

Transplant Regulations and Performance Improvement

Tiffany E. Kaiser, Pharm.D., M.S., FCCP
Transplant Clinical Pharmacist
Director, Solid Organ Transplant Quality
University of Cincinnati
Cincinnati, Ohio



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Conflict of Interest Disclosure

No financial relationships with commercial interests to disclose

AND

No discussion of off-label or investigational use of medications

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Learning Objectives

- Review regulations for solid organ transplantation (SOT) programs.
- Compose policies and procedures for SOT pharmacists that are consistent with transplant regulatory requirements.
- Identify opportunities for SOT pharmacists to participate in Quality Assessment and Performance Improvement (QAPI) activities to enhance the safety and effectiveness of medication-use process in SOT.
- Evaluate compliance with institutional SOT guidelines in order to identify areas failing to meet expectations and implement performance improvement initiatives.
- Implement processes for cost effective care focusing on continuous quality improvement, patient safety and outcomes in order to justify modifications in transplantation pharmacy services.
- Diagram involvement of SOT pharmacists in collaborative relationships with interdisciplinary transplant team to promote quality patient care across the continuum.

3

SOT and Regulations

4

The National Organ Transplant Act (NOTA)

- Passed by Congress in 1984 to create a task force to address nation's critical organ donation shortage and improve the organ matching and placement process.

<https://optn.transplant.hrsa.gov/governance/about-the-optn/> [Accessed 4/1/22]

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The National Organ Transplant Act (NOTA)

OPO

- Organ Procurement Organizations

SRTR



- Scientific Registry of Transplant Recipients

OPTN

- Organ Procurement and Transplantation Network

<https://optn.transplant.hrsa.gov/governance/about-the-optn/> [Accessed 4/1/22]

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The National Organ Transplant Act (NOTA)

OPO
 • Organ Procurement Organization



- Increase # of registered donors
- Coordinate donation process

SRTR
 • Scientific Registry of Transplant Recipients

OPTN
 • Organ Procurement and Transplantation Network

<https://optn.transplant.hrsa.gov/governance/about-the-optn/> [Accessed 4/1/22]

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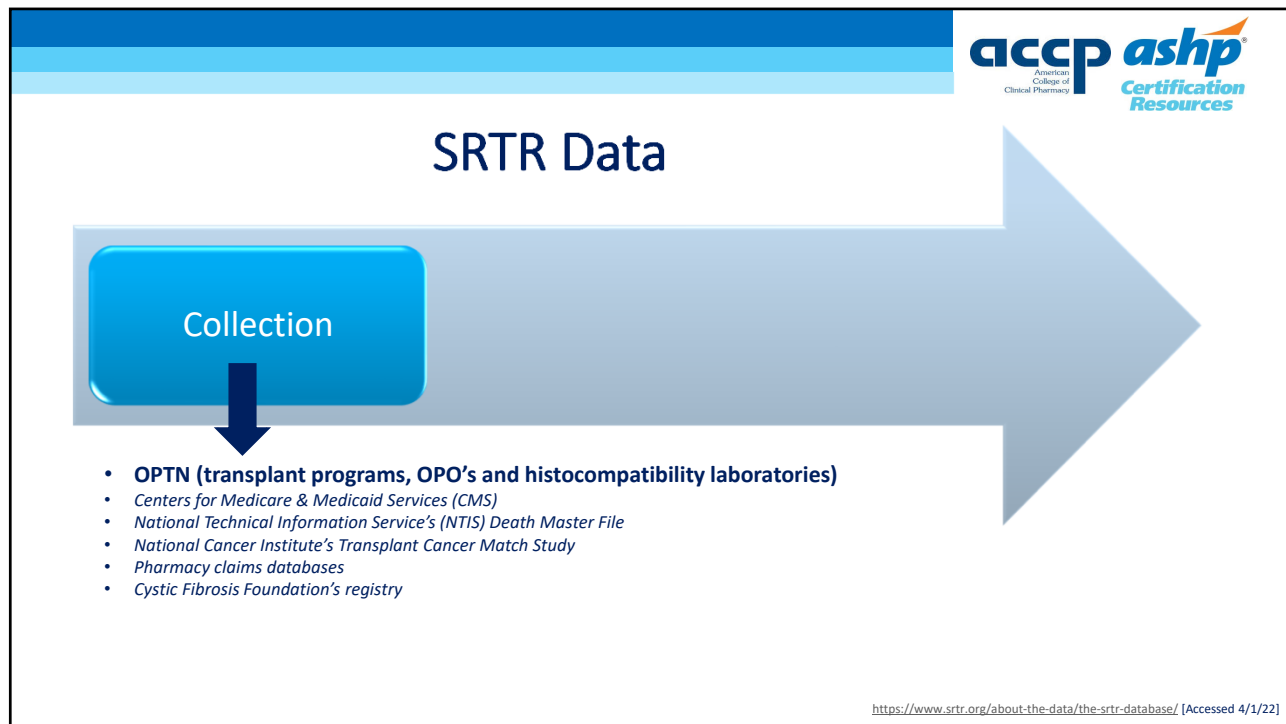
- Supports the ongoing evaluation of the scientific and clinical status of solid organ transplantation

OPTN
 • Organ Procurement and Transplantation Network

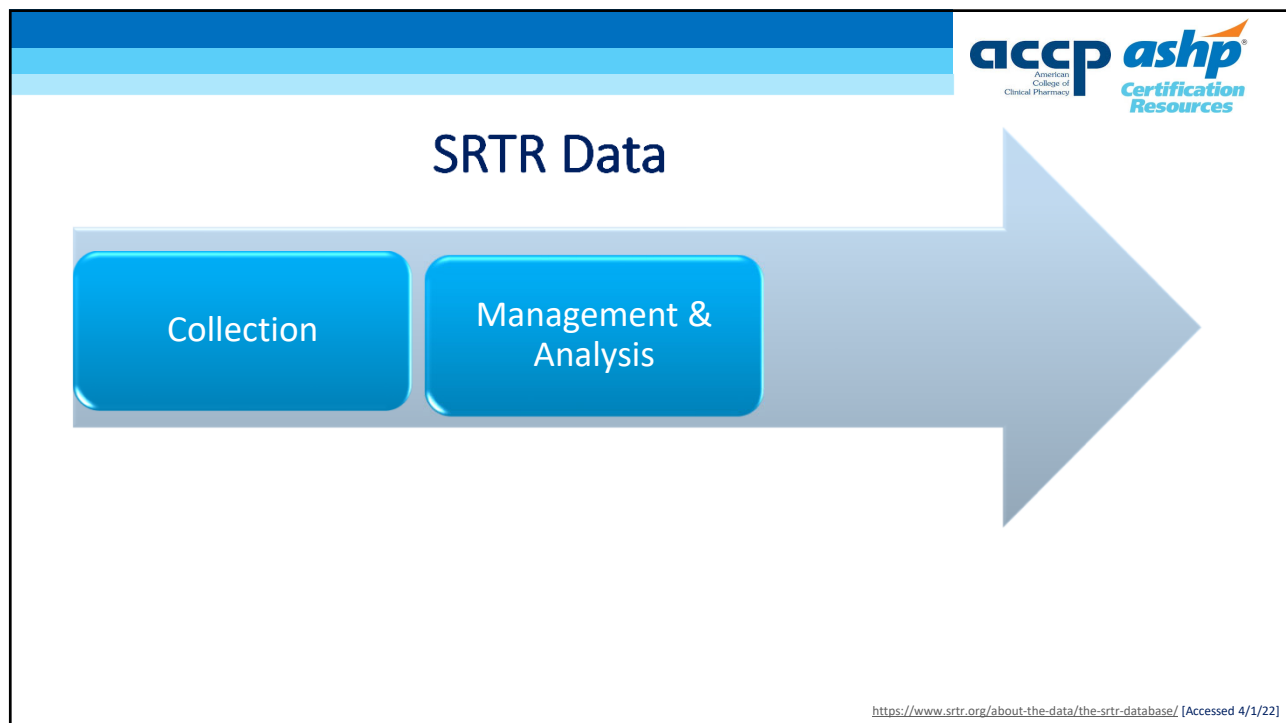
- Managed by Chronic Disease Research Group, a division of the Hennepin Healthcare Research Institute under contract from the federal government

<https://optn.transplant.hrsa.gov/governance/about-the-optn/> [Accessed 4/1/22]
<https://www.govinfo.gov/content/pkg/COMPS-8773/pdf/COMPS-8773.pdf> [Accessed 4/1/22]; www.srtr.org/ [Accessed 4/1/22]

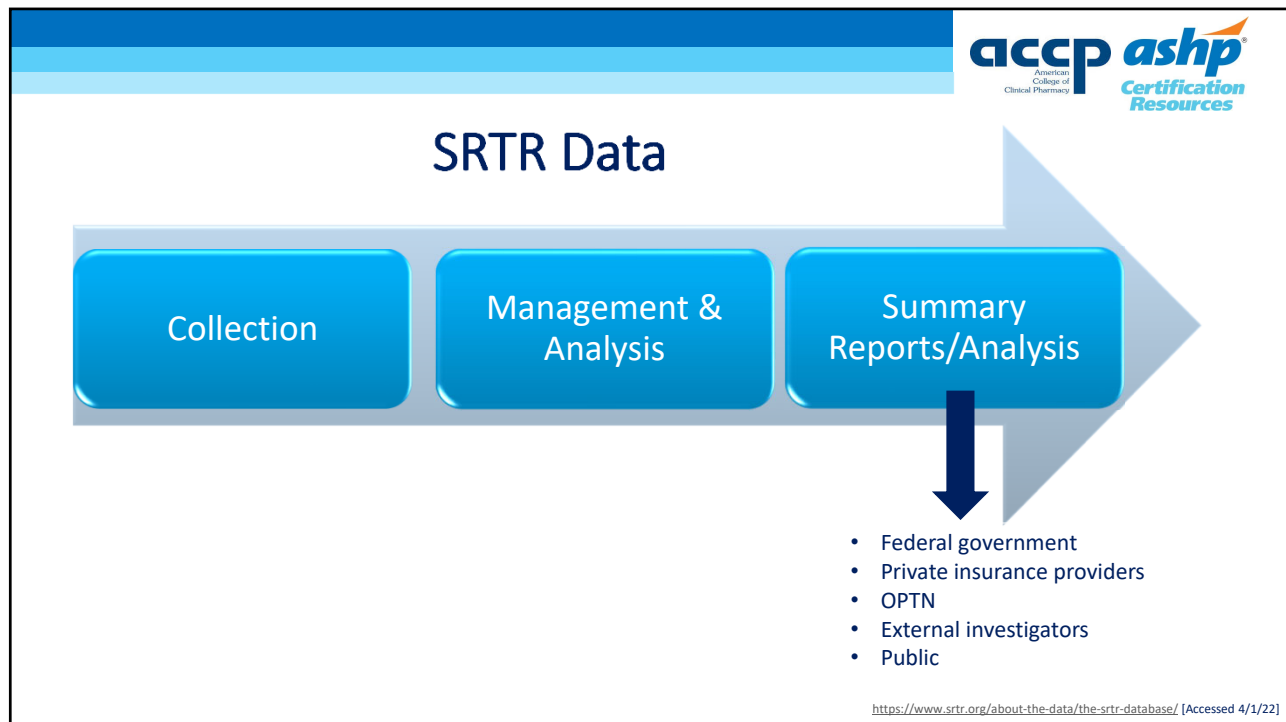
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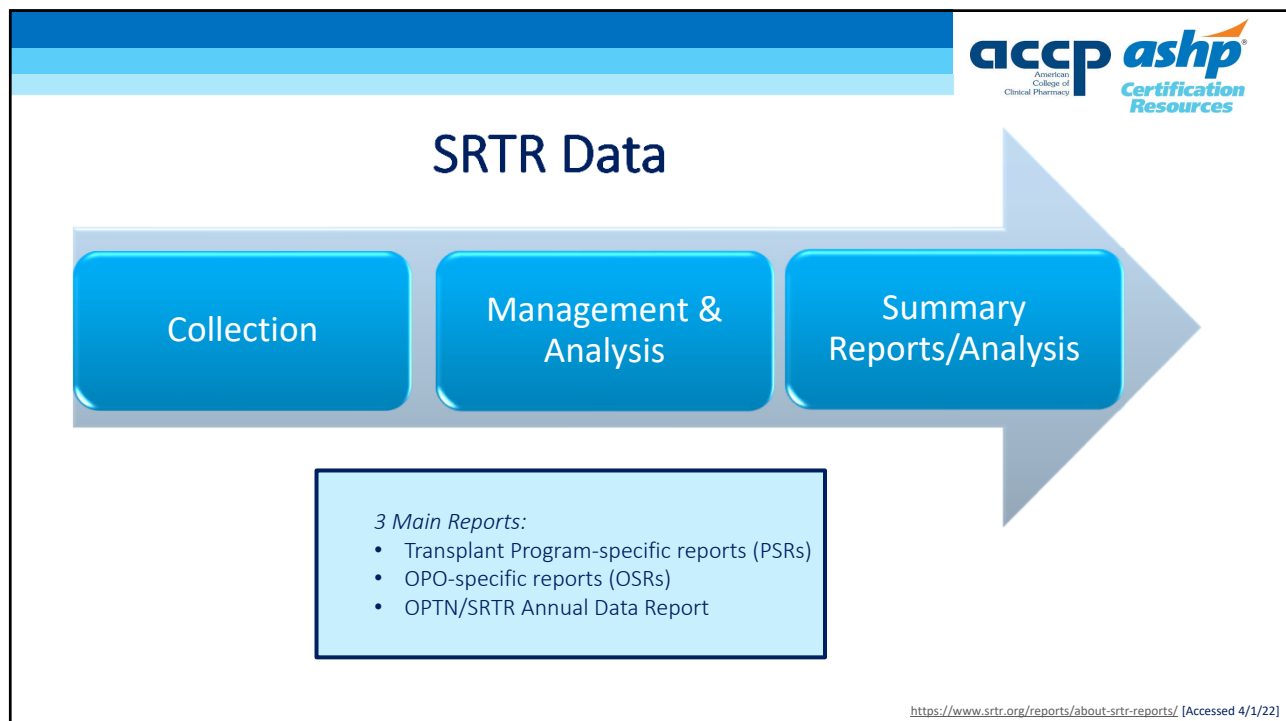
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SRTR Reports


