OPTN Data Advisory Committee Feedback to HRSA on New Data Collection

January 31, 2024

Agenda

- Introductions
  - DAC Chairs and MPSC Workgroup Chair
  - HRSA Staff

- Review HRSA's request

- Review feedback on Ventilated Referral data collection

- Review feedback on Pre-Waitlist data collection

- Discussion and Next Steps

HRSA Request

On November 13, 2023, the OPTN Contracting Officer's Representative (COR) from HRSA, Chris McLaughlin, attended the DAC meeting and requested the following

- Feedback on the drafted **ventilated referral notification** data collection
  - Data elements and definitions

- Feedback on the drafted **referral evaluation registration** data collection
  - Data elements and definitions by organ (kidney, liver, lung, heart)

- OPTN COR shared DAC's feedback will be considered when
  - Finalizing the HHS Secretarial Directive – coming in early 2024
  - HRSA intends to include the new data collection forms in the 2023 OPTN Data System package

- Feedback due to HRSA on January 31, 2024

NOTE: The 2023 OPTN Data System OMB package, which contains OPTN board approved policy projects is on hold awaiting this finalized new data collection. Project implementations will likely be delayed in 2024, at least 6 months, until the package is submitted to OMB for approval.

HRSA Request for DAC Feedback Regarding New OPTN Data Collection: **Ventilated Referrals Data Collection**

OPTN Membership and Professional Standards Committee (MPSC)

OPO Performance Monitoring Enhancement Workgroup
Presenter: Rick Hasz, Workgroup Lead

Workgroup Background

- The MPSC OPO Performance Monitoring Enhancement Workgroup worked for several months in 2023 to discuss and standardize OPO's referral data collection

- The concept paper and proposed OPO data capture tool was presented and endorsed by the DAC in Dec 2023 for Winter 2024 public comment
  - On Jan 16th, the OPTN Executive Committee postponed releasing paper to avoid community confusion and aligning it with the forthcoming Secretarial Directive

- Proposed logic-based, data capture tool described in the concept paper
  - captures referrals on ventilated and non-ventilated donors,
  - captures 100% of the data describing donor potential and hospital donation process,
  - provides more granular data,
  - accurately captures donation potential, and
  - includes reasons a referral does not progress to donation

- Early discussions with Electronic Donor Record (EDR) vendors
  - Alignment on building new capabilities in 2024

Workgroup Approach to HRSA Request

- HRSA provided a draft Ventilated Referral Notification (VRN) form
  - drafted form is based on the existing Death Notification Registration (DNR) form
  - additional data fields were included
  - expectation is to collect data on all ventilated referrals

- Data fields represent what CMS wants the OPTN to collect from OPOs to understand
  - donation potential, and
  - reasons why ventilated referrals do not proceed to donation

- Workgroup reviewed the draft form and captured feedback

Themes of Workgroup Feedback to HRSA

- HRSA, CMS, MPSC workgroup and OPOs are all aligned on the common goal to collect data on the phases of donation from referral to donor registration

- Many of the new data fields provided in the VRN form are not granular enough to ensure collection of meaningful and useful data; therefore, suggestions have been made

- VRN form, as provided by HRSA, would not meet intent of determining donor potential and reasons for a referral not proceeding to donation

Feedback Summary

- Draft VRN form includes 64 data fields
  - 28 fields (44%) currently collected on Death Notification Registration (DNR) Form
    - Since already collected, these do not need to be discussed
  - 36 new data fields (56%)
    - 2 of 36 new fields are suggested as <u>optional</u> data collection (KDPI and Payer Status) – require additional discussion

- Categorization of 36 new data fields
  - 13 – can be collected as is or with **some** clarification
  - 14 – can be collected but need **significant** clarification
  - 7 – not available or poses significant burden so **needs more investigation**
  - 2 – **require discussion** as currently outside OPTN scope

- See workbook for detailed feedback on each data field

36 new data fields categorized by feedback

Review Feedback	Process	Demographic	Terminal Step	Hospital Interference
Some clarification	• Time of Ventilated Referral • Approach/es • Time of Approach/es • Authorization Time Stamp • Organ Recovery	• Onsite Response • Time of Onsite Response • Organ Recovery Center • KDPI (if calculated)	• Decline • Time of Decline • Cardiac Arrest Prior to OR • Time of Cardiac Arrest Prior to OR	NA
Significant clarification	• Availability of Remote EMR Access • Referral Medically Ruled Out (MRO)	• Height • Weight • HIV Status • Cardiac Time of Death (CTOD)	• Closed Before OR • Time of Patient Close • Patient Did Not Expire • Closed In OR • Time of Patient Close • Allocation Exhausted • Time Allocation Exhausted	• Unreported/Missed Ventilated Referral
Not available significant burden	NA	• Referral Type	NA	• Report to Hospital (yes/no) • Report to Hospital (detail) • Report to Hospital Accepted • Remediation Plan to Hospital (yes/no) • Remediation Plan to Hospital (detail) • Remediation Plan Accepted
Outside OPTN scope/discuss	NA	•Tissue Authorization •Payer Status	NA	NA

