Reporting Safety Events

In the event of a donor-derived infectious disease transmission, a living donor event, or any other threat to patient safety, members should use the OPTN Patient Safety Reporting Portal to report the event.

Using the OPTN Patient Safety Reporting Portal to report an event

01

Login to the OPTN Computer System (known as Secure Enterprise SM) and navigate to the portal by selecting "Patient Safety Events"

02

Select "Add an Event" under one of the following as appropriate:

- Disease Transmission Event
- Living Donor Event Functionality
- Safety Situation

03

Complete the information on the screen and select the submit button

Reported events are confidential and can only be viewed within the system by OPTN contractor staff and the user who submitted the report.

Staff will send an acknowledgment within 4 hours of receiving an event during normal business hours. Events submitted after business hours will receive an acknowledgment email the next business day.

Reporting requirements for disease transmission

Report disease transmission events through the OPTN Patient Safety Reporting Portal **within 24 hours** of knowledge of event.

When to report

Transplant programs report:
When an organ recipient is suspected to have, is confirmed positive for, or has died from a potential transmissible disease or medical condition (including infections and malignancies) **AND** there is substantial concern that it could be from a transplanted organ.

Organ procurement organizations (OPOs) report when:

- Results indicate disease or conditions defined on the pathogens of special interest list
- Malignancy or findings highly suggestive of malignancy recognized post-procurement

What to report

- Institution reporting
- Donor ID or recipient SSN
- Recipient status
- Suspected or proven disease or disorder
- Date and method of detection
- Planned course of follow-up testing and treatment

Include all case specific details to give OPTN contractor staff a full understanding of the event (attach test results, notes or other documents pertinent to the event).

Reporting requirements for living donor events

Report living donor events through the OPTN Patient Safety Reporting Portal **within 72 hours** of knowledge of event.

When to report

- Aborted procedures after living donor receives anesthesia
- Living donor death within two years of donation
- Living donor listed on the waiting list within two years after donation
- Living kidney donor begins dialysis as ESRD patient within two years after donation
- Living donor organs recovered but not transplanted
- Living donor organ recovered and transplanted into someone other than intended recipient

What to report

Information required:

- Living Donor ID
- Type of event
- Date of event
- Institution reporting

Include all case specific details to give OPTN contractor staff a full understanding of the situation.

Living donor aborted procedures and events where a living donor organ is recovered and not transplanted into any recipient must also be reported in the OPTN Computer System.

Reporting requirements for patient safety events

Report the following patient safety events through the OPTN Patient Safety Reporting portal **within 72 hours** of knowledge of event.

When to report

Patient safety events that require reporting

Transplant hospitals must report when:

- A transplant of the incorrect organ into an organ recipient occurs
- A transplant of an organ into the incorrect organ recipient occurs
- A donor organ is identified as incorrect during pre-transplant verification processes required by *OPTN Policy 5.8.A and 5.8.B*
- The potential transplant recipient is identified as incorrect during pre-transplant verification processes required by *OPTN Policy 5.8.A and 5.8.B*
- An organ was delivered to the incorrect transplant hospital and resulted in non-use of the organ
- The incorrect organ was delivered to the transplant hospital and resulted in non-use of the organ
- An ABO typing error or discrepancy is caught before or during pre-transplant verification processes required by *OPTN Policy 5.8.A and 5.8.B*

OPOs must report when:

- Transplant hospital procurement staff leave the operating room without allowing host OPO to package and label deceased donor organs and tissue typing specimens as required
- An ABO typing error or discrepancy is caught after verification process required by *OPTN Policy 2.6.C* **AND** after a match run has been executed

Histocompatibility laboratories must report when:

- A donor, candidate, or recipient HLA typing critical discrepancy occurs, as defined by *OPTN Policy 4.4*
- An incorrect donor or candidate sample was used for a physical crossmatch
- An incorrect donor HLA typing or incorrect candidate HLA antibody test was analyzed for a virtual crossmatch

Additional patient safety events to report

Report any event that presents a specific and time-sensitive risk to patient health or public safety at OPTN institutions. These events include:

- Near misses
- Policy and protocol related deficiencies and deviations
- Quality of care concerns
- Inequitable patterns of behavior by members

What to report

Suggested information includes:

- Institution reporting
- Waitlist ID
- Donor ID
- Timeline of events
- Date event occurred
- Institution names
- Names of those involved
- Impact on patients

Include all case specific details to give OPTN contractor staff a full understanding of the event.

Outside of the OPTN Patient Safety Reporting Portal, there are two safety circumstances that necessitate communication with OPTN contractor staff: potential patient safety concerns and allocation concerns.

Potential patient safety concerns

When an individual wishes to **anonymously report** a concern or inform the OPTN contractor of any potential policy or bylaw violation at a member institution(s).

To anonymously report a concern, please call the OPTN Confidential Reporting line at 866-787-4909.

Staff monitor the OPTN Confidential Reporting line from 8:30 a.m. to 10:00 p.m. ET and maintain confidentiality. After 5:00 p.m., calls are forwarded to a voice messaging system that staff monitor until 10:00 p.m. ET to address reports that may need immediate attention.

Suggested information to report:

- Donor ID/Patient name
- Timeline of events
- Dates/times
- Institution names
- Names of those involved
- Impact on patient(s)

Include all relevant case-specific details to give OPTN contractor staff a full understanding of the concern.

This avenue of reporting should only be used when an individual wishes to remain anonymous.

Allocation concerns

Allocation concerns occur when:
A recognized potential violation of OPTN policies, bylaws, or OPTN Final Rule occurs at a member institution related to organ allocation.

To report a concern, please send an inquiry to:

Mail
UNOS Member Quality Department
Attention: Allocation Analyst
700 North 4th St. Richmond, VA 23219

Email
Secure email to your regional Allocation Analyst.
If you do not know your Analyst, you may email MQfeedback@unos.org.

Include all case specific details to give OPTN contractor staff a full understanding of the concern.

Suggested information to include:

- Donor ID
- Organ type
- Contributing factors
- Timeline of events
- Dates/times
- Institution names
- Names of staff involved
- Impact on patients

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