PSR

- Transplant PROGRAM SPECIFIC REPORT**
- Published semiannually for each SOT program in the US
- Contain information about candidates waiting for transplant, outcomes on the waiting list, the transplant recipients, the donors, and the outcomes after transplant

Waiting List	Transplant	Living Donor
<ul style="list-style-type: none"> Demographics Medical characteristics Transplant rates WL mortality rates Survival from listing Time to transplant Offer acceptance 	<ul style="list-style-type: none"> Recipient demographics Medical characteristics Donor characteristics Graft survival (1 month, 1 year, 3 year) Patient survival (1 month, 1 year, 3 year) 	<ul style="list-style-type: none"> Donation follow-up

<https://www.srtr.org/reports/about-srtr-reports/> [Accessed 4/1/22]

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SRTR – Program Performance

Survival (Adults and Pediatrics)	1 month	1 year	3 year
Adult survival with functioning graft	✓	✓	✓
Adult survival with functioning graft (deceased donors)	✓	✓	✓
Adult survival with functioning graft (living donors)	✓	✓	✓
Adult patient survival	✓	✓	✓
Adult patient survival (deceased donor)	✓	✓	✓
Adult patient survival (living donor)	✓	✓	✓

<https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports#intro> [Accessed 4/1/22]

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SRTR – Program Performance

- Risk Adjusted Models
 - Considers many characteristics of transplant recipients and donors
 - Fit separately for organ type, age group (adult and pediatric), donor type (living and deceased) and cohort (1 month, 1 year and 3 year)
 - Refit every PSR cycle (same covariates, values may change depending on data collected during reporting period)
 - Rebuilt every 3 years (3 year rolling cycle per organ type)
- Expected survival
 - Reflects the fraction of recipients at the transplant program who would be expected to be alive or have a functioning graft at each time point, based on the national experience for similar patients

Refer to <https://www.srtr.org> for additional statistical model details

<https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports#intro> [Accessed 4/1/22]

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SRTR – Program Performance

- Observed survival is compared with expected survival
 - Observed = observed number of deaths or graft failures
 - Expected = expected number of deaths or graft failures based on national experience
 - Hazard ratio (HR)
 - Used to estimate program's death rate compared with the expected death rate, based on donor and recipient characteristics
- Ratio >1.0 more deaths occurred than would be expected based on national experience
- Ratio < 1.0 fewer death occurred than would be expected based on national experience

Examples	
HR = 1.2	Death rate on average, 20% higher than the national rate
HR = 1.0	Death rate was the same as the national rate
HR = 0.75	Death rate on average, 25% less than the national rate

Refer to <https://www.srtr.org> for additional statistical model details

<https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports#intro> [Accessed 4/1/22]

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Example – Transplant Program XYZ

- Adult 1 year patient survival for kidney deceased graft recipients

January 2021 Single organ transplants performed between 7/1/17 and 12/31/19	XYZ	U.S.
# of transplants evaluated	299	30,522
Estimated probability of survival at 1 year (unadjusted for patient and donor characteristics)	98.48%	96.96%
Expected probability of survival at 1 year (adjusted for patient and donor characteristics)	97.08%	---
# of observed deaths during 1 st year after transplant	4	818
# of expected deaths during 1 st year after transplant	7.90	---
Estimated hazard ratio	0.61	---
95% credible interval for hazard ratio	[0.22, 1.18]	---

Hazard ratio provides an **ESTIMATE** of how XYZ program results compare with what was expected based on modeling of transplant outcomes from all US programs

The 95% credible interval indicates the location of the program's true HR with 95% probability.

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95% credible interval for hazard ratio	[0.22, 1.18]	---

Program XYZ 1 year patient survival

- The best estimate is 39% lower risk of patient death compared to an average program
- Performance could plausibly range from 78% reduced risk up to 18% increased risk

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SRTR PSR

Patient and Graft Survival (2.5 year cohort)

PSR Release	1 month	1 year	3 year
July 2020	1/1/17 – 6/30/19		7/1/14 – 12/31/16
Jan 2021 ¹	7/1/17 – 12/31/19		1/1/15 – 6/30/17
July 2021	1/1/18 – 6/30/20		7/1/15 – 12/31/17
Jan 2022	7/1/18 – 12/31/20		1/1/16 – 6/30/18
July 2022	1/1/19 – 6/30/21		7/1/16 – 12/31/18

¹ All risk-adjusted transplant performance metrics (transplant rate, waitlist mortality rate, offer acceptance rate, overall mortality following listing, posttransplant outcomes) did not include data after March 12, 2020, the day prior to the declaration of a national public health emergency on March 13, 2020. Follow-up for all risk-adjusted outcomes of waitlist candidates and transplant recipients was stopped (i.e. statistically censored) on March 13, 2020. Refer to <https://www.srtr.org/faqs/covid-19-related-changes/> for additional information

<https://www.srtr.org/reports/psr-reporting-timeline/> [Accessed 4/15/22]
<https://www.srtr.org/faqs/covid-19-related-changes/> [Accessed 4/15/22]

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SRTR Reports

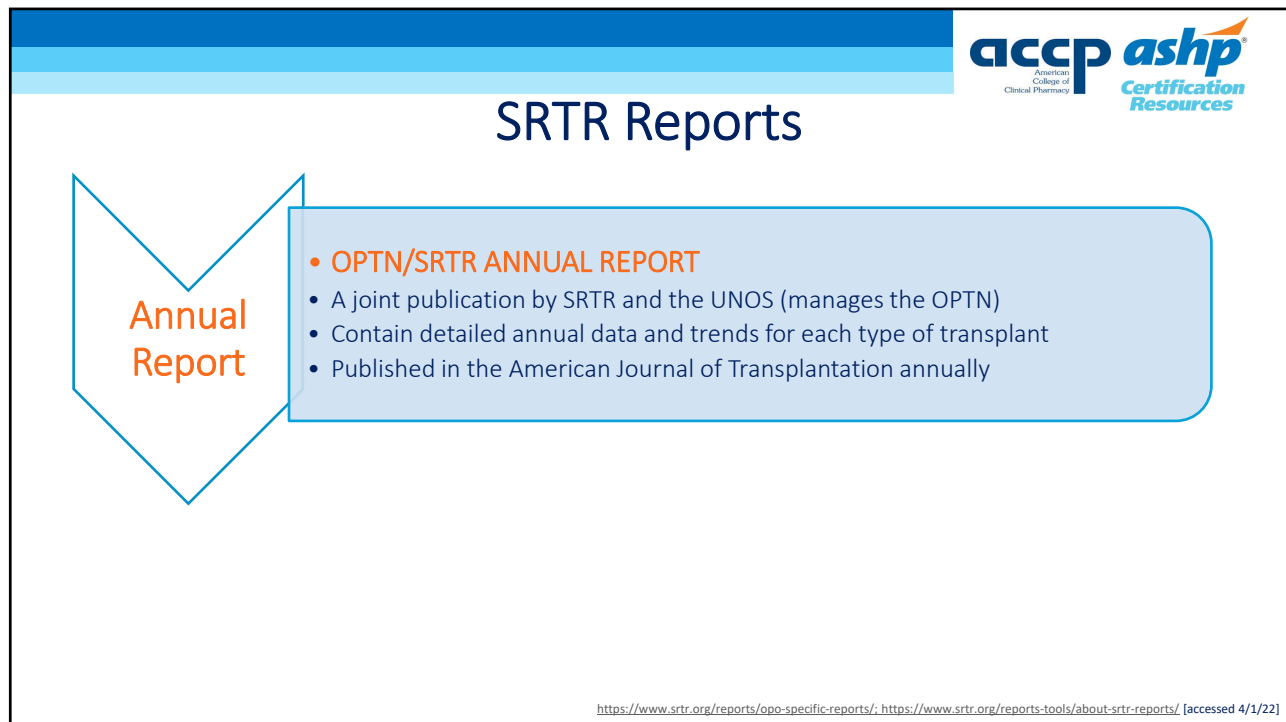


 OSR

- **ORGAN PROCUREMENT ORGANIZATION SPECIFIC REPORT (OSR)**
- Published semiannually for each organ procurement organization (OPO) in the US
- Contain detailed information
 - Donor service area (DSA) description (overview, population density and death rates)
 - Donors procured by the OPO (donor data)
 - Donation rates from eligible deaths (donor rates)
 - Utilization of donor organs (organ yield)
 - Programs receiving organs from donors procured by OPO

<https://www.srtr.org/reports/about-srtr-reports/> [Accessed 4/15/22]
<https://www.srtr.org/reports/opo-specific-reports/> [Accessed 4/15/22]