Considerations for the proposed data capture tool

- Some data fields are not currently in the proposed data capture tool but could be **added**

  - Patient home zip code

  - Time for some of the outcome determinations (4 fields)

- Some data fields are **outside scope** and need to be discussed

  - Donor data that could be captured from OPTN Computer System (2 fields)

    - cardiac time of death and KDPI

  - Data that is not captured on individual referrals - best captured in other ways

    - Data fields on hospital interference reporting and remediation (6)

    - Availability of remote EMR access

    - Not relevant to organ donation (2) (tissue authorization and payer status)

Next Steps

- Workgroup extends an offer to HRSA and CMS to meet and review the proposed data capture tool and the feedback on the drafted VRN form

- Workgroup will incorporate feedback into the proposed data capture tool

- Provide public comment during OMB cycle

- Incorporate forthcoming secretarial directive feedback into concept paper and determine how to release information to the community
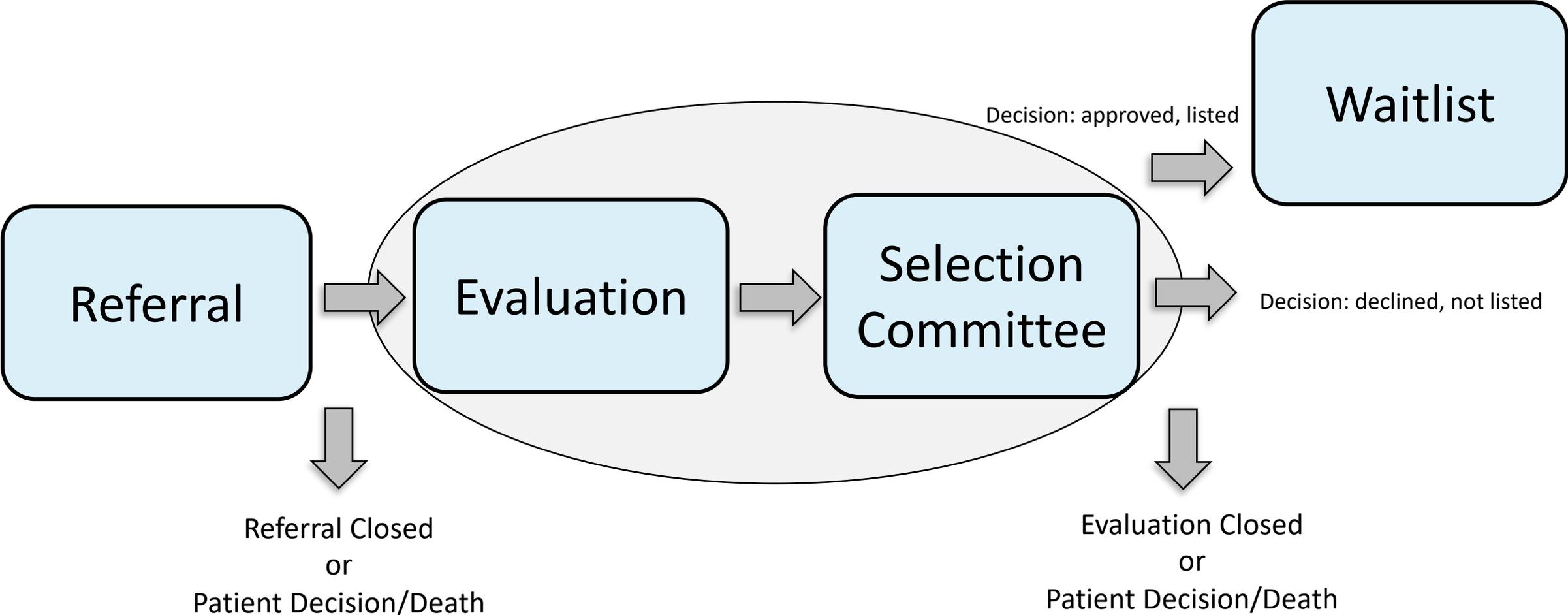
Thank You

