAC will be reviewing the request and providing feedback to HRSA by the end of January 2024. Since there is some overlap with this project, the MPSC and the Workgroup are including a description of the request and the review plan for awareness. This review for feedback is being expedited so that the additional data collection can be included in the OPTN's Data System Office of Management and Budget (OMB) clearance package. Inclusion in the OMB package will allow the OPTN to begin the additional data collection after approval in late 2024. CMS informed HRSA that the referral data, specifically ventilated referrals, which is currently collected by the OPTN, is insufficient to meet the current requirement.

Section 486.328 of the CMS OPO Conditions for Coverage (CfCs) includes:

> An OPO must provide individually-identifiable, hospital-specific donation and transplantation data and other information to the Organ Procurement and Transplantation Network, the Scientific Registry of Transplant Recipients, and HHS, as requested by the Secretary. The data may include, but are not limited to:
>
> (1) Number of hospital deaths;
> (2) Results of death record reviews;
> (3) Number and timeliness of referral calls from hospitals;
> (4) [Reserved]
> (5) Data related to non-recovery of organs;
> (6) Data about consents for donation;
> (7) Number of donors;
> (8) Number of organs recovered, by type of organ; and
> (9) Number of organs transplanted, by type of organ.[20]

HRSA worked with CMS to create the drafted ventilated referral notification form. The Workgroup and the DAC will review the requested data elements and provide feedback to HRSA on which data elements on donor ventilated referrals could be collected in a standardized way in the near term; which data elements need further clarification from HRSA; and which data elements will need further investigation and potentially included in a second phase of data collection. Additional information will be made available as the work progresses.

NOTA and Final Rule Analysis

The concepts outlined in this paper are offered under the authority of NOTA, which requires the OPTN to "adopt and use standards of quality for the acquisition and transportation of donated organs."[21] The collection of additional data on the donation process could result in the creation of standards and performance improvement related to procurement. The OPTN Final Rule requires that "[t]he OPTN shall design appropriate plans and procedures, including survey instruments, a peer review process, and data systems, for purposes of: . . . (iii) Conducting ongoing and periodic reviews and evaluations of each member OPO and transplant hospital for compliance with these rules and OPTN policies."[22] One component of the OPTN's ongoing and periodic reviews and evaluations of OPOs and transplant

[19] 42 CFR §121.11(b).
[20] 42 CFR §486.328(a).
[21] 42 USC §274(b)(2)(E)
[22] 42 CFR §121.10(b)(1)(iii)

hospitals is performance monitoring. This responsibility is further defined by the OPTN Contract Task 3.6 OPTN member compliance and performance monitoring, quality improvement, and sanctioning, which states:

> "The Contractor shall monitor OPTN member performance, including threats to patient health and public safety, maintain and develop efforts to improve OPTN member performance, and impose sanctions when warranted. The Contractor shall develop processes to:
>
> - monitor and review OPTN member performance, including threats to patient health and public safety;
> - evaluate, assess, and monitor over time all OPTN members for compliance with the requirements of NOTA, the OPTN final rule, OPTN Bylaws and policies;
> - educate and encourage OPTN member compliance with the requirements of National Organ Transplantation Act (NOTA), the OPTN final rule, OPTN Bylaws, and OPTN policies; and
> - promote member performance improvement to meet OPTN strategic planning goals as identified in Task 3.2.7."[23]

Performance monitoring is the OPTN's approach to identifying OPOs and transplant programs that are not performing according to key metrics that may implicate a patient safety concern. In order to properly evaluate OPO performance, the OPTN must collect additional data to support development of metrics that evaluate OPO performance throughout the phases of the donation process.

Conclusion

The MPSC recognizes the need to incorporate metrics that evaluate multiple phases of donation, to create a more holistic approach to evaluation of OPO performance. However, the OPTN collects limited data on the aspects of the donation process that precede registration as a donor. OPOs collect a large amount of data but there is inconsistency in processes and how the data points are defined. Therefore, before consideration can be given to appropriate metrics, the OPTN needs to develop new quality data collection that incorporates consistent processes and data definitions.