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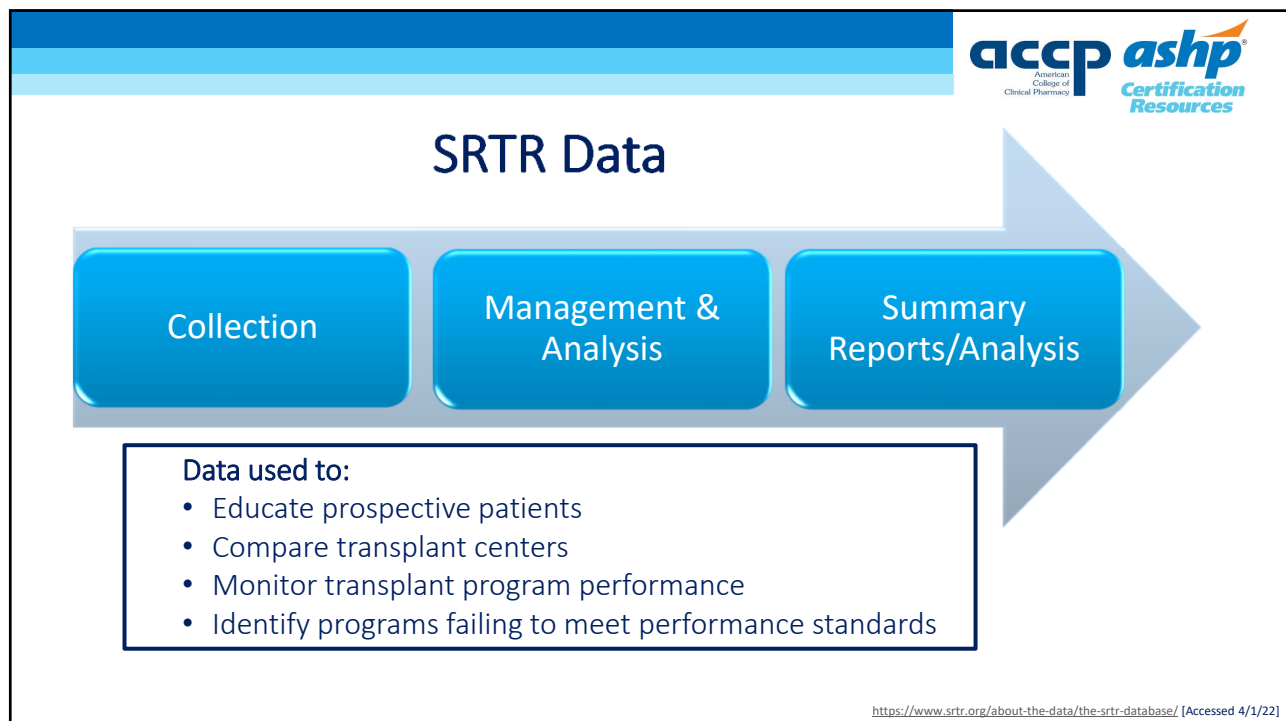
SRTR Reports

Annual Report

- **OPTN/SRTR ANNUAL REPORT**
 - A joint publication by SRTR and the UNOS (manages the OPTN)
 - Contain detailed annual data and trends for each type of transplant
 - Published in the American Journal of Transplantation annually

<https://www.srtr.org/reports/optn-specific-reports/>; <https://www.srtr.org/reports-tools/about-srtr-reports/> [accessed 4/1/22]

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SRTR Data


Collection Management & Analysis Summary Reports/Analysis

Data used to:

- Educate prospective patients
- Compare transplant centers
- Monitor transplant program performance
- Identify programs failing to meet performance standards

<https://www.srtr.org/about-the-data/the-srtr-database/> [Accessed 4/1/22]

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The National Organ Transplant Act (NOTA)

OPO

- Organ Procurement Organizations

SRTR

- Scientific Registry of Transplant Recipients

OPTN

- Organ Procurement and Transplantation Network


- Maintains the national network for organ procurement and allocation and promotes organ donation

**The Final Rule
2000**

- Managed by UNOS (United Network for Organ Sharing), awarded contract from the federal government.

www.livingdonorassistance.org/Documents/NOTA.pdf
<https://optn.transplant.hrsa.gov/governance/about-the-optn/> [Accessed 4/1/22]
<https://www.govinfo.gov/content/pkg/FR-2000-03-22/pdf/00-7177.pdf>

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OPTN

- Increase the number of transplants
- Provide equity in access to transplants
- Improve waitlisted patient, living donor, and transplant recipient outcomes
- Promote living donor and transplant recipient safety
- Promote the efficient management of the OPTN

<https://optn.transplant.hrsa.gov/governance/about-the-optn/> [Accessed 4/1/22]

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OPTN Governance

- Board of Directors
 - Policies (operational rules)
 - Bylaws (membership requirements)
- Committees
 - Made up of transplant professionals, patients and donor affair representatives and members of the public

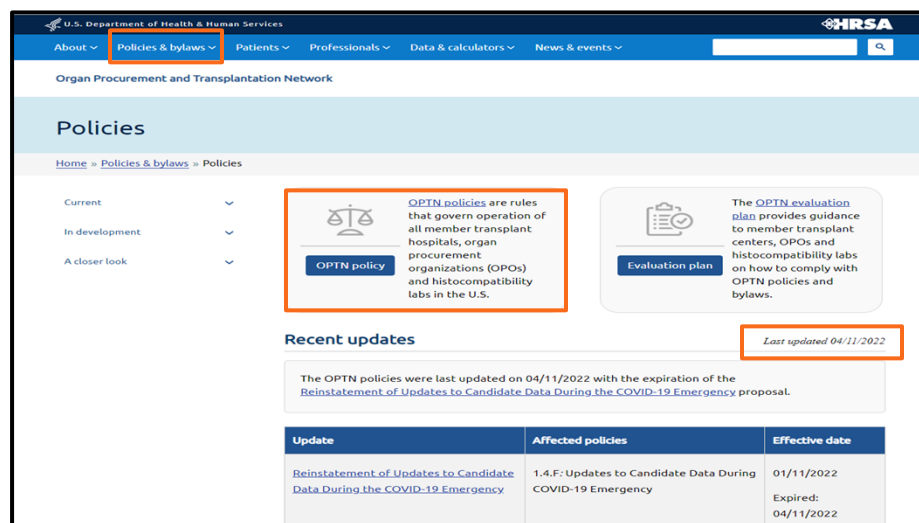
The OPTN will have the following permanent standing Committees:

- Ethics
- Heart Transplantation
- Histocompatibility
- Kidney Transplantation
- Liver and Intestinal Organ Transplantation
- Living Donor
- Lung Transplantation
- Membership and Professional Standards
- Minority Affairs
- Operations and Safety
- Organ Procurement Organization
- Pancreas Transplantation
- Patient Affairs
- Pediatric Transplantation
- Policy Oversight Committee
- Transplant Administrators
- Transplant Coordinators

<https://optn.transplant.hrsa.gov/governance> [Accessed 4/1/22]

https://optn.transplant.hrsa.gov/media/lgbmah/optn_bylaws.pdf [Accessed 4/15/22]

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U.S. Department of Health & Human Services

HRSA

About ▾ Policies & bylaws ▾ Patients ▾ Professionals ▾ Data & calculators ▾ News & events ▾

Organ Procurement and Transplantation Network

Policies

Home » Policies & bylaws » Policies

Current ▾

In development ▾

A closer look ▾

OPTN policy

OPTN policies are rules that govern operation of all member transplant hospitals, organ procurement organizations (OPOs) and histocompatibility labs in the U.S.

Evaluation plan

The OPTN evaluation plan provides guidance to member transplant centers, OPOs and histocompatibility labs on how to comply with OPTN policies and bylaws.

Recent updates

The OPTN policies were last updated on 04/11/2022 with the expiration of the Reinstatement of Updates to Candidate Data During the COVID-19 Emergency proposal.


Update	Affected policies	Effective date
Reinstatement of Updates to Candidate Data During the COVID-19 Emergency	1.4.F: Updates to Candidate Data During COVID-19 Emergency	01/11/2022 Expired: 04/11/2022

Last updated 04/11/2022

OPTN Policies, Effective date 4/11/22


Available at https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf [accessed 4/14/221]

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ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Policies



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Policy 6: Allocation of Hearts and Heart-Lungs	89
Policy 7: Allocation of Intestines	125
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Policy 3: Candidate Registrations, Modifications, and Removals

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3.1 Access to Computer Systems

Only the following categories of members may access the match system:

- Transplant hospitals
- Organ procurement organizations (OPO)
- Histocompatibility laboratories

The waiting list may only be accessed by members, and members may not use the match system for non-members or add candidates to the waiting list on behalf of non-member transplant hospitals.


3.1.A Non-member Access

Members may not use the match system for non-members or allow non-members access to the match system unless *all* of the following requirements are met:

- The non-member is assisting the member with facilitating organ transplants, placing organs for purposes other than transplantation, or reporting data to the OPTN.


OPTN Policies, Effective date 4/11/22
https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf [Accessed 4/14/22]

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8.1 Calculated Panel Reactive Antibody (CPRA)

CPRA is the percentage of donors expected to have one or more of a candidate's indicated unacceptable antigens. CPRA will be calculated automatically when a transplant hospital reports unacceptable antigens to the OPTN according to Policy 5.3.A: *Reporting Unacceptable Antigens for Calculated Panel Reactive Antibody (CPRA)*.


8.2 Exceptions

8.2.A Deceased Donor Kidneys with Discrepant Human Leukocyte Antigen (HLA) Typings

Allocation of deceased donor kidneys is based on the HLA typing identified by the donor histocompatibility laboratory. If the recipient HLA laboratory identifies a different HLA type for the deceased donor and the intended recipient cannot be transplanted, the kidney must be allocated according to Policy 5.9: *Released Organs*. When reallocating the kidney, the OPO has the discretion to use either the HLA typing identified by the donor histocompatibility laboratory or the recipient HLA laboratory.

OPTN Policies, Effective date 4/11/22
https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf [Accessed 4/14/22]

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OPTN

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- Members must
 - Report accurate data on candidates, recipients and donors using standardized forms (TIEDI* = Transplant Information Electronic Data Interchange)
 - Adhere to timely data submission requirements
 - 95% of required forms within 3 months of due date
 - 100% of required forms within 6 months of due date

OPTN Policies, Effective date 4/11/22
https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf [Accessed 4/15/22]

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Example: Standardized Forms

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Transplant hospitals	<i>Organ specific transplant recipient follow-up (TRF)</i>	<i>Either of the following:</i> <ul style="list-style-type: none"> 30 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure 14 days from notification of the recipient's death or graft failure 	Each recipient followed by the hospital
Transplant hospitals	<i>Organ specific transplant recipient registration (TRR)</i>	60 days after transplant hospital removes the recipient from the waiting list	Each recipient transplanted by the hospital
Transplant hospitals	<i>Liver Post-Transplant Explant Pathology</i>	60 days after transplant hospital submits the recipient feedback form	Each liver recipient transplanted by the hospital
Transplant hospitals	<i>Recipient feedback</i>	1 day after the transplant	Each heart, intestine, kidney, liver, lung, or pancreas recipient transplanted by the hospital
Transplant hospitals	<i>Candidate Removal Worksheet</i>	1 day after the transplant	Each VCA recipient transplanted by the hospital
Transplant hospitals	<i>Recipient malignancy (PTM)</i>	30 days after the transplant hospital reports the malignancy on the transplant recipient follow-up form	Each heart, intestine, kidney, liver, lung, or pancreas recipient with a reported malignancy that is followed by the hospital.

