UW ORGAN AND TISSUE DONATION

448 Science Drive
Suite 250
Madison, WI 53711

(608) 265-0356
(608) 890-9988 Fax
uwotd@uwhealth.org

January 3, 2025

Re: *Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Process Data for Organ Procurement and Transplantation Network (OPTN)*

Dear HRSA:

The University of Wisconsin – Organ and Tissue Donation (UW OTD) appreciates the opportunity to respond to the notice titled *"Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Process Data for Organ Procurement and Transplantation Network."* While we support HRSA's efforts to enhance organ donation and transplantation practices, we have significant concerns regarding the feasibility of collecting certain data fields as proposed. We respectfully request that HRSA consider the operational challenges associated with these requirements and allow for flexibility in reporting.

Data Fields Typically Available

UW OTD generally collects and can submit the following fields:

- Donor ID
- OPO
- Donor Hospital
- OPO Record ID
- Case Detail/How Did You Learn of This Case?
- Patient Last Name
- Patient First Name
- Sex
- Age
- Onsite Response
- Date of Onsite Response (if performed)
- Time of Onsite Response (if performed)
- Organ Recovery Center (if a donor)
- KDPI (if available, not required)
- Date of Ventilated Referral
- Date of Death Record Review
- Time of Ventilated Referral
- Organ Recovery
- Remote electronic medical record access
- Referral Medically Ruled Out (MRO)

- Time Medically Ruled Out (MRO)
- Approaches (additional clarity would be needed for OPOs if a hospital approaches inappropriately without OPO or without using a designated requestor)
- Time of Approach (if performed)
- First Person Authorization (HRSA should be acutely aware that this may not be always available due to unidentified patients, but "Unknown" as an option helps OPOs during this process)
- Family Authorization (if performed)
- Authorization Time Stamp (if performed)
- Time of Decline
- Allocation Exhausted
- Time Allocation Exhausted
- Cardiac Arrest Prior to OR
- Time of Cardiac Arrest prior to OR (HRSA should recognize these times may not be accurate depending on when a physician declared death vs when the patient actually had a cardiac arrest)
- Close Case Referral Before OR
- Time of Case Close
- Time of OR Case Close
- Describe Hospital Interference
- Report to Hospital Including Remediation Plans
- Information Provided in Report to Hospital
- Report to Hospital Accepted
- Remediation Plan to Hospital
- Information Provided in Remediation Plan
- Remediation Plan to Hospital Accepted

Data Fields Requiring Additional Actions

The following data fields are not currently collected by UW OTD or may require significant additional steps by either the OPO, the hospital, or both. In many cases, these data points are not readily available in hospital records, can be challenging to obtain, or are not documented until much later in the care process:

- **Patient Home Zip Code** – Not always collected on unidentified patients, often incorrect in EMR.
- **Ethnicity** – Not always documented for mixed-race or unidentified patients. It is appreciated that HRSA gives "ethnicity not reported" as a selection.
- **Race** – Not always documented for mixed-race or unidentified patients.
- **Gender Identity** – Often not documented by hospitals.
- **Height** – Not routinely recorded by hospitals under urgent circumstances.
- **Weight** – Not routinely recorded by hospitals under urgent circumstances.
- **HIV Status** – Not always known by hospitals. (okay to document Unknown)
- **Patient Record Type** – Often remains "not specified," especially if a referral is closed prior to brain death evaluation.

- **First Person Authorization Restrictions** – Same limitations as above.
- **Circumstances of Death** – Etiology may be unknown at referral and therefore not accurately recorded.
- **Mechanism of Death** – Similar to circumstances of death; may be unknown at time of referral.
- **Cause of Death -** Like circumstances of death, this may be unknown at time of referral or when the OPO closes the referral later in the process.
- **Cardiac Date of Death-** May not be consistently documented or available.
- **Cardiac Time of Death**– May not be consistently documented or available.
- **Tissue Authorization** – Not always known, especially if the patient is ineligible or ruled out. Not routinely in the hospital EMR if tissue is recovered post-mortem. In addition, the OPO may be unaware if a tissue bank followed the referral after the OPO closed and placing this burden on the OPO requires additional resources.
- **Payer Status** – Difficult to obtain in urgent or unidentified-patient scenarios and is not currently part of referral processes. Unknown is a choice but will add additional burden to determine especially for unidentified patients.
- **Family Objection** – Not always documented, especially if referral is closed before any approach or if FPA is unavailable.
- **Hospital Interference** – This would need clear definition and may not always be known to the OPO.
- **Time of Objection leading to Case Close** – Similar to Family objection**,** may not be recorded.
- **Cardiac Arrest Prior to OR**
- **Time of Cardiac Arrest prior to OR**
- **Outside Expiration Time for DCD Recovery** – Often unreliable (e.g., delayed physician declaration in non-ICU floors).
- **Length of Outside Expiration Time for DCD Recovery** – Same reliability concerns as above.