The MPSC is proposing a new approach to OPTN data collection by focusing on the development of a standardized module that includes consistent definitions, use of yes or no question logic, and algorithms that can be incorporated into OPOs' electronic donor records as a first step. The incorporation of standardized responses and logic that direct the user through predetermined questions based on the users' responses to simple yes/no questions drive consistent processes and data documentation, addresses concerns about the quality of self-reported OPO data, and increases the reliability and integrity of the data collected. The data captured through this standardized module can then be transferred electronically to the OPTN Computer System. The new data collection is intended to define donation potential and to identify when and why potential donors do not proceed to donation; thereby providing essential data to evaluate opportunities for improvement in both OPO processes and in collaboration with donor hospitals. Additionally, to cross-check the validity of the data collected from OPOs and address concerns about the quality of self-reported data, the Workgroup is considering the development of data collection requirements for transplant hospitals to report in-hospital death data that includes ventilatory status and ICD-10 codes. Hospitals routinely report this data to other agencies, including OPOs, so the Workgroup does not believe this would require a significant additional data burden for transplant hospitals.

[23] Organ Procurement and Transplantation Network; HHSH250201900001C. April 1, 2019.

This concept paper provides information and requests feedback about the proposed MPSC approach, the data capture, the logic, and the algorithms to be included in the module, and potential data collection on in-hospital deaths from transplant hospitals.

Appendix A: Draft Data Capture Tool

REQUIRED FOR ALL RECORDS; REQUIRED FOR ALL REFERRALS
REQUIRED FOR ALL VENTILATED PATIENTS (INCLUDING MISSED ORGAN REFERRALS <= 75 YEARS OF AGE)
REQUIRED FOR ALL ORGAN REFERRALS (VENTILATED PATIENTS REFERRED TO THE OPO)
REQUIRED IF OPO ONSITE RESPONSE = YES

Record Source

○ Donor Hospital Referral ○ Hospital Death Record Review (Ventilated Patient <= 75 Years Old)

Hospital Information (Initial Referral)

REQUIRED FOR ALL REFERRALS

Hospital Name _____

Date/Time Referred _____

Date/Time Admitted _____

Hospital unit type at time of referral

○ ED
○ ICU
○ Medical Floor

Was the patient transferred to another hospital following initial referral? ○ Yes ○ No

If yes, Hospital Name _____

Patient Demographic Information

REQUIRED FOR ALL RECORDS

Patient Name _____

DOB _____ ☐ DOB Unknown

Birth Sex ○ Male ○ Female

Age_____Unit ○ Years ○ Months ○ Days

Race (Check all that apply)

☐ American Indian or Alaskan Native
☐ Asian
☐ Black or African American
☐ Native Hawaiian or Pacific Islander
☐ White
☐ Other

Hispanic Ethnicity

○ Hispanic or Latino
○ Not Hispanic or Latino
○ Unknown

Hospital Referral Process

Was the patient on a ventilator or other mechanical support (e.g. ECMO, LVAD) at time of referral? ○ Yes ○ No

REQUIRED FOR ALL REFERRALS

If no, specify (select one): [Complete Classification of Cause of Death for Non-Ventilated Referrals]

○ Patient never ventilated
○ Patient extubated within 1 hour prior to referral, cardiac arrested [Complete Circumstances of Cardiac Arrest]
○ Patient cardiac arrested while on ventilator within 1 hour prior to referral [Complete Circumstances of Cardiac Arrest]

If yes,

Was the referral made in time to allow OPO staff to travel onsite to evaluate patient or approach family in person?

○ Yes ○ No

REQUIRED FOR ALL VENTILATED REFERRALS

What was the patient's MAP at time of referral? ____

Patient's neuro status at time of referral (select one):

○ Not brain dead, patient has some neuro reflexes present
○ Patient has no neuro reflexes present
○ One or more brain death exams consistent with brain death completed
○ Patient pronounced brain dead
○ Patient in hypothermia protocol

Prior to the initial referral, did the healthcare team approach the family about organ donation or limitation or withdrawal of life-sustaining therapies? ○ Yes ○ No ○ Unk

If yes, check all that apply:

☐ Donation
☐ Withdrawal of support of life-sustaining therapies
☐ Limitation of life-sustaining therapies

Did OPO staff evaluate the patient onsite at the referring hospital? ○ Yes ○ No

If no, select Yes to one of the below:

REQUIRED FOR ALL VENTILATED REFERRALS

If no, was there a medical contraindication to donation? ○ Yes ○ No

If yes, Complete Medical Suitability Evaluation.

If there was no medical contraindication to donation, did the patient cardiac arrest prior to OPO arrival? ○ Yes ○ No

If yes, Complete Cardiac Arrest Circumstances.

If the patient didn't cardiac arrest prior to OPO arrival, patient determined not brain dead, not a DCD candidate? ○ Yes ○ No

If yes, Complete Final Neurological Assessment at Case Disposition.