- Rick Hasz, OPO Performance Monitoring Enhancement Workgroup Chair, rhasz@donors1.org

- Sharon Shepherd, MPSC Project Manager, sharon.shepherd@unos.org

HRSA Request for DAC Feedback Regarding New OPTN Data Collection: **Pre-Waitlist Data Collection**

OPTN Data Advisory Committee (DAC)

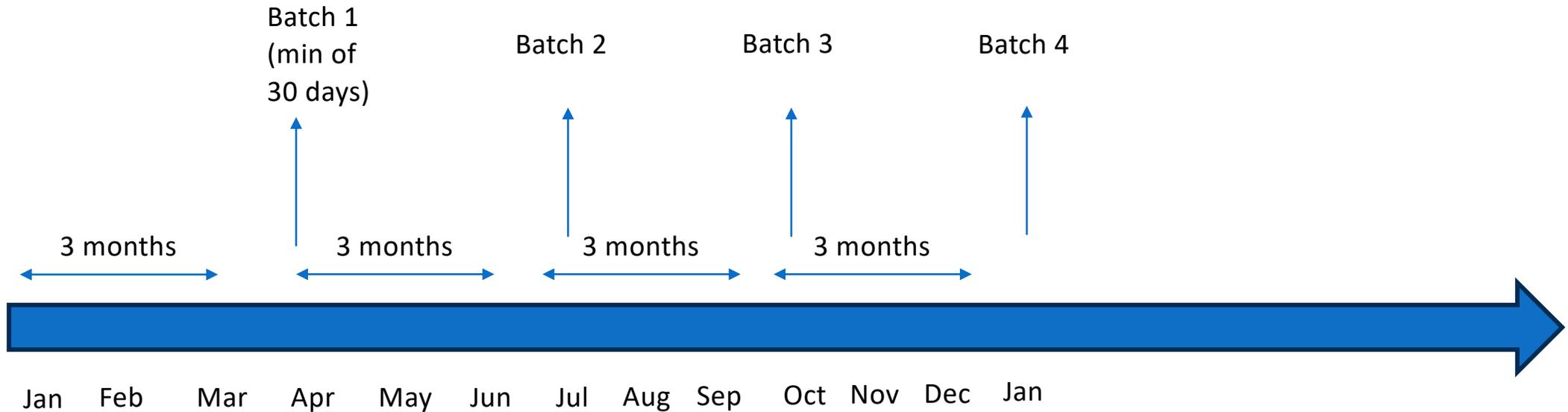*Presenter: Sumit Mohan, MD, Chair*

Pre-waitlist Process

Pre-waitlist Data Collection Approach

Patient referral and evaluation data is also known as pre-waitlist data

- Two separate data collection events (referral event, evaluation event)

- Each event has start and end triggers that mandate 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

- Targeting quarterly data collection cycle

- Transplant programs will not be able to edit the data after event closure

- Option to submit the data in bulk or manually at predefined intervals **(see next slide)**

Cadence of Batch Reports

Batch 1 (min of 30 days) — Apr

Batch 2 — Jul

Batch 3 — Oct

Batch 4 — Jan

3 months | 3 months | 3 months | 3 months

Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec Jan

Elements of Batch Reports:

- Referrals
- Evaluations
- Selection Committee

- Referrals
- Evaluations
- Selection Committee

- Referrals
- Evaluations
- Selection Committee

Confirm Open Referrals
Confirm Open Evals

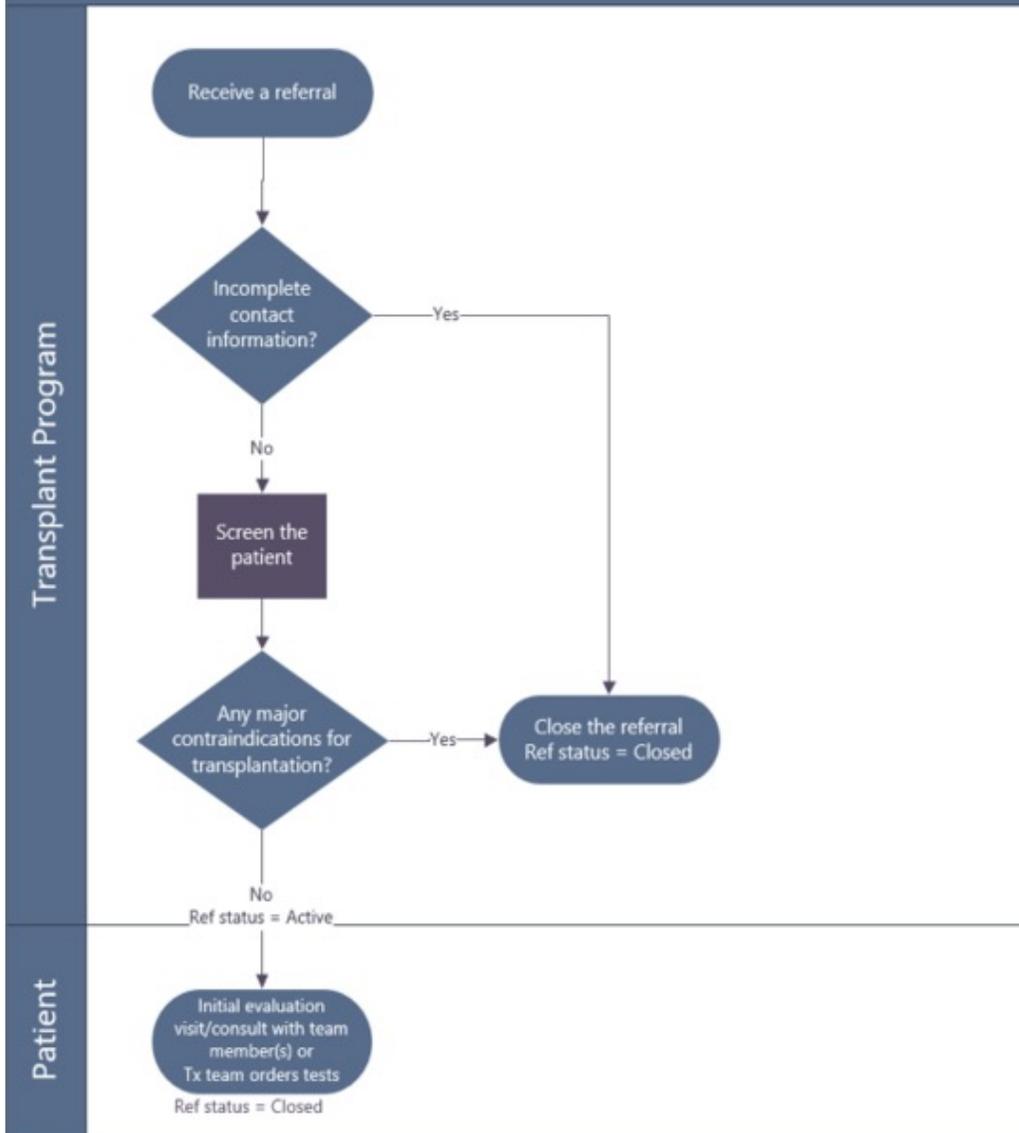Confirm Open Referrals
Confirm Open Evals

Summary of pre-waitlist data changes

After workgroup review/discussion, the following summarizes the data collection - Details captured on subsequent slides

- For referral event
  - 27 data elements to be collected

- For evaluation event
  - 32 data elements to be collected

- Nearly half of the pre-waitlist data is also collected in the Transplant Candidate Recipient (TCR) form

- 5 of the 12 new elements are collected at both referral and evaluation
  - Patient Medical Record Number (MRN), Middle Name, Phone Number, Permanent Street Address, Source of Payment Secondary Insurance