OPTN Policies, Effective date 4/11/22
https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf [Accessed 4/15/22]

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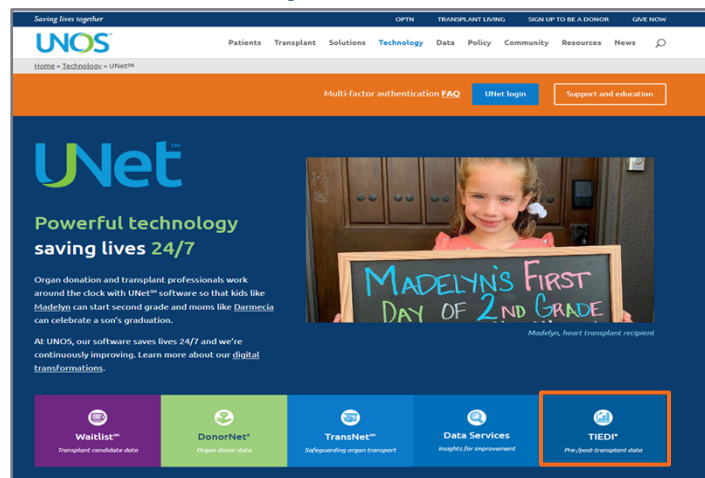
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https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf [Accessed 4/15/22]

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UNetSM electronic platform

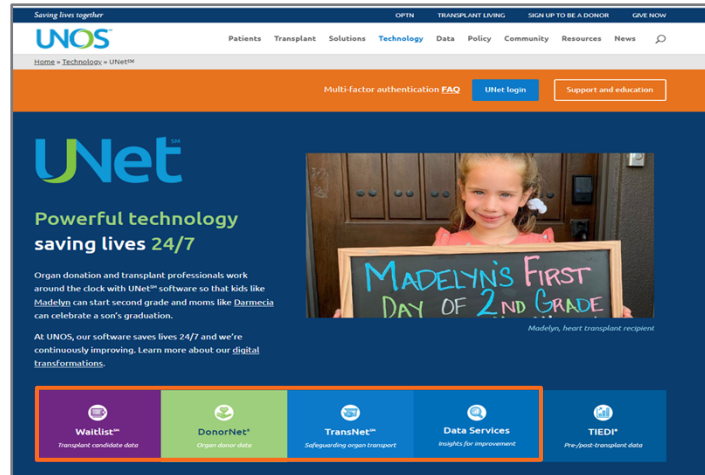


The screenshot shows the UNet website interface. At the top, there's a navigation bar with links like Patients, Transplant, Solutions, Technology, Data, Policy, Community, Resources, and News. Below this, a banner features the UNet logo and the text "Powerful technology saving lives 24/7". A photo of a young girl, Madelyn, holding a sign that says "MADELYN'S FIRST DAY OF 2ND GRADE" is displayed. Below the banner, there are five colored boxes representing different services: Waitlist™ (Transplant candidate data), DonorNet™ (Organ donor data), TransNet™ (Self-reporting organ transplant), Data Services (Insights for improvement), and TIEDI™ (Pre/post-transplant data). The TIEDI™ box is highlighted with an orange border.

<https://unos.org/technology/unet/> [Accessed 4/14/22]

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UNetSM electronic platform



<https://unos.org/technology/unet/> [Accessed 4/14/22]

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OPTN | ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK


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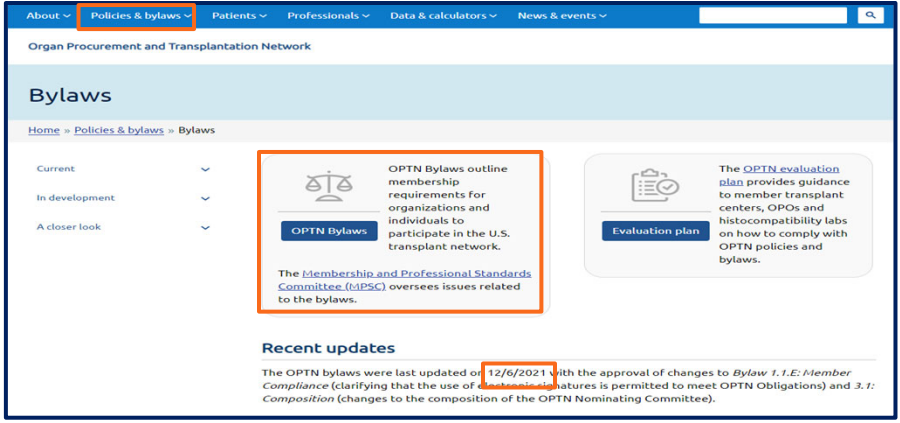
OPTN Policies, Effective date 4/11/22
https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf [Accessed 4/14/22]

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OPTN Bylaws

- Outline membership requirements



OPTN Bylaws, Effective date 12/6/21
https://optn.transplant.hrsa.gov/media/lgbbmah/optn_bylaws.pdf [Accessed 4/14/22]

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OPTN Bylaws (summary)

Articles


- I: Membership
- II: Board of Directors
- III: Nominating Committee
- IV: Executive Committee
- V: Executive Director
- VI: Officers
- VII: Permanent Standing Committees
- VIII: Financial Considerations
- IX: Regions
- X: Amendment of Charter and Bylaws
- XI: Adoptions of Policies

Appendices

- A: Membership Application and Review
- B: Organ Procurement Organizations
- C: Histocompatibility Laboratories
- D: Transplant Hospitals and Transplant Programs**
- E: Kidney Transplant Programs
- F: Liver Transplant Programs and Intestinal Transplant Programs
- G: Pancreas and Pancreatic Islet Transplant Programs
- H: Heart Transplant Programs
- I: Lung Transplant Programs
- J: Vascularized Composite Allograft (VCA) Transplant Programs
- K: Transplant Program Inactivity, withdrawal and Termination
- L: Reviews and Actions
- M: Definitions

OPTN Bylaws, Effective date 12/6/21
https://optn.transplant.hrsa.gov/media/lgbbmah/optn_bylaws.pdf [Accessed 4/14/22]

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OPTN Bylaws

What is the Role of Transplant Pharmacist?

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OPTN Bylaws, Effective date 12/6/21
https://optn.transplant.hrsa.gov/media/lgbmhahi/optn_bylaws.pdf [Accessed 4/14/22]

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OPTN Bylaws

D.9 Other Transplant Program Personnel

Transplant programs must have other support personnel on staff to ensure quality patient care. The sections below provide details of support staff that a transplant program is required to have on staff.

A. Clinical Transplant Coordinator

B. Financial Coordinator

C. Clinical Transplant Pharmacist

D. Medical Expert Support

E. Mental Health and Social Support

OPTN Bylaws, Effective date 12/6/21
https://optn.transplant.hrsa.gov/media/lgbmhahi/optn_bylaws.pdf [Accessed 4/14/22]

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C. Clinical Transplant Pharmacist

Each transplant program should identify at least one Clinical Transplant Pharmacist on staff who will provide pharmaceutical expertise to transplant recipients. The Clinical Transplant Pharmacist should be a member of the transplant team, providing comprehensive pharmaceutical care to transplant recipients.

The Transplant Pharmacist will work with patients and their families, and members of the transplant team, including physicians, surgeons, nurses, clinical coordinators, social workers, financial coordinators and administrative personnel. The Transplant Pharmacist should be a licensed pharmacist with experience in transplant pharmacotherapy.

OPTN Bylaw
Appendix D.9C

- ✓ Provide pharmaceutical expertise to transplant recipients
- ✓ Member of transplant team
- ✓ Work with patients and their families and members of the transplant team
- ✓ Licensed pharmacist
- ✓ Experience in transplant pharmacotherapy

OPTN Bylaws, Effective date 12/6/21
https://optn.transplant.hrsa.gov/media/lgbmhahi/optn_bylaws.pdf [Accessed 4/14/22]

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OPTN Bylaws, Effective date 12/6/21
https://optn.transplant.hrsa.gov/media/lgbmhahi/optn_bylaws.pdf [Accessed 4/15/22]

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PERFORMANCE Monitoring

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OPTN Bylaws, Effective date 12/6/21
https://optn.transplant.hrsa.gov/media/jgbbmah/1/optn_bylaws.pdf [Accessed 4/15/22]

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PERFORMANCE Monitoring

- Functional Inactivity (Appendix D.11.A)
 - Each transplant program must remain functionally active by performing a minimum number of transplants
 - Functional inactivity defined according to table D-1
 - Reviews and actions (Appendix L)

Table D-1: Functional Inactivity

For this transplant program type:	Functional inactivity is defined as:
Kidney, Liver or Heart	Failure to perform at least 1 transplant in 3 consecutive months
Lung	Failure to perform at least 1 transplant in 6 consecutive months
Stand-alone pediatric	Failure to perform at least 1 transplant in 12 consecutive months
Pancreas	Both of the following: <ol style="list-style-type: none"> Failure to perform at least 2 transplants in 12 consecutive months Either of the following in 12 consecutive months: <ul style="list-style-type: none"> A median waiting time of the program's kidney-pancreas and pancreas candidates that is above the 67th percentile of the national waiting time The program had no kidney-pancreas or pancreas candidates registered at the program
Islet, intestinal, and VCA	No functional inactivity definitions have been established

OPTN Bylaws, Effective date 12/6/21
https://optn.transplant.hrsa.gov/media/jgbbmah/1/optn_bylaws.pdf [Accessed 4/15/22]

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PERFORMANCE Monitoring

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OPTN Bylaws, Effective date 12/6/21
https://optn.transplant.hrsa.gov/media/lgbbmahi/optn_bylaws.pdf [Accessed 4/15/22]

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PERFORMANCE Monitoring

- Transplant Program Performance (Appendix D.12.A)
 - 1 year survival outcomes (SRTR performance metrics)
 - Identify programs for review if they are not meeting performance requirements

Program Size	Survival	OPTN Criteria <i>A or B must be true</i>
≥ 10 transplants in a 2.5 year period	Higher hazard ratio of death or graft failure than would be expected for that program	A. Probability Hazard Ratio > 1.2 > 75% B. Probability Hazard Ratio > 2.5 > 10%
≤ 9 transplants in a 2.5 year period	If program has ≥ 1 or more events	

OPTN Bylaws, Effective date 12/6/21
https://optn.transplant.hrsa.gov/media/lgbbmahi/optn_bylaws.pdf [Accessed 4/15/22]

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Example – Transplant Program XYZ

- Adult 1 year patient survival for kidney decreased graft recipients

January 2021 Single organ transplants performed between 7/1/17 and 12/31/19	XYZ	U.S.
# of transplants evaluated	299	30,522
Estimated probability of survival at 1 year (unadjusted for patient and donor characteristics)	98.48%	96.96%
Expected probability of survival at 1 year (adjusted for patient and donor characteristics)	97.08%	---
# of observed deaths \leq 1 year after transplant	4	818
# of expected deaths \leq 1 year after transplant	7.90	---
Estimated hazard ratio (HR)	0.61	---
95% credible interval for hazard ratio	[0.22, 1.18]	---

Performance Criteria

Program Size	Survival	OPTN Criteria <i>A or B must be true</i>
≥ 10 tpx in a 2.5 year period	Higher HR of death or graft failure than would be expected for that program	A. Probability HR > 1.2 > 75% B. Probability HR > 2.5 > 10%

Program XYZ

- HR < 1.0
- There is a lower risk of patient death compared to the average program
- **Performance review would not be triggered**

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Example – Transplant Program ABC

- Adult 1 year patient survival for kidney decreased graft recipients

January 2021 Single organ transplants performed between 7/1/17 and 12/31/19	ABC	U.S.
# of transplants evaluated	241	15,513
Estimated probability of survival at 1 year (unadjusted for patient and donor characteristics)	90.31%	93.08%
Expected probability of survival at 1 year (adjusted for patient and donor characteristics)	93.66%	---
# of observed deaths \leq 1 year after transplant	21	1,013
# of expected deaths \leq 1 year after transplant	14.10	---
Estimated hazard ratio (HR)	1.43	---
95% credible interval for hazard ratio	[0.91, 2.07]	---