OPO Onsite Response Times

Date/Time TC Arrival to Referring Hospital	Date/Time TC Departure from Referring Hospital

REQUIRED FOR ALL VENTILATED PATIENTS EVALUATED ONSITE

Height_____Unit ○ in ○ cm Weight_____Unit ○ lb ○ kg

Cause/Mechanism/Manner of Death

REQUIRED FOR ALL RECORDS

Cause of Death

- ○ Anoxia
- ○ Cerebrovascular Accident (CVA)
- ○ Head Trauma
- ○ CNS Tumor
- ○ Other Specify: _____
- ○ Unknown

Mechanism of Death

- ○ Asphyxiation
- ○ Blunt Injury
- ○ Cardiovascular
- ○ Death from Natural Causes
- ○ Drowning
- ○ Drug Intoxication
- ○ Electrical

Mechanism of Death (Contd)

- ○ Gunshot Wound
- ○ Intracranial Hemorrhage/Stroke
- ○ Seizure
- ○ SIDS
- ○ Stab
- ○ None of the Above

Circumstances of Death

- ○ Child-Abuse
- ○ Death from Natural Causes
- ○ Homicide
- ○ MVA
- ○ Non-MVA
- ○ Suicide
- ○ None of the Above

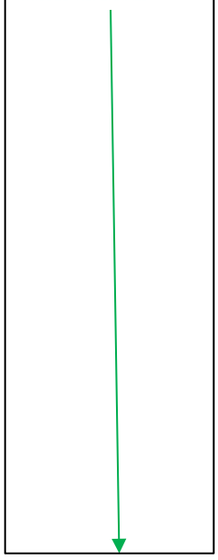
Contributing causes of/factors to patient's death (check all that apply):

- ☐ Cancer: Breast
- ☐ Cancer: Colon
- ☐ Cancer: Leukemia
- ☐ Cancer: Liver
- ☐ Cancer: Lymphoma
- ☐ Cancer: Lung
- ☐ Cancer: Melanoma
- ☐ Cancer: Pancreatic
- ☐ Cancer: Other
- ☐ Cardiovascular: Abdominal Aortic Aneurysm
- ☐ Cardiovascular: Thoracic Aortic Aneurysm
- ☐ Cardiovascular: Cardiac Arrhythmia
- ☐ Cardiovascular: Cardiac Arrest
- ☐ Cardiovascular: Cardiomegaly
- ☐ Cardiovascular: Cardiomyopathy
- ☐ Cardiovascular: Congestive Heart Failure (CHF)
- ☐ Cardiovascular: Acute Myocardial Infarction (AMI)
- ☐ Cardiovascular: Probable AMI
- ☐ Cardiovascular: Pulmonary Embolism (PE)
- ☐ Cardiovascular: Cardiopulmonary Arrest
- ☐ Cardiovascular: Respiratory Failure
- ☐ Cardiovascular: Sudden Cardiac Death

- ☐ Infection: HIV/AIDS
- ☐ Infection: COVID-19
- ☐ Infection: Pneumonia
- ☐ Infection: Sepsis
- ☐ Infection: Other
- ☐ Liver Disease: ESLD
- ☐ Liver Disease: NASH
- ☐ Liver Disease: Cirrhosis
- ☐ Kidney Disease: ESRD
- ☐ Lung Disease: Asthma
- ☐ Lung Disease: ARDS
- ☐ Lung Disease: COPD
- ☐ Lung Disease: Cystic Fibrosis
- ☐ Lung Disease: Other
- ☐ Pediatric: Anencephalicbirth
- ☐ Pediatric: FetalDemise
- ☐ Pediatric: Prematurity
- ☐ Pediatric: Stillbirth
- ☐ Pediatric: SIDS

NOK Authorization Process

REQUIRED FOR ALL VENTILATED PATIENTS INCLUDNG MISSED REFERRALS



Advanced Directives

Was a registry accessed? ○ Yes ○ No

If yes,

Which registry was accessed (check all that apply): ☐ State/DMV Registry ☐ DLA Registry

Did the patient have the donor designation on a registry? ○ Yes ○ No

If yes, on which registry: ☐ State/DMV Registry ☐ DLA Registry

Did the patient have the donor designation on another form of Advanced Directive? ○ Yes ○ No

If yes, specify (select one):

- ○ Donor Card
- ○ Living Will
- ○ Other

Was there written evidence of opposition to donation by decedent? ○ Yes ○ No

If yes, specify (select one):

- ○ Living Will
- ○ Power of Attorney
- ○ Other

NOK Approach

REQUIRED FOR ALL VENTILATED PATIENTS INCLUDNG MISSED REFERRALS

Was the NOK approached regarding organ donation or notified of patient's donor designation? ○ Yes ○ No

If no, why (select one)?