- After discussion, no organ specific data was identified for collection

Referral Event
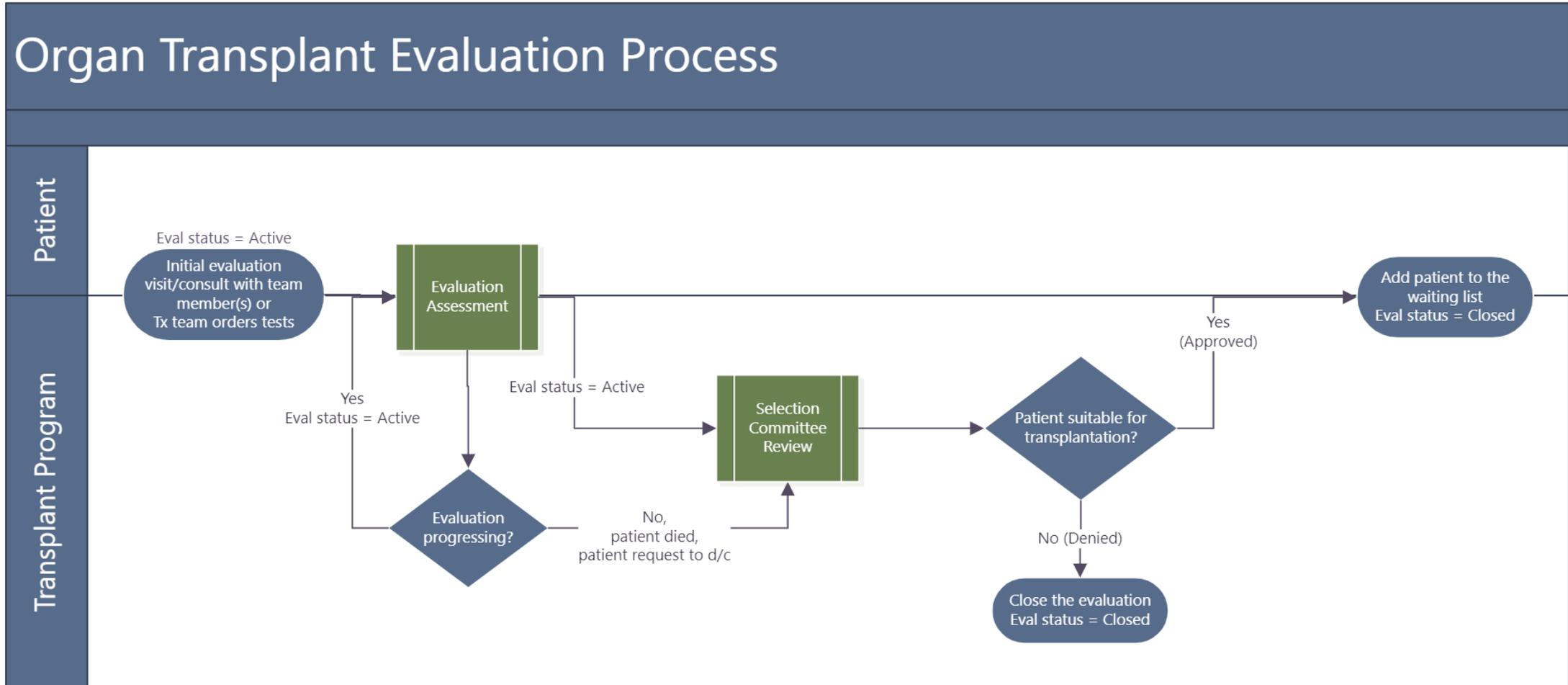

Organ Transplant Referral Process

Referral Event

Pre-Waitlist Data Collection Form

Fields to be provided by transplant programs

	Referral Event	
Form Section	Field Label	Notes
OPTN Patient Identification	Transplant Center	Required, report value
OPTN Patient Identification	Transplant Center Code	Required, report value
OPTN Patient Identification	Patient MRN	Required, report value
OPTN Patient Identification	Organ	Required, report value
Patient Demographics	First Name	Required, report value
Patient Demographics	Middle Name	Required, may use status UNK, N/A
Patient Demographics	Last Name	Required, report value
Patient Demographics	DOB	Required, report value
Patient Demographics	Birth Sex	Required, report value
Patient Demographics	SSN	Required, may use status UNK, N/A
Patient Demographics	Race	Required, may use not reported
Patient Demographics	Ethnicity	Required, may use not reported
Contact Information	Primary Phone Number	Required, report value
Contact Information	Permanent Street Address	Required, may use status UNK, N/A
Contact Information	City	Required, report value
Contact Information	State of Permanent Residence	Required, report value
Contact Information	Permanent Zip Code	Required, report value
Contact Information	Country	Required, report value
Financial Resources	Source of Payment/Primary	Required, may use status UNK, N/A
Financial Resources	Source of Payment/Secondary	Required, may use status UNK, N/A
Referral Details	Referral Date	Required, report value
Referral Details	Referral Status	Required, report value = Active, Closed, Canceled
Referral Details	Referral Status/ Referral Closure Reason	conditional for referral status - Closed
Referral Details	Referral Status/Referral Cancelation Reason	conditional for referral status - Canceled
Referral Details	Referral Status /Death Date	conditional for referral reason option - Patient Died
Referral Details	Referral Status/Referral Closure Date	close a referral without Evaluation Start Date
Referral Details	Evaluation Start Date	completed 1st appointment or ordered testing

Evaluation Event

Organ Transplant Evaluation Process

Patient

Transplant Program

Eval status = Active

Initial evaluation visit/consult with team member(s) or Tx team orders tests

Evaluation Assessment

Eval status = Active

Yes
Eval status = Active

Evaluation progressing?