Performance Criteria

Program Size	Survival	OPTN Criteria ¹ <i>A or B must be true</i>
≥ 10 tpx in a 2.5 year period	Higher HR of death or graft failure than would be expected for that program	A. Probability HR > 1.2 > 75% B. Probability HR > 2.5 > 10%

OPTN Bylaws, Effective date 12/6/21

¹This information is provided for your center's review only and will not appear on the public version of the BSRs at www.ccrp.org

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Review Criteria

Review Criteria (not public)*

Transplants performed between 07/01/2016 and 12/31/2018

	Adult (18+) 1-Year		Pediatric (<18) 1-Year	
	Graft Survival	Patient Survival	Graft Survival	Patient Survival
MPSC Review Criteria				
Number of transplants	249	241	–	–
Observed events	27	21	–	–
Expected events	18,212	14,096	–	–
Probability HR exceeds 1.20	0.808	0.771	–	–
Probability HR exceeds 2.50	0.000	0.001	–	–
Identified for review (Standard Criteria)	Yes	Yes	–	–
Identified for review (Small Volume)	No	No	–	–

- This information is provided for your center's review only and will not appear on the public version of the PSRs at www.srtr.org

✓

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✓


Program Size	Survival	OPTN Criteria ¹ <i>A or B must be true</i>
≥ 10 txp in a 2.5 year period	Higher HR of death or graft failure than would be expected for that program	A. Probability HR > 1.2 > 75% B. Probability HR > 2.5 > 10%

Program ABC

- HR > 1.0
- There is a higher risk of patient death compared to the average program
- **Performance review would be triggered**

¹ OPTN Bylaws, Effective date 12/6/21
 * This information is provided for your center's review only and will not appear on the public version of the PSRs at www.srtr.org

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NEW – PERFORMANCE Monitoring

- Approved by OPTN board of directors (12/6/21)
- Bylaw revisions include changes to transplant program performance review process including
 - New measures of performance
 - Addition of language codifying the current peer visit process
 - Addition/revision of relevant definitions

<https://optn.transplant.hrsa.gov/news/two-new-transplant-performance-metrics-to-implement-july-14-2022/>

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NEW – PERFORMANCE Monitoring


CURRENT <u>POST-Transplant</u> <ul style="list-style-type: none"> 1 year patient and graft survival 	NEW <u>POST-Transplant</u> <ul style="list-style-type: none"> 90-day post transplant graft survival rate 1-year post-transplant graft survival conditional on 90-day graft survival <u>PRE-Transplant</u> <ul style="list-style-type: none"> Pre-transplant mortality rate Offer acceptance rate
--	--

OPTN will implement the new metrics in phases over the next 3 years

2 Post metrics (effective 7/14/22)
 Offer acceptance rates (no earlier than July 2023)
 Pre-transplant mortality rate (no earlier than July 2024)

<https://optn.transplant.hrsa.gov/news/two-new-transplant-performance-metrics-to-implement-july-14-2022/>

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OPTN Member Monitoring

Transplant Program Compliance Reviews

- ✓ Membership Criteria
- ✓ OPTN Policies and Bylaws
- ✓ Performance

https://optn.transplant.hrsa.gov/media/2937/optn_member_monitoring_processes.pdf [Accessed 4/14/22]

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OPTN – Member Monitoring

- Members & Professional Standards Committee (MPSC)
 - Monitors member compliance
 - Reviews and actions (*Appendix L*)
 - Conducts confidential peer review
 - Focus is on corrective action versus punishment

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OPTN Bylaws, Effective date 12/6/21
https://optn.transplant.hrsa.gov/media/igbbmah/optn_bylaws.pdf [Accessed 4/15/22]

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ACTIVE LEARNING: Question #1

- Which data source is used by the MPSC to evaluate a heart transplant program's 1 year graft survival?
 - A. UNOS Program Specific Report (PSR)
 - B. SRTR Program Specific Report (PSR)
 - C. CMS Program Specific Report (PSR)
 - D. OPO Program Specific Report (PSR)

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ACTIVE LEARNING: Question #1

- Which data source is used by the MPSC to evaluate a heart transplant program's 1 year graft survival?
 - A. UNOS Program Specific Report (PSR)
 - B. SRTR Program Specific Report (PSR)
 - C. CMS Program Specific Report (PSR)
 - D. OPO Program Specific Report (PSR)

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ACTIVE LEARNING: Question #2

- According to the estimated hazard ratio which liver transplant programs have a lower risk of 1 year graft loss compared to an average transplant program (select all that apply) ?

Transplant Program	Estimated Hazard Ratio
A	0.75
B	0.99
C	1.00
D	1.28

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ACTIVE LEARNING: Question #2

- According to the estimated hazard ratio which liver transplant programs have a lower risk of 1 year graft loss compared to an average transplant program (select all that apply) ?

Transplant Program	Estimated Hazard Ratio
A	0.75
B	0.99
C	1.00
D	1.28

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ACTIVE LEARNING: Question #3

- Per the OPTN Bylaws which liver transplant program may be considered for 1 year outcome review by the Members and Professional Standing Committee (MPSC) based on their estimated hazard ratio (select all that apply) ?

Transplant Program	Estimated Hazard Ratio
A	0.75
B	0.99
C	1.00
D	1.28

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ACTIVE LEARNING: Question #3

- Per the OPTN Bylaws which liver transplant program may be considered for 1 year outcome review by the Members and Professional Standing Committee (MPSC) based on their estimated hazard ratio (select all that apply) ?

Transplant Program	Estimated Hazard Ratio
A	0.75
B	0.99
C	1.00
D	1.28

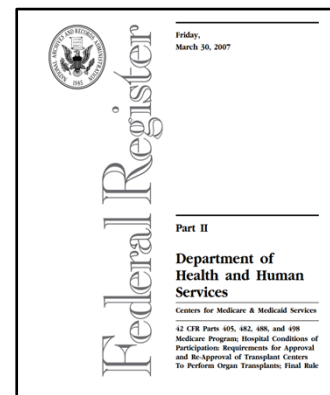
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Centers for Medicare and Medicaid Services (CMS)

- To obtain approval a transplant program must
 - Be located within a hospital that has a Medicare provider agreement
 - Meet all hospital Conditions of Participation (CoP)
 - Meet all Transplant Conditions of Participation (CoP)


Key Terminology

Interpretive Guidelines	<ul style="list-style-type: none"> Developed to provide clarification on interpreting the regulations (CoP)
Tag number	<ul style="list-style-type: none"> A user-friendly system to identify a specific regulation (instead of identifying by its full reference/number)




<https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Downloads/trancenterreg2007.pdf>

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<h2>State Operations Manual</h2> <h3>Appendix X – Guidance to Surveyors: Organ Transplant Programs</h3> <h4>Table of Contents</h4> <p><i>(Rev. 200, Issued: 02-21-20)</i></p>	
Part I – The Standard Organ Transplant Program Survey Protocol I. Introduction II. Survey Protocol Tasks Task 1 - Pre-survey: off-site Preparation Task 2 - Entrance Activities Task 3 - Sample Selection Task 4 - Tracer for Selected Patients and Living Donors including Observations of Care, Interviews and Medical Record Review Task 5 - Administrative Review Task 6 - Personnel Record Review (If Indicated) Task 7 - Pre-exit Task 8 - Exit Conference Task 9 - Post Survey Activities III. Alternate Survey Protocol: Pediatric Heart Program Task 1 - Pre-survey: off-site Preparation Task 2 - Entrance Activities Task 3 - Sample Selection Task 4 - Review of Transplant Patient Medical Records Task 5 - Staff Interview Task 6 - Personnel Record Review Task 7 - Administrative Review Task 8 - Pre-exit Task 9 - Exit Conference Task 10 - Post Survey Activities	Part II – Interpretive Guidelines for Organ Transplant Surveys 42 C.F.R. 482.72 OPTN Membership 42 C.F.R. 482.74 Notification to CMS 42 C.F.R. 482.76 Pediatric Transplants 42 C.F.R. 482.78 Emergency preparedness for Transplant <i>Programs</i> 42 C.F.R. 482.80 Data Submission, Clinical Experience and Outcome Requirements for <u>Initial Approval</u> 42 C.F.R. 482.82 Data Submission, Clinical Experience and Outcome Requirements <u>Re-approval</u> 42 C.F.R. 482.90 Patient and Living Donor Selection 42 C.F.R. 482.92 Organ Recovery and Receipt 42 C.F.R. 482.94 Patient and Living Donor Management 42 C.F.R. 482.96 Quality Assessment and Performance Improvement (QAPI) 42 C.F.R. 482.98 Human Resources 42 C.F.R. 482.100 Organ Procurement 42 C.F.R. 482.102 Patient and Living Donor Rights 42 C.F.R. 482.104 Additional Requirements for Kidney Transplant <i>Programs</i>


State Operations Manual Appendix X. Guide to Surveyors: Organ Transplant Programs (Rev. 200, Issued: 02-21-20). Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_x_otp.pdf

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<h2>CMS Transplant CoPs</h2>	
<ul style="list-style-type: none"> • General Requirements <ul style="list-style-type: none"> – 482.72 OPTN Membership – 482.74 Notification to CMS – 482.76 Pediatric Transplants • Data Submission, Clinical Experience and Outcome Requirements <ul style="list-style-type: none"> – 482.78 Emergency preparedness – 482.80 Data Submission, Clinical Experience and Outcome Requirements for Initial Approval – 482.82 Data Submission, Clinical Experience and Outcome Requirements Re-approval 	<ul style="list-style-type: none"> • Process Requirements <ul style="list-style-type: none"> – 482.90 Patient and Living Donor Selection – 482.92 Organ Recovery and Receipt – 482.94 Patient and Living Donor Management – 482.96 Quality Assessment and Performance Improvement (QAPI) – 482.98 Human Resources – 482.100 Organ Procurement – 482.102 Patient and Living Donor Rights – 482.104 Additional Requirements for Kidney Transplant Centers

State Operations Manual Appendix X. Guide to Surveyors: Organ Transplant Programs (Rev. 200, Issued: 02-21-20). Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_x_otp.pdf

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CMS Transplant CoP's


- General Requirements
 - 482.72 OPTN Membership
 - 482.74 Notification to CMS
 - 482.76 Pediatric Transplants

➔

X011	§482.74 (a)	Condition: Notification to CMS Change in key staff members Notified of termination of agreement with OPO Notified of inactivation
X012	482.74 (a)(1)	
X014	482.74 (a)(2)	
X015	482.74 (a)(3)	

State Operations Manual Appendix X, Guide to Surveyors: Organ Transplant Programs (Rev. 200, Issued: 02-21-20). Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_x_otp.pdf

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CMS Transplant CoP's

- General Requirements
 - 482.72 OPTN Membership
 - 482.74 Notification to CMS
 - 482.76 Pediatric Transplants
- Data Submission, Clinical Experience and Outcome Requirements
 - 482.78 Emergency preparedness
 - 482.80 Data Submission, Clinical Experience and Outcome Requirements for Initial Approval
 - 482.82 Data Submission, Clinical Experience and Outcome Requirements Re-approval

➔

X031	§482.80	Condition: Data Submit/Experience/Outcomes, Initial Approval
X032	482.80 (a)	
X033	482.80 (b)	Standard: Clinical experience (volume) init approval
X035	482.80(c)(1-4)	Outcomes: patient/graft survival init approval
X036	482.80 (c)(5)	Kidney transplant volume – new program, initial approval

State Operations Manual Appendix X, Guide to Surveyors: Organ Transplant Programs (Rev. 200, Issued: 02-21-20). Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_x_otp.pdf

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CMS Transplant CoP's

- Program initial approval
 - **482.80 (a) Standard: Data submission**
 - No later than 90 days after the due date established by the OPTN, a transplant program must submit to the OPTN at least 95% of the required data on all transplants (deceased and living donor) it has performed.
 - **482.80 (b) Standard: Clinical experience**
 - To be considered for initial approval, an organ-specific transplant program must generally perform 10 transplants over a 12-month period.
 - *Includes: Adult Heart, Adult Lung, Adult Liver, Adult Intestinal and/or Multivisceral*

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CMS Transplant CoP's

- Program initial approval
 - **482.80 (c) Standard: Outcome requirements**
 - The program's observed survival (patient and graft) will be compared to the program's expected survival (patient and graft) at 1-year post-transplant using the data contained in the most recent SRTT PSR.