- ○ Medical contraindication identified prior to approach [Complete Medical Suitability Evaluation]
- ○ Patient cardiac arrested prior to NOK approach [Complete Circumstances of Cardiac Arrest]
- ○ Not brain dead, not a DCD candidate [Complete Final Neurologic Assessment at Case Disposition]
- ○ Medical examinerrestriction
- ○ No NOK identified *Drop-Down List: Gift Document, Hospital Administrator, Court Order, Other*

If yes,

Who approached the NOK 1st regarding organ donation? ○ OPO staff ○ Hospital staff

NOK relationship to patient (select one):

- ○ Agent of the decedent
- ○ Spouse
- ○ Adult Son or Daughter
- ○ Parent
- ○ Adult Sibling
- ○ Adult Grandchild
- ○ Adult Grandparent

- ○ Adult Niece or Nephew
- ○ Adult Aunt or Uncle
- ○ Any other adult related by blood, marriage or adoption
- ○ A guardian of the person of the decedent at the time of his or her death
- ○ Any other person authorized or under obligation to dispose of the body

Date/Time OPO NOK donation conversation _____

Timing of NOK donation conversation was:

- ○ Before pronouncement of brain death or discontinuation of ventilator or other mechanical support.

  If timing of NOK approach was before pronouncement of brain death or discontinuation of ventilator or other mechanical support, why? (select one best answer):

  - ○ Hospital staff early mention of donation
  - ○ Hemodynamic instability of patient
  - ○ Decision to limit, decelerate or withdraw life-sustaining therapies from patient
  - ○ Family initiated donation discussion
  - ○ Family understand non-survivable nature of injury
- ○ After pronouncement of brain death

Did NOK authorize organ donation or assent to patient's donor designation? ○ Yes ○ No

If no, and patient was donor designated, did the OPO move forward in opposition of NOK? ○ Yes ○ No

If yes, was authorization obtained for ○ BD Donation ○ DCD Donation ○ Both BD and DCD Donation

Medical Examiner Communication Process

Did the OPO notify the medical examiner/coroner? ○ Yes ○ No

REQUIRED FOR ALL VENTILATED REFERRALS

If yes, did the medical examiner/coroner accept the case? ○ Yes ○ No

If yes, did the medical examiner/coroner decline donation for all organs? ○ Yes ○ No

Final Neurological Assessment at Case Disposition

At time of case disposition, did the patient have any brainstem reflexes present? ○ Yes ○ No

If no, patient did not have any brainstem reflexes present at case disposition:

Was the patient pronounced brain dead? ○ Yes ○ No

If yes,

Date/Time pronounced brain dead _____

If no, why (select one)?

- ○ Patient was on sedatives/paralytics
- ○ Patient cardiac arrested prior to brain death pronouncement
- ○ NOK declined blood pressure/vent support
- ○ Patient was in hypothermia protocol

If yes, the patient had one or more brainstem reflexes present, complete DCD evaluation:

REQUIRED FOR ALL VENTILATED PATIENTS INLCUDING MISSED ORGAN REFERRALS NOT APPEARING BRAIN DEAD

DCD Evaluation

Final brainstem reflexes on last evaluation prior to case disposition or attempted DCD recovery (select Absent, Present or Not Done for every reflex):

Pupillary Reaction

○ Absent ○ Present ○ Not Done

Corneals

○ Absent ○ Present ○ Not Done

Doll's Eyes

○ Absent ○ Present ○ Not Done

Cold Calorics

○ Absent ○ Present ○ Not Done

Cough

○ Absent ○ Present ○ Not Done

Gag

○ Absent ○ Present ○ Not Done

Painful Stimuli

○ Absent ○ Present ○ Not Done

Spontaneous Breathing

○ Absent ○ Present ○ Not Done

Did the patient have a primary non-neurological injury? ○ Yes ○ No

If yes, select cause of primary injury (select one):

- ○ Spinal Cord Injury
- ○ Respiratory Failure due to Pulmonary Disease
- ○ ALS
- ○ Other

Did the patient have a supportive device in Place? ○ Yes ○ No

If yes, check all that apply: ☐ VAD ☐ ECMO ☐ Balloon Pump ☐ Pacer/AICD

Down time (any period pre-hospital or in hospital with no cardiac rhythm and/or blood pressure): ○ Yes ○ No ○ Unknown

Cardiac compressions (pre-hospital or in hospital resuscitation): ○ Yes ○ No ○ Unknown

Time since injury (days): _____

Was a respiratory drive assessment completed? ○ Yes ○ No

If no, why (select one)?