No, patient died, patient request to d/c

Selection Committee Review

Patient suitable for transplantation?

Yes (Approved)

No (Denied)

Add patient to the waiting list
Eval status = Closed

Close the evaluation
Eval status = Closed

Evaluation Event Data

Red text indicates new data collection

Pre-Waitlist Data Collection Form

Fields to be provided by transplant programs

Form Section	Evaluation Event	
	Field Label	Notes
OPTN Patient Identification	Transplant Center	Required, report value
OPTN Patient Identification	Transplant Center Code	Required, report value
OPTN Patient Identification	Patient MRN	Required, report value
OPTN Patient Identification	Organ	Required, report value
Patient Demographics	First Name	Required, report value
Patient Demographics	Middle Name	Required, may use status UNK, N/A
Patient Demographics	Last Name	Required, report value
Patient Demographics	DOB	Required, report value
Patient Demographics	Birth Sex	Required, report value
Patient Demographics	SSN	Required, may use status UNK, N/A
Patient Demographics	Race	Required, may use status UNK, N/A
Patient Demographics	Ethnicity	Required, may use status UNK, N/A
Contact Information	Primary Phone Number	Required, report value
Contact Information	Permanent Street Address	Required, may use status UNK, N/A
Contact Information	City	Required, report value
Contact Information	State of Permanent Residence	Required, report value
Contact Information	Permanent Zip Code	Required, report value
Contact Information	Country	Required, report value
Financial Resources	Source of Payment/Primary	Required, may use status UNK, N/A
Financial Resources	Source of Payment/Secondary	Required, may use status UNK, N/A
Financial Resources	Working for Income	Required, may use status UNK, N/A
Patient Measurements	Height (cm)	Required, may use status UNK, N/A
Patient Measurements	Weight (kg)	Required, may use status UNK, N/A
Patient Measurements	BMI	Autocalculated, Required, may use status UNK, N/A
Evaluation Details	Initial Evaluation Appointment Completion Date	Required, report value
Evaluation Details	Primary Diagnosis	Required, may use status UNK, N/A
Evaluation Details	Evaluation Status	Required, report value = Active, Closed, Canceled
Evaluation Details	Evaluation Status/Evaluation Cancelation Reason	Required, conditional for evaluation status - Canceled
Evaluation Details	Selection Committee Date	Required, may use status UNK, N/A
Evaluation Details	Selection Committee Decision	Required, Approved, Denied
Evaluation Details	Selection Committee Decision/Declined Reason	Required, conditional for Selection Committee decision option - Denied
Evaluation Details	Selection Committee Decision/Death Date	Required, conditional for declined reason option - Patient Died

Pre-waitlist Workbook

- Drafted choice lists for key data elements

  - Referral Closure Reasons

  - Evaluation Cancellation Reasons

  - Selection Committee Decision Declined Reasons

- Drafted OMB form mock-ups

  - In review of the drafted referral evaluation registration form, the proposed data collection provided by DAC includes the data elements needed to determine if a patient is suitable for transplantation

  - Some of the TCR data elements needed for the waitlist event are used to determine medical urgency

- Drafted data dictionary

Pre-Waitlist Next Steps

- Follow-up with Patient Affairs Committee (PAC) to review their feedback

- Seek input from the Vascularized Composite Allograft (VCA) committee on drafted data collection – February/March 2024

- Seek participation from transplant programs for a pilot effort

- Begin conversations with Electronic Medical Record (EMR) vendors

- Provide public comment during OMB cycle

- Requests for HRSA
  - Appreciate support in prioritizing EMR vendor engagement
  - Provide resources to support new benchmark reporting for transplant programs

Discussion

Overall Next Steps

- Email final DAC deliverables to HRSA

- Layout a community communication plan

- Develop an evaluation and monitoring approach

- Begin preparing a response for 60-day OMB package public comment

- Submit public comment to Federal Register regarding
  - Adding pre-waitlist and ventilated referral data to OPTN OMB package (60-day period)
  - Comments on new data collection forms (30-day period)
  - Federal Register public comment dates – TBD by HRSA

Thank You

If you have additional feedback, please reach out

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- Nadine Hoffman, UNOS Director of Enterprise Data Management, Nadine.Hoffman@unos.org

- Sevgin Hunt, UNOS Enterprise Data Management, Sevgin.Hunt@unos.org