State Operations Manual Appendix X, Guide to Surveyors: Organ Transplant Programs (Rev. 200, Issued: 02-21-20). Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_x_otp.pdf

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CMS Transplant CoP's

- Program initial approval
 - **482.80 (c) Standard: Outcome requirements**
 - The programs observed survival (patient and graft) will be compared to the program's expected survival (patient and graft) at 1-year post-transplant using the data contained in the most recent SRTR PSR.
 - Survival (patient and graft) is not considered acceptable when the following criteria are met

CMS <i>Initial program approval</i>	Survival	Criteria <i>A, B and C must be true</i>
10 transplants over 12 month period	Observed lower than expected for that program	A) One-sided p-value is less than 0.05 B) # of observed events minus # of expected events is > 3 C) # of observed events divided # of expected events is > 1.85

Exception: Doesn't apply to heart-lung, intestine (intestine, combined liver-intestine or multivisceral), pancreas

State Operations Manual Appendix X, Guide to Surveyors: Organ Transplant Programs (Rev. 200, Issued: 02-21-20). Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_x_otp.pdf

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CMS Transplant CoP's

- General Requirements
 - 482.72 OPTN Membership
 - 482.74 Notification to CMS
 - 482.76 Pediatric Transplants
- Data Submission, Clinical Experience and Outcome Requirements
 - 482.78 Emergency preparedness
 - 482.80 Data Submission, Clinical Experience and Outcome Requirements for Initial Approval
 - 482.82 Data Submission, Clinical Experience and Outcome Requirements Re-approval

Effective 11/29/2019

51732 Federal Register / Vol. 84, No. 189 / Monday, September 30, 2019 / Rules and Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 416, 418, 441, 460, 482, 483, 484, 485, 486, 488, 491, and 494

[CMS-3346-F; CMS-3334-F; CMS-3295-F]

RIN 0938-A723

Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

The regulations at § 482.43(b) and § 485.640(b) regarding hospital and critical access hospital (CAH) antibiotic stewardship programs must be implemented by March 30, 2020.

FOR FURTHER INFORMATION CONTACT: For issues related to Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction, contact Kristin Shifflett, (410) 786-4133. For issues related to Fire Safety Requirements for Certain Dialysis Facilities, contact Kristin Shifflett, (410) 786-4133. For issues related to the Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care, contact CAPT Scott Cooper, USPHS, (410) 786-9465, Mary Collins, (410) 786-3189, Alpha-Banu Wilson, (410) 786-8687, or Kianna Banks, (410) 786-3498.

SUPPLEMENTARY INFORMATION: We note that this rule finalizes provisions that

7. Comprehensive Outpatient Rehabilitation Facility (CORF)—Utilization Review Plan

8. Critical Access Hospitals

9. Community Mental Health Center

10. Portable X-Ray Services

11. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

12. Emergency Preparedness for Providers and Suppliers

13. Technical Corrections

14. Waiver of Proposed Rulemaking

C. Collection of Information Requirements

II. Final Rule: Fire Safety Requirements for Certain Dialysis Facilities

A. Background

B. Provisions of the Proposed Rule and Analysis and Response to Public Comments

1. 2012 Edition of the Life Safety Code

2. Incorporation by Reference

3. Ambulatory Health Care Occupancies

4. 2012 Edition of the Health Care Facilities Code

5. Technical Corrections

C. Collection of Information Requirements

III. Final Rule: Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care

<https://www.govinfo.gov/content/pkg/FR-2019-09-30/pdf/2019-20736.pdf>

State Operations Manual Appendix X, Guide to Surveyors: Organ Transplant Programs (Rev. 200, Issued: 02-21-20). Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_x_otp.pdf

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Post Transplant 1 year Survival

Regulatory Summary

OPTN	Survival	Criteria (A or B must be true)
≥ 10 transplants in a 2.5 year period	Higher hazard ratio of mortality or graft failure than would be expected for that program	A. Probability Hazard Ratio > 1.2 > 75% B. Probability Hazard Ratio > 2.5 > 10%
≤ 9 transplants in a 2.5 year period	If program has ≥ 1 or more events	

CMS <i>Initial program approval</i>	Survival	Criteria (A, B and C must be true)
10 transplants over 12 month period <i>Exception: Doesn't apply to heart-lung, intestine</i>	Observed lower than expected for that program	A) One-sided p-value is less than 0.05 B) # of observed events minus # of expected events is > 3 C) # of observed events divided # of expected events is > 1.85

https://optn.transplant.hrsa.gov/media/lgbmhah/optn_bylaws.pdf [Accessed 4/14/22]

State Operations Manual Appendix X, Guide to Surveyors: Organ Transplant Programs (Rev. 200, Issued: 02-21-20). Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_x_otp.pdf

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CMS Transplant CoP's

What is the Role of Transplant Pharmacist?

- General Requirements
 - 482.72 OPTN Membership
 - 482.74 Notification to CMS
 - 482.76 Pediatric Transplants
- Data Submission, Clinical Experience and Outcome Requirements
 - 482.78 Emergency preparedness
 - 482.80 Data Submission, Clinical Experience and Outcome Requirements for Initial Approval
 - 482.82 Data Submission, Clinical Experience and Outcome Requirements Re-approval
- Process Requirements
 - 482.90 Patient and Living Donor Selection
 - 482.92 Organ Recovery and Receipt
 - 482.94 Patient and Living Donor Management
 - 482.96 Quality Assessment and Performance Improvement (QAPI)
 - 482.98 Human Resources
 - 482.100 Organ Procurement
 - 482.102 Patient and Living Donor Rights
 - 482.104 Additional Requirements for Kidney Transplant Programs

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482.90 - Patient and Living Donor Selection

- Standard *What is the Role of Transplant Pharmacist?*
 - Transplant program must use written patient/donor selection criteria in determining if a patient/donor is suitable for transplantation/donation

482.90 (a) - Patient selection	
482.90 (a1)	Psychosocial evaluation for transplant candidate
482.90(a2)	Candidate's blood type documentation
482.90 (a3)	Patient selection criteria documentation
482.90 (a4)	Provide selection criteria to patient/dialysis facility
482.90 (b) - Living donor selection	
482.90 (b1)	Psychosocial evaluation for living donor
482.90 (b2)	Suitability for donation documentation
482.90 (b3)	Informed consent documentation

Interpretive
Guidelines
TAG X051

- Transplant programs required to develop their own hospital-approved selection criteria
- Selection criteria must clearly define all the factors that are considered in determining suitability for transplantation/donation
- Must not exclude groups or individuals without supporting documentation
- Must be evidence that the written selection criteria are followed for the selection of candidates/donors

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482.94 - Patient and Living Donor Management

- STANDARD
 - Transplant programs must have written patient management policies for the transplant and discharge phases of transplantation
 - If the transplant program performs living donor transplants, the program must also have written donor management policies for the donor evaluation, donation and discharge phases of living donation

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482.94 - Patient and Living Donor Management

Definitions

- STANDARD
 - Transplant programs must have written patient management policies for the transplant and discharge phases of transplantation

Transplant Phases

- Transplant: Begins when the potential transplant candidate is evaluated for transplantation and continues through the completion of the transplantation surgery
- Discharge: Begins at the transplant candidate admission to the hospital and continues through to his/her discharge from the inpatient stay

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482.94 - Patient and Living Donor Management

Definitions

- STANDARD
 - If the transplant program performs living donor transplants, the program must also have written donor management policies for the donor evaluation, donation and discharge phases of living donation

Living Donor Phases

- Evaluation: Begins from the first presentation by the potential donor until the time he/she enters the OR for the donation surgery.
- Donation: Begins from the time the potential donor enters the OR for the donation surgery until the donor is discharged from the inpatient surgery stay
- Discharge: Begins at admission to the hospital and continues through the donor's discharge from the inpatient stay

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482.94 - Patient and Living Donor Management

- STANDARD *What is the Role of Transplant Pharmacist?*
 - Transplant programs must have written patient management policies for the transplant and discharge phases of transplantation
 - If the transplant program performs living donor transplants, the program must also have written donor management policies for the donor evaluation, donation and discharge phases of living donation

482.94 (a)	Patient and Living Donor Care
482.94 (b)	Waiting List Management
482.94 (c)	Patient Records
482.94 (d)	Social Services
482.94 (e)	Nutritional Services

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482.94 - Patient and Living Donor Management

What is the Role of Transplant Pharmacist?

482.94 (a)	Patient and Living Donor Care
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STANDARD

- Each patient/living donor is under the care of a multidisciplinary patient care team coordinated by a physician throughout all phases of care

482.94 (a1)	Patient	Transplant and discharge phases
482.94 (a2)	Living Donor	Evaluation, donation and discharge phases

Interpretive Guidelines TAG X082

- Patient and donor management policies must ensure that each patient/donor is under the care of a multidisciplinary patient care team coordinated by a physician throughout all phases of care

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482.94 - Patient and Living Donor Management

What is the Role of Transplant Pharmacist?

482.94 (b)	Waiting List Management
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STANDARD

- Transplant program must keep their waiting list up to date on an ongoing basis


482.94 (b1)	Updating of waiting list patients' clinical information
482.94 (b2)	Removal from the waitlist list
482.94 (b3)	OPTN notification of waiting list removal

Interpretive Guidelines TAG X084

- Transplant programs should determine how often waiting list patients should be evaluated and provided ongoing assessments.
- Policies and procedures should include details on updating the waiting list and pre-transplant clinical information including what type of information, who is designated to update and the timeframe that these updates must be completed and reviewed.

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482.94 - Patient and Living Donor Management

What is the Role of Transplant Pharmacist?


482.94 (c)	Patient Records	<i>STANDARD</i>	<ul style="list-style-type: none"> Transplant programs must maintain up-to-date and accurate patient management records for each patient who is on the waiting list and who is admitted for transplantation
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482.94 (c1)	Patient informed of waiting list status
482.94 (c2)	Patient notification of removal from waiting list
482.94 (c3)	Upon admission for organ transplant, written record maintenance

482.94 (c3i)	Multidisciplinary patient care planning during TRANSPLANT period
482.94 (c3ii)	Multidisciplinary DISCHARGE planning for post-transplant care

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482.94: Patient and Living Donor Management

What is the Role of Transplant Pharmacist?

482.94 (c3i)	Multidisciplinary patient care planning during TRANSPLANT period	Interpretive Guidelines TAG X090	<ul style="list-style-type: none"> Multidisciplinary care plan includes ongoing assessments to identify any new patient needs and/or to determine if any currently identified needs have changed This multidisciplinary team participates in patient care planning from evaluation through transplantation At time of initial evaluation, each member of the team participates in the evaluation of the patient; it may not be necessary for all team disciplines to see the patient again until transplant unless there are identified needs Following transplant, each discipline must, as appropriate <ol style="list-style-type: none"> 1) Reassess the recipient following surgery 2) See the recipient as often as indicated by identified issues 3) See the recipient prior to discharge Written records to demonstrate multidisciplinary care planning
482.94 (c3ii)	Multidisciplinary DISCHARGE planning for post-transplant care		

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482.94: Patient and Living Donor Management

What is the Role of Transplant Pharmacist?