- ○ Level of sedation
- ○ Respiratory status
- ○ Hemodynamicstatus
- ○ Hospital restricted
- ○ Other

If yes, time off ventilator (in minutes): _____

Respiratory Drive Assessment (Final)

Date/Time	HR	Systolic BP	Diastolic BP	RR	SPO2	NIF	TV	Min Vent

Is the patient considered a DCD candidate? ○ Yes ○ No

If no, check all that apply:

- ☐ Age and medical condition (check additional boxes below)
- ☐ Respiratory/Hemodynamic Status
- ☐ Neurologic Status
- ☐ Organ Function (If selected, check all that apply)
  - ☐ Heart (If selected, check all that apply)
    ☐Age ☐ EF ____ ☐ Heart Disease ☐ Expedited Recovery/Instability
  - ☐Lungs (If selected, check all that apply)
    ☐Age ☐ pO2s paO2_____/fiO2_____ ☐ Lung Disease ☐ Expedited Recovery/Instability
  - ☐Kidneys (If selected, check all that apply)
    ☐Age ☐ Creatinine _____ ☐ Hypertension ☐ Diabetes ☐ Kidney Disease ☐ Expedited Recovery/Instability
  - ☐Liver (If selected, check all that apply)
    ☐Age ☐ Steatosis ☐ LFTs AST_____ ALT _____ ☐ Donor BMI ☐ Liver Disease ☐ Expedited Recovery/Instability
  - ☐Pancreas (If selected, check all that apply)
    ☐Age ☐ Diabetes ☐ Expedited Recovery/Instability

Organ Allocation

Was organ allocation attempted (electronic notification sent for at least 1 organ)? ○ Yes ○ No

If no, why (select one)?

- ○ Medical contraindication identified prior to allocation [Complete Medical Suitability Evaluation]
- ○ Patient cardiac arrested prior to allocation [Complete Cardiac Arrest Circumstances]
- ○ Medical examiner restriction

If yes,

Organ	Allocated?	If No, Why (select one)	If Yes, Accepted?
Kidney	○ Yes ○ No	○ Organ function [Complete kidney specific exclusions] ○ Medical examiner restriction ○ NOK declined	○ Yes ○ No
Liver	○ Yes ○ No	○ Organ function [Complete liver specific exclusions] ○ Medical examiner restriction ○ NOK declined	○ Yes ○ No
Heart	○ Yes ○ No	○ Organ function [Complete heart specific exclusions] ○ Medical examiner restriction ○ NOK declined	○ Yes ○ No
Lung	○ Yes ○ No	○ Organ function [Complete lung specific exclusions] ○ Medical examiner restriction ○ NOK declined	○ Yes ○ No
Pancreas	○ Yes ○ No	○ Organ function ○ Medical examiner restriction ○ NOK declined	○ Yes ○ No
Intestine	○ Yes ○ No	○ Organ function ○ Medical examiner restriction ○ NOK declined	○ Yes ○ No

Organ Recovery

Was the patient taken to the OR for organ recovery or was DCD recovery attempted? ○ Yes ○ No

REQUIRED IF ANY ORGANS ACCEPTED OR PATIENT TAKEN TO OR FOR RECOVERY

If DCD recovery attempted, location of discontinuation of ventilator or other mechanical support:
○ ICU ○ PACU ○ OR ○ DCU ○ Other

Recovery Location ○ Hospital OR ○ OPO Recovery Center

If no, why (select one)?

○ Patient cardiac arrested prior to recovery [Complete Circumstances of Cardiac Arrest]

○ No recipients identified

If yes,

Method of Recovery

○ DBD

○ Controlled DCD

○ Maastricht Category II DCD (In-hospital unexpected cardiocirculatory death)

○ Maastricht Category IV DCD (Cardiac arrest while brain dead)

Date/Time Cross Clamp _____ ☐ N/A DCD attempted, did not die

Was at least one organ recovered for transplant? ○ Yes ○ No

REQUIRED IF THERE IS A DATE/TIME CROSS-CLAMP

If no, why (select one)?