Data Points and True Impact of Burden on OPOs

Critically, we must distinguish between **data entry time** (e.g., the act of typing information into a form) and **data collection time** (e.g., locating, verifying, and documenting unavailable information). Many of these data points are not clearly present in the hospital electronic medical record (EMR); gathering them often requires thorough reviews of clinical notes, contacting multiple hospital staff, or consulting with families. These tasks can add significant hours to each referral process. UW OTD has concerns with the time burden that HRSA estimated given that the data collection for the time above seems to be immeasurable.

While we acknowledge that these data fields could provide additional insight for improving organ donation outcomes, there are substantial practical challenges in collecting them, particularly given the time-sensitive and unpredictable nature of organ procurement. UW OTD receives approximately 2,600 referrals annually. Up to 66 data fields would mean potentially **171,600 data points** per year to report and compile.

25 of the additional data fields are described above and would require significant changes in workflows and may not be reliable data. This would require UW OTD to customize our EMR system which comes with a financial cost. Each customization item in this system would draw resources away from other documentation updates or improvements.

Difficulty and Inaccurate Data Collection Risks

Additional family interactions may become necessary at a time of acute grief, which could place undue emotional stress on the family and complicate the donation conversation. Furthermore, fields like *cardiac time of death*, *first person authorization*, *HIV status*, and *family contact information* may not be reliably available at or after the time of referral. The OPO may close a referral and never have a need to go back into the system to collect more data. Additional data collected would put an additional burden on the OPO. For example, if a patient arrives and dies quickly, the hospital staff may never record height, weight, or primary language. Patients may also arrive unresponsive, and information may not be reported to the hospital (e.g. race, ethnicity, etc.). In missed or sudden referrals, it may be impossible to gather all necessary information in real-time. Obtaining death dates and times after a referral is closed is also not routine for UW OTD; doing so would require additional follow-up with hospitals or families, who may be uncertain about exact times—especially if the patient was transferred to palliative or hospice care. The times recorded are the declared times of death, which may not correspond to the patient's actual cardiac cessation. The actual cardiac cessation time is critical for the organ donation process, which is why UW OTD does not retrospectively collect declaration times.

Advisory Board Feedback

UW OTD presented these additional data requirements to our Advisory Board, which includes hospital administrators and liaisons. They unanimously expressed concern about the undue burden on donor hospitals, particularly in situations where the requested information is not readily available, would impose significant demands on staff, or would require additional follow-up with families during a highly sensitive period. As UW OTD, we may be placed in the difficult position of asking hospital staff to gather information, such as a patient’s weight or height, during an actively grieving situation, further intensifying the emotional and logistical challenges for all involved. While this data is important, and UW OTD will make every good faith effort to collect and report the data, UW OTD and donor hospitals need flexibility from HRSA in case patient information is not available.

Improvement Suggestion and Flexibility

Requiring OPOs to collect all these fields for every referral—without the option to indicate when information is unavailable—places an excessive burden on both OPO and hospital staff and increases the risk of incomplete or inaccurate data. As a constructive solution, **we recommend that HRSA allow fields to be marked as “Not Available” or “Not Applicable”** when such data is not documented in real-time. While this appears to be available for some fields, it may be necessary for many fields which contributes to the concerns we have with the reliability of this

data collection. This approach would help prevent penalties for missing data, maintain resource efficiency, and ensure that reporting remains as accurate as possible without detracting from our mission of organ procurement. In addition, UW OTD needs HRSA to clarify the categorization of fields under "Terminal Step" and "Process Step" sections, as the current document does not specify which data points belong to each category. This clarification is essential to ensure accurate and consistent data collection and reporting as well as the time burden on UW OTD for data submission. Without these adjustments, there is a significant risk that the data collected may lack integrity or validity, which could directly impact the organ donation process and compromise its effectiveness.

Summary

We appreciate the opportunity to provide feedback on this important matter. UW OTD remains committed to collaborating with HRSA to optimize organ donation processes and outcomes. We strongly believe that a flexible reporting system that accommodates real-world hospital and OPO constraints will ultimately serve the best interests of patients, donors, and their families.

Thank you for your consideration.

Michael Anderson PA-C
Director
UW Organ and Tissue Donation

Adam K. Schneider, DNP, AGACNP-BC, APNP
Manager, Clinical Quality and Compliance
UW Organ and Tissue Donation