482.94 (c3i)	Multidisciplinary patient care planning during TRANSPLANT period
482.94 (c3ii)	Multidisciplinary DISCHARGE planning for post-transplant care

Interpretive Guidelines TAG X091

- Discharge planning begins on admission
- Each member of the multidisciplinary team must be involved in assessing the needs of the patient in preparation for discharge from the hospital
- Areas of assessment include medical, psychosocial and financial
- Medical record must contain documentation that the multidisciplinary team participated in the development of the discharge plan to address the individual needs of the patient (see example of components next slide)

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Components of a multidisciplinary discharge plan may include, but are not limited to:

- A description of the recommended follow-up appointments and the practitioners expected to perform the follow-ups (such as the transplant program, a local physician, or both);
- Contact numbers of transplant program staff that can be contacted for questions;
- The clinical signs and symptoms indicative of a potential complication from transplantation that would necessitate a call to the doctor;
- A transplant recipient/living donor specific nutrition plan, as applicable;
- A plan for addressing psychosocial issues (for example available supports, adaptation to stress of transplant, etc.);
- Activity restrictions and limitations (for example driving after taking pain medication);
- Need for coordination of other health services (for example physical or occupational therapies, home care, etc.) and assistance in securing these health services;
- **Medication and administration, including the transplant recipient's schedule for taking medication and the process to obtain the medication; and**
- Any assistance required to access local medical care, equipment or support

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CMS Transplant CoPs

What is the Role of Transplant Pharmacist?

- **General Requirements**
 - 482.72 OPTN Membership
 - 482.74 Notification to CMS
 - 482.76 Pediatric Transplants
- **Data Submission, Clinical Experience and Outcome Requirements**
 - 482.78 Emergency preparedness
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- **Process Requirements**
 - 482.90 Patient and Living Donor Selection
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 - 482.98 Human Resources
 - 482.100 Organ Procurement
 - 482.102 Patient and Living Donor Rights
 - 482.104 Additional Requirements for Kidney Transplant Centers

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482.98 Human Resources

What is the Role of Transplant Pharmacist?

- **STANDARD**
 - The transplant program must ensure that all individuals who provide services and/or supervise services at the program, including individuals furnishing services under contract or arrangement, are qualified to provide or supervise such services.

482.98 (a)	Director of Transplant Program
482.98 (b)	Transplant Surgeon and Physician
482.98 (c)	Clinical Transplant Coordinator
482.98 (d)	Independent Living Donor Advocate
482.98 (e)	Transplant Team

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482.98: Human Resources

What is the Role of Transplant Pharmacist?

482.98 (e) – Transplant Team

- The transplant program must identify a multi-disciplinary transplant team and describe the responsibilities of each member of the team.
- The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and **pharmacology**.

Interpretive Guidelines TAG X125

- While it is desirable that each multidisciplinary team include a pharmacist member, there may be other disciplines on the team who may also be qualified to provide pharmacology services.
- Examples of individuals other than pharmacists who are qualified to provide pharmacology services on the team are a physician, advanced nurse practitioner, or physician assistant

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CMS Transplant CoP's

What is the role of the Transplant Pharmacist?

SUMMARY

Regulations				
CMS	482.90	TAG X051	Patient Selection	
	482.94 (a)	TAG X082	Care via Multidisciplinary Team	
	482.94 (b1)	TAG X084	Waiting List Management	
	482.94 (c3)	TAG X090	Care planning/documentation during transplant phase	
	482.94 (cii)	TAG X091	Discharge planning/documentation during discharge phase	
	482.98 (e)	TAG X125	Transplant Team (responsibilities, qualification, training)	

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ACTIVE LEARNING: Question #4

- Your Transplant Administrative Director is wanting to review the OPTN regulations pertaining to pharmacists, where would you advise her to look for the OPTN membership requirements?
 - A. Bylaws
 - B. Policies
 - C. Conditions of Participation
 - D. TIEDI application

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ACTIVE LEARNING: Question #4

- Your Transplant Administrative Director is wanting to review the OPTN regulations pertaining to pharmacists, where would you advise her to look for the OPTN membership requirements?
 - A. Bylaws
 - B. Policies
 - C. Conditions of Participation
 - D. TIEDI application

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ACTIVE LEARNING: Question #5

- Which transplant regulations require a PGY-2 specialty trained transplant pharmacist to be a member of the transplant multidisciplinary team?
 - A. OPTN
 - B. CMS
 - C. Both OPTN and CMS
 - D. Neither OPTN or CMS

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ACTIVE LEARNING: Question #5

- Which transplant regulations require a PGY-2 specialty trained transplant pharmacist to be a member of the transplant multidisciplinary team?
 - A. OPTN
 - B. CMS
 - C. Both OPTN and CMS
 - D. Neither OPTN or CMS

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ACTIVE LEARNING: Question #6

- Per the CMS regulations for the candidate evaluation which statement best reflects the requirements of the pharmacology expert on the transplant multidisciplinary team?

A pharmacology assessment of the transplant candidate is:

- A. Not required
- B. Not required as a pharmacology expert is not a member of the transplant multidisciplinary team
- C. Required and must be completed prior to placing the candidate on the waiting list
- D. Required and must be completed prior to placing the candidate on the waiting list if specified within the transplant program's policies

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ACTIVE LEARNING: Question #6

- Per the CMS regulations for the candidate evaluation which statement best reflects the requirements of the pharmacology expert on the transplant multidisciplinary team?

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- D. Required and must be completed prior to placing the candidate on the waiting list if specified within the transplant programs policies

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Transplant Multidisciplinary Team Policy

What is the Role of the Transplant Pharmacist?

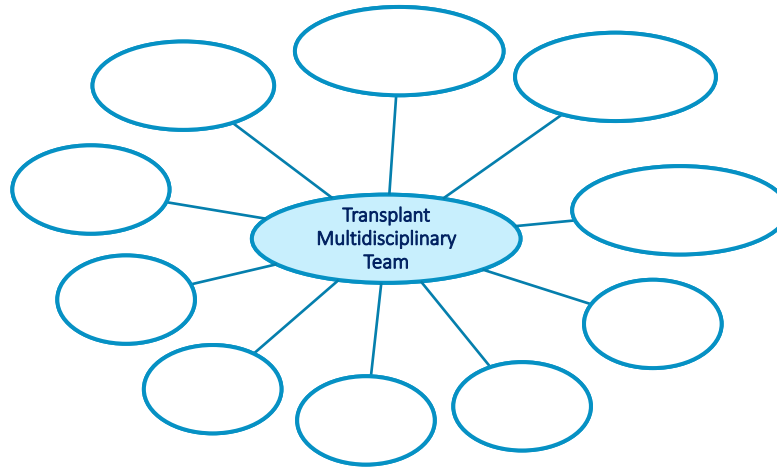
91

Multidisciplinary Transplant Team Policy

- Written policy describing policy and procedures for the multidisciplinary transplant team
- Includes
 - Composition
 - Qualifications
 - Responsibilities

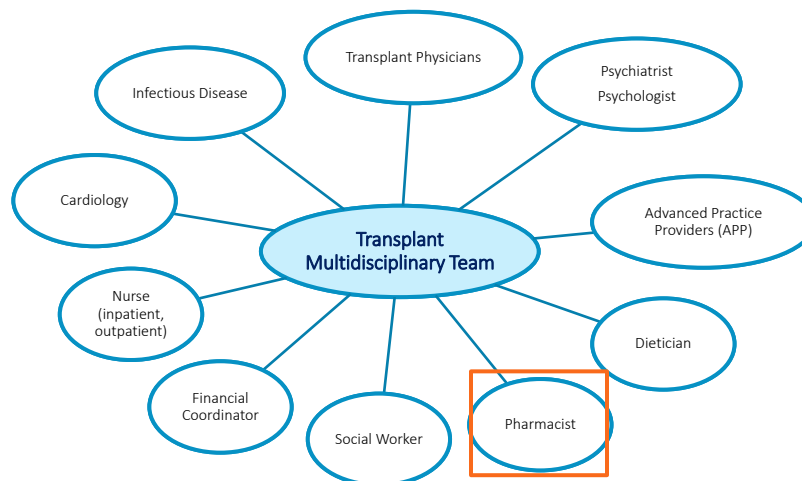
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Multidisciplinary Transplant Team Policy



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Multidisciplinary Transplant Team Policy



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Multidisciplinary Transplant Team Policy

Transplant Pharmacist

What do the Transplant Regulations tell us?

OPTN	<ul style="list-style-type: none"> ✓ Clinical Transplant Pharmacist ✓ Provide pharmaceutical expertise to transplant recipients ✓ Works with patients and their families and members of the transplant team ✓ Should be a licensed pharmacist ✓ Experience in transplant pharmacotherapy
CMS	<ul style="list-style-type: none"> ✓ Individuals with the appropriate qualifications, training, and experience in the relevant areas of pharmacology

https://optn.transplant.hrsa.gov/media/lgbmahi/optn_bylaws.pdf [Accessed 4/15/22]
https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_x_opt.pdf

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Multidisciplinary Transplant Team Policy

Transplant Pharmacist

Others?

Pharmacy Organizations	Definition
Hospital	
Pharmacy Department	
	Qualifications
Transplant Program	

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Multidisciplinary Transplant Team Policy


Transplant Pharmacist

Others?

Pharmacy Organizations	Definition <ul style="list-style-type: none"> Transplant Pharmacists provide patient care that optimizes medication therapy and promotes health, and disease prevention in transplantation.¹
Hospital	<ul style="list-style-type: none"> Solid Organ Transplantation Pharmacists provide evidence-based, patient-centered medication therapy management and care for patients throughout all phases of solid organ transplantation at all ages and in various healthcare settings²
Pharmacy Department	<ul style="list-style-type: none"> Transplant pharmacists have a strong presence in the areas of pharmacogenomics, innovative collaborative drug therapy management (CDTM), and prospective practice management³
Transplant Program	Qualifications

¹ Adapted from <https://www.accp.com/stunet/compass/definition.aspx> [Accessed 4/15/22]
² www.bpsweb.org/bps-specialties/solid-organ-transplantation-pharmacy/ [Accessed 4/15/22]
³ Maldonado AQ, Hall RC, Pilch NA et al. Am J Health-Syst Pharm. 2020;77:222-32

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Multidisciplinary Transplant Team Policy


Transplant Pharmacist

Others?

Pharmacy Organizations	Definition <ul style="list-style-type: none"> Transplant Pharmacists provide patient care that optimizes medication therapy and promotes health, and disease prevention in transplantation.¹
Hospital	<ul style="list-style-type: none"> Solid Organ Transplantation Pharmacists provide evidence-based, patient-centered medication therapy management and care for patients throughout all phases of solid organ transplantation at all ages and in various healthcare settings²
Pharmacy Department	<ul style="list-style-type: none"> Transplant pharmacists have a strong presence in the areas of pharmacogenomics, innovative collaborative drug therapy management (CDTM), and prospective practice management³
Transplant Program	Qualifications <ul style="list-style-type: none"> PharmD ± years of experience Post graduate experience (PGY1, PGY2, fellowship) State licensure Continuing education Transplant specific education/training

¹ Adapted from <https://www.accp.com/stunet/compass/definition.aspx> [Accessed 4/15/22]
² www.bpsweb.org/bps-specialties/solid-organ-transplantation-pharmacy/ [Accessed 4/15/22]
³ Maldonado AQ, Hall RC, Pilch NA et al. Am J Health-Syst Pharm. 2020;77:222-32

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Multidisciplinary Transplant Team Policy

Transplant Pharmacist

Which phases of care?