○ Medical contraindication discovered in OR [Complete Medical Suitability Evaluation]

○ Organs ruled out in OR

○ Organs refused, lists not exhausted

○ Organs refused, lists exhausted

Circumstances of Cardiac Arrest

If the patient cardiac arrested precluding recovery, what were the primary circumstances of the arrest? (Select one)

REQUIRED IF PATIENT CARDIAC ARRESTED SELECTED ANYWHERE IN THE DTT FORM ABOVE

○ Patient cardiac arrested despite maximum resuscitative efforts

○ Patient cardiac arrested, hospital withdrew support of life-sustaining therapies

○ Patient cardiac arrested, hospital limited life-sustaining therapies

Date/Time cardiac arrest _____

Medical Suitability Evaluation

Was the patient medically suitable? ○ Yes ○ No

REQUIRED FOR ALL VENTILATED PATIENTS INCLUDING MISSED ORGAN REFERRALS - MUST BE NO IF MEDICAL CONTRAINDICATION SELECTED ANYWHERE IN THE DTT FORM ABOVE

○ If No, why? (Select one) ○ General donor exclusion ○ Organ function

Terminal values: Creatinine _____ AST_____ALT_____paO2_____/ fiO2 _____ EF ____

REQUIRED FOR ALL VENTILATED REFERRALS EVALUATED ONSITE OR IF CREATININE, LFTS, PO2s, EF GIVEN AS REASON ORGAN IS NOT SUITABLE FOR DCD RECOVERY

If medically unsuitable due to general donor exclusion, check all that apply:

- ☐ Age
- ☐ Aplastic anemia, agranulocytosis
- ☐ Body weight less than 5 kg
- ☐ Body mass index (BMI) greater than 50 kg/m2
- ☐ Current malignant neoplasms, except non-melanoma skin cancers such as basal cell and squamous cell cancer and primary CNS tumors without evident metastatic disease
- ☐ Previous malignant neoplasms with current evident metastatic disease
- ☐ History of melanoma
- ☐ Hematologic malignancies: leukemia, Hodgkin's disease, lymphoma, multiple myeloma
- ☐ No discernible cause of death
- ☐ Active fungal, parasitic, viral, or bacterial meningitis or encephalitis

If Active fungal, parasitic, viral, or bacterial meningitis or encephalitis, select at least one:

- ☐Bacterial: tuberculosis, gangrenous bowel or perforated bowel or intra-abdominal sepsis
- ☐Viral: HIV infection by serologic or molecular detection
- ☐Viral: rabies
- ☐Viral: reactive hepatitis B surface antigen
- ☐Viral: retroviral infections including viral encephalitis or meningitis
- ☐Viral: active herpes simplex
- ☐Viral: varicella zoster
- ☐Viral: cytomegalovirus viremia or pneumonia
- ☐Viral: acute Epstein Barr virus (mononucleosis)
- ☐Viral: West Nile virus infection
- ☐Viral: SARS
- ☐Fungal: cryptococcus
- ☐Fungal: aspergillus
- ☐Fungal: histoplasma
- ☐Fungal: coccidioides
- ☐Fungal: active candidemia
- ☐Fungal: invasive yeast infection
- ☐Parasites: trypanosoma cruzi(Chagas')
- ☐Parasites: Leishmania
- ☐Parasites: strongyloides
- ☐Parasites: malaria (plasmodium sp.)
- ☐Prion: Creutzfeldt-Jacob disease

Organ Specific Exclusions (if medically unsuitable due to organ function, one selection is required for every organ):

Kidney (Select one)

REQUIRED IF MEDICALLY UNSUITABLE DUE TO ORGAN FUNCTION
REQUIRED IF **KIDNEY** NOT ALLOCATED DUE TO ORGAN FUNCTION

- ○ Greater than 70 years old
- ○ Age 50-69 years with history of type 1 diabetes for more than 20 years
- ○ Polycystic kidney disease
- ○ Glomerulosclerosis greater than or equal to 20% by kidney biopsy
- ○ Terminal serum creatinine greater than 4.0 mg/dL

- ○ Chronic renal failure
- ○ No urine output for 24 hours or longer

Liver (Select one)

REQUIRED IF MEDICALLY UNSUITABLE DUE TO ORGAN FUNCTION
REQUIRED IF **LIVER** NOT ALLOCATED DUE TO ORGAN FUNCTION

- ○ Cirrhosis
- ○ Terminal total bilirubin greater than or equal to 4 mg/dL
- ○ Portal hypertension
- ○ Macrosteatosis greater than or equal to 50% or fibrosis greater than or equal to stage II
- ○ Fulminant hepatic failure
- ○ Terminal AST/ALT greater than 700 U/L

Heart (Select one)

REQUIRED IF MEDICALLY UNSUITABLE DUE TO ORGAN FUNCTION
REQUIRED IF **HEART** NOT ALLOCATED DUE TO ORGAN FUNCTION

- ○ Greater than 60 years old
- ○ 45 years old or older with a history of 10 or more years of HTN or 10 or more years of type 1 diabetes
- ○ History of coronary artery bypass graft (CABG)
- ○ History of coronary stent/intervention
- ○ Current or past medical history of myocardial infarction (MI)
- ○ Severe vessel diagnosis as supported by cardiac catheterization (that is more than 50 percent occlusion or 2+ Vessel disease)
- ○ Acute myocarditis or endocarditis, or both
- ○ Heart failure due to cardiomyopathy
- ○ Internal defibrillator or pacemaker
- ○ Moderate to severe single valve or 2-valve disease documented by echo or cardiac catheterization, or previous valve repair
- ○ Serial echo results showing severe global hypokinesis
- ○ Myxoma
- ○ Congenital defects (surgically corrected or not)

Lung (Select one)

REQUIRED IF MEDICALLY UNSUITABLE DUE TO ORGAN FUNCTION
REQUIRED IF **LUNG** NOT ALLOCATED DUE TO ORGAN FUNCTION

- ○ Greater than 65 years old
- ○ Terminal PaO2/FiO2 less than 250 mmHg
- ○ Asthma is the cause of death
- ○ Underlying lung disease (e.g. COPD, ILD, CF, PAH)
- ○ Previous lobectomy
- ○ Multiple blebs documented on computed axial tomography (CAT) scan
- ○ Pneumonia as indicated on computed tomography (CT), X-ray, bronchoscopy, or cultures
- ○ Bilateral severe pulmonary contusions as per CT

Classification of Cause of Death for Non-Ventilated Referrals

Check one:

- ☐Aneurysm: AAA
- ☐Aneurysm: Thoracic AA
- ☐Anoxia: Drug overdose
- ☐Anoxia: Asphyxiation
- ☐Anoxia: Drowning
- ☐Anoxia: Hanging
- ☐Anoxia: Smoke inhalation
- ☐Anoxia: Anaphylactic Shock
- ☐Anoxia: SIDS
- ☐Anoxia: Aspiration
- ☐Anoxia: Seizure
- ☐Cancer: Primary CNS Tumor
- ☐Cancer: Leukemia
- ☐Cancer: Lymphoma
- ☐Cancer: Lung Cancer
- ☐Cancer: Colon Cancer
- ☐Cancer: Pancreatic Cancer
- ☐Cancer: Melanoma
- ☐Cancer: Other non-CNS primary cancer
- ☐Cardiac: Arrhythmias
- ☐Cardiac: Cardiac arrest
- ☐Cardiac: Cardiomegaly
- ☐Cardiac: Cardiomyopathy
- ☐Cardiac: CHF
- ☐Cardiac: Myocardial Infarction
- ☐Cardiac: Probably Myocardial Infarction
- ☐Cardiac: Cardiopulmonary Arrest
- ☐Cardiac: Sudden Cardiac Death
- ☐CVA: ICB
- ☐CVA: ICH
- ☐CVA: SAH
- ☐CVA: Brain Aneurysm
- ☐Liver Disease: ESLD
- ☐Liver Disease: Liver Disease
- ☐Liver Disease: Hepatitis
- ☐Kidney Disease: ESRD
- ☐Kidney Disease: Kidney Disease
- ☐Fetal Demise: Anencephalic Birth
- ☐Fetal Demise: Fetal Demise
- ☐Fetal Demise: Pediatric Prematurity
- ☐Fetal Demise: Stillbirth
- ☐Gastrointestinal (GI): GI Bleed
- ☐Gastrointestinal (GI): Bowel Obstruction
- ☐Gastrointestinal (GI): Bowel Perforation
- ☐Gastrointestinal (GI): Necrotic Bowel
- ☐Infection: HIV
- ☐Infection: AIDS
- ☐Infection: Meningitis, bacterial or Viral
- ☐Infection: Sepsis
- ☐Infection: Septic Shock
- ☐Infection: CJD
- ☐Infection: Other prion diseases
- ☐Infection: Pneumonia
- ☐Infection: Other infections not otherwise classified
- ☐Lung Disease: Asthma
- ☐Lung Disease: COPD
- ☐Lung Disease: Cystic Fibrosis
- ☐Multi-System Failure: MSOF
- ☐Multi-System Failure: Multi-System Failure
- ☐Pulmonary Embolism: Pulmonary Embolism
- ☐Respiratory Failure: Respiratory Failure
- ☐Head Trauma: Closed head injury
- ☐Head Trauma: Subdural hematoma
- ☐Head Trauma: GSW (if to head)
- ☐Head Trauma: MVA (if head injury)
- ☐Head Trauma: Child abuse (if head trauma noted)
- ☐Trauma: GSW (if not to the head)
- ☐Trauma: MVA (unless head injury noted)
- ☐Trauma: Stabbing
- ☐Trauma: Burns
- ☐Trauma: Electrocution
- ☐Trauma: Child abuse (unless head trauma noted)
- ☐Trauma: Blunt force trauma (unless to head)
- ☐Other: Natural Causes
- ☐Other: Unknown Cause
- ☐Other: Other cause not otherwise specified