PRE	PERI	POST
Transplant/Donation	Transplant/Donation	Transplant/Donation

Important to consider definition of phases (regulations versus specific transplant program)


CMS Regulations

Transplant		Transplant and Discharge	
Donation	Evaluation	Donation and Discharge	

OPTN Regulations

	Recipient
--	-----------

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Multidisciplinary Transplant Team Policy

Transplant Pharmacist

Which patient populations?

	PRE	PERI	POST
	Transplant/Donation	Transplant/Donation	Transplant/Donation
Adults			
Pediatrics			

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Multidisciplinary Transplant Team Policy

Transplant Pharmacist

Which organs?	PRE Transplant/Donation	PERI Transplant/Donation	POST Transplant/Donation
Adults			
Kidney			
Pancreas			
Heart			
Lung			
Pediatrics			
Kidney			
Liver			


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Multidisciplinary Transplant Team Policy

Transplant Pharmacist

Responsibilities	PRE	Transplant/ Donation	POST
Adult – transplant candidate, recipients and living donor			
Kidney		<ul style="list-style-type: none"> ✓ OPTN ✓ CMS ✓ State ✓ Hospital 	
Liver		<ul style="list-style-type: none"> ✓ Transplant program ✓ Pharmacy department ✓ Practice standards/best practices 	

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Multidisciplinary Transplant Team Policy

Transplant Pharmacist


PRE Phase

Conducts initial assessment and any reevaluation that may occur during the waiting list period. Presents risks and mitigation plans as part of the multidisciplinary selection committee. Must document transplant pharmacy activities based on individual center policies developed in accordance with regulatory requirements

<u>Pharmacologic risk</u>	<u>Immunologic risk</u>	<u>Non-pharmacologic</u>
<ul style="list-style-type: none"> Anticoagulation Drug interactions Medications related to mental health, chronic pain Medication allergies Hormonal contraceptive and replacement therapy Current use of immunomodulators Issues with drug absorption Illicit substance use Use of herbal supplements 	<ul style="list-style-type: none"> Review history to help guide immunosuppressant therapy selection and/or need for desensitization therapies 	<ul style="list-style-type: none"> Vaccine delivery Infectious <ul style="list-style-type: none"> - Prophylaxis and treatment Socially related factors <ul style="list-style-type: none"> - Nonadherence - Communication barriers - Financial - Transportation

Am J Health Syst Pharm 2020;77(3):222-32; Am J Transplant 2015;15(10):2683-90; Am J Health Syst Pharm 2015;72:781-93; Am J Transplant 2011;11:1576-83

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Multidisciplinary Transplant Team Policy

Transplant Pharmacist

PERI Phase



Work with healthcare professionals involved in all settings to ensure seamless medication use process, provision of transplant medication education, and discharge planning through each transition of care. Must document transplant pharmacy activities based on individual center policies developed in accordance with regulatory requirements

- Consultation services for medications related to induction, maintenance and discharge immunosuppression and their potential impact on other treatments or disease state management
- Guidance on patient specific medication selection, dosing, dosage adjustments
- Drug information to transplantation surgeons, physicians, nurses and other clinicians
- Care to living donors, including pain management, bowel care, fluid and electrolyte management and education of after care
- Provides medication education to recipient and caregiver prior to discharge

Other responsibilities may include: administrative, clinical research, professional development

Am J Health Syst Pharm 2020;77(3):222-32; Am J Transplant 2015;15(10):2683-90; Am J Health Syst Pharm 2015;72:781-93; Am J Transplant 2011;11:1576-83

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Multidisciplinary Transplant Team Policy

Transplant Pharmacist

POST Phase and Ambulatory Setting



Works as member of the multidisciplinary team to ensure long-term management of allograft is optimized.

- Immunosuppressant regimen modification according to patient-specific needs, adverse effects, and laboratory parameters
- Provides ongoing medication and adherence education
- Detects, monitors and creates treatment plans for acute cellular rejection, antibody mediated rejection and chronic allograft vasculopathy
- Modifies opportunistic infections prophylaxis and treatment regimens based on renal function and tolerability; and provides guidance in detection and management of opportunistic infections

Other responsibilities may include: administrative, clinical research, professional development

Am J Health Syst Pharm 2020;77(3):222-32; Am J Transplant 2015;15(10):2683-90; Am J Health Syst Pharm 2015;72:781-93; Am J Transplant 2011;11:1576-83

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Multidisciplinary Transplant Team Policy

Transplant Pharmacist

Responsibilities	PRE	Transplant/ Donation	POST
Adult – transplant candidate, recipients and living donor			
Kidney		✓ OPTN ✓ CMS ✓ State ✓ Hospital ✓ Transplant program ✓ Pharmacy department ✓ Practice standards/best practices	
Liver			

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Transplant Program ABC

Clinical Transplant Pharmacist	<ul style="list-style-type: none"> Responsible for the pharmacological management of the transplant patients and living donors throughout the phases of transplantation and donation. Responsibilities vary per phase and include but are not limited to the following: 	
	Evaluation or Pre-Donation	
	Transplant or Donation Phase	
	Post-Transplant or Post-Donation	

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Transplant Program ABC

Clinical Transplant Pharmacist	<ul style="list-style-type: none"> Responsible for the pharmacological management of the transplant patients and living donors throughout the phases of transplantation and donation. Responsibilities vary per phase and include but are not limited to the following: 	
	Evaluation or Pre-Donation	<ul style="list-style-type: none"> Provide a pharmacological assessment for each potential recipient and potential living donor at the time of evaluation for transplantation or donation by reviewing the patient's medical history Provide written documentation of the above activities within the patient's EMR including the reason for whether the patient meets selection criteria to be used as a basis for selection committee decision criteria Educate the patient/family/caregiver regarding immunosuppressive medication dosing, potential side effects, and answer medication related questions when requested by the multidisciplinary team Annual follow-up for patients who have not been transplanted or donated within the first year of the date of selection committee approval Collaborate and communicate with the multidisciplinary team

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Transplant Program ABC


Clinical Transplant Pharmacist	<ul style="list-style-type: none"> Responsible for the pharmacological management of the transplant patients and living donors throughout the phases of transplantation and donation. Responsibilities vary per phase and include but are not limited to the following: 	
	Evaluation or Pre-Donation	<ul style="list-style-type: none"> Provide a pharmacological assessment for each potential recipient of potential living donor at the time of evaluation for transplantation or donation by reviewing the patient's medical history Provide written documentation of the above activities within the patient's EMR including the reason for whether the patient meets selection criteria to be used as a basis for selection committee decision criteria Educate the patient/family/caregiver regarding immunosuppressive medication dosing, potential side effects, and answer medication related questions when requested by the multidisciplinary team Annual follow-up for patients who have not been transplanted or donated within the first year of the date of selection committee approval Collaborate and communicate with the multidisciplinary team

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Transplant Program ABC

Clinical Transplant Pharmacist	<ul style="list-style-type: none"> Responsible for the pharmacological management of the transplant patient's and living donors throughout the phases of transplantation and donation. Responsibilities vary per phase and include but are not limited to the following: 	
	Transplant or Donation Phase	<ul style="list-style-type: none"> Participation in multidisciplinary team care, communication and discharge planning Assist the multidisciplinary team in education of the patient/family/caregiver regarding immunosuppression management Provide written documentation of the above activities within the patients EMR Collaborate and communicate with the multidisciplinary team


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Transplant Program ABC

Clinical Transplant Pharmacist	<ul style="list-style-type: none"> Responsible for the pharmacological management of the transplant patients and living donors throughout the phases of transplantation and donation. Responsibilities vary per phase and include but are not limited to the following: 	
	Transplant or Donation Phase	<ul style="list-style-type: none"> Participation in multidisciplinary team care, communication and discharge planning Assist the multidisciplinary team in education of the patient/family/caregiver regarding immunosuppression management Provide written documentation of the above activities within the patients EMR Collaborate and communicate with the multidisciplinary team

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Transplant Program ABC

Clinical Transplant Pharmacist	<ul style="list-style-type: none"> Responsible for the pharmacological management of the transplant patients and living donors throughout the phases of transplantation and donation. Responsibilities vary per phase and include but are not limited to the following: 	
	Post-Transplant or Post-Donation	<ul style="list-style-type: none"> Follow up with each transplant recipient or living donor regarding medication management and adherence when requested by the multidisciplinary team Provide written documentation of the above activities within the patient's EMR (if applicable) Collaborate and communicate with the multidisciplinary team

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Transplant Program ABC

- Members of the multidisciplinary team will communicate regarding the care and discharge planning of living donors and recipients in order to:
 - Collaboratively create a treatment plan for the patient during the transplant phase and before discharge from the hospital
 - Provide appropriate patient education for the patient/family/caregiver
 - Ensure that the patient has a safe place to go after they leave the hospital and a plan for home health or appropriate caregivers to provide necessary follow-up care
 - Communication amongst the multidisciplinary team will occur through verbal or documentation in the EMR

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Transplant Program ABC

- Each member of the multidisciplinary team is made available during all phases of transplant or donation care
- Multidisciplinary team transplant education
 - All staff who are newly hired and caring for transplant candidates, recipients or potential living donors, or living donors will receive transplant specific orientation through computer-based training (CBT).
 - Annual specific CBTs will be assigned to staff.
 - Additional, ongoing transplant educational opportunities are available to the members of the transplant multidisciplinary team.

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ACTIVE LEARNING: Question #7

- Patient BD received a simultaneous kidney pancreas transplant 14 days ago. A CMS surveyor that is currently on site conducting a transplant survey locates transplant pharmacy assessments and written documentation in BD's medical chart on post transplant day 2 and 12. Based on this information and that provided within your program's multidisciplinary team policy is the pharmacy team in compliance?

Transplant Multidisciplinary Team Policy - *Pharmacist*

- Assess and provide written documentation for each transplant recipient within 72 hours of transplantation
- Re-assess and provide written documentation for every transplant recipients every 7 days

115

ACTIVE LEARNING: Question #7

- Patient BD received a simultaneous kidney pancreas transplant 14 days ago. A CMS surveyor that is currently on site conducting a transplant survey locates transplant pharmacy assessments and written documentation in BD's medical chart on post transplant day 2 and 12. Based on this information and that provided within your program's multidisciplinary team policy is the pharmacy team in compliance?

Transplant Multidisciplinary Team Policy - *Pharmacist*

- Assess and provide written documentation for each transplant recipient within 72 hours of transplantation
- Re-assess and provide written documentation for every transplant recipients every 7 days

- A. Yes, in compliance with center policy
- B. Yes, in compliance with center and CMS CoP's
- C. No, not in compliance with center or CMS CoP's
- D. No, not in compliance with center policy

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ACTIVE LEARNING: Question #7

- Patient BD received a simultaneous kidney pancreas transplant 14 days ago. A CMS surveyor that is currently on site conducting a transplant survey locates transplant pharmacy assessments and written documentation in BD's medical chart on post transplant day 2 and 12. Based on this information and that provided within your program's multidisciplinary team policy is the pharmacy team in compliance?

Transplant Multidisciplinary Team Policy - Pharmacist

- Assess and provide written documentation for each transplant recipient within 72 hours of transplantation
- Re-assess and provide written documentation for every transplant recipients every 7 days

- A. Yes, in compliance with center policy
- B. Yes, in compliance with center and CMS CoP's
- C. **No, not in compliance with center or CMS CoP's**
- D. No, not in compliance with center policy

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Multidisciplinary Transplant Team Policy

Transplant Pharmacist - Summary

- Ensure responsibilities are defined to be in accordance with
 - Transplant regulations
 - Practice standards/best practices
 - Institutional policies and procedures (hospital, pharmacy and transplant)
- Actions must equal what is written in policies
 - Continual audit/revisions to ensure this always occurs
- Too many details