Appendix B: Algorithm Maps

Below are examples of the potential outcome algorithms that would be incorporated into the module for different potential donor outcomes and for determining timely notification of the OPO by the donor hospital:

Figure 1: Referral Outcome Algorithm for All Outcomes

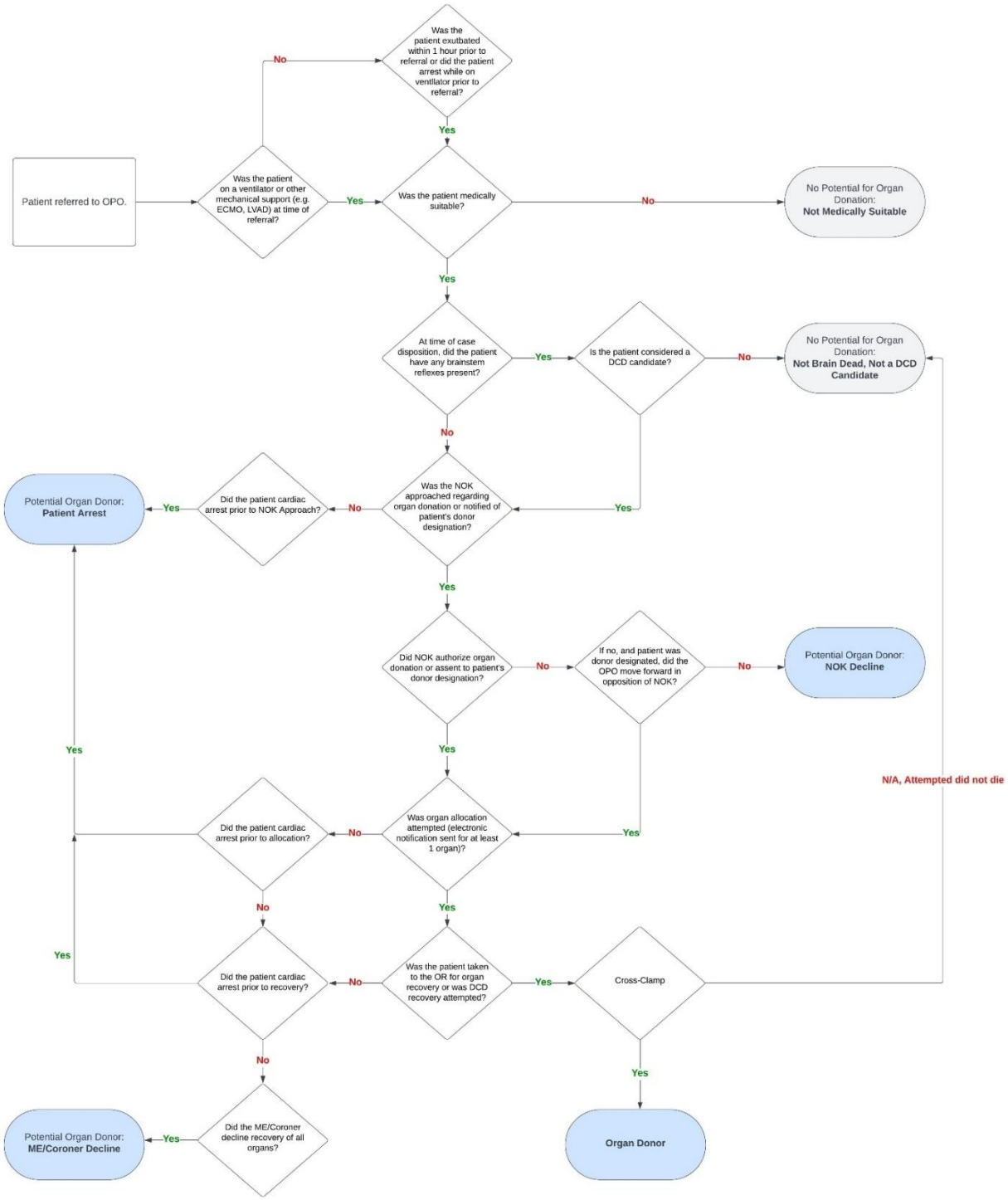


Figure 2: Referral Process Metric Algorithm for Timely Notification of OPO By Donor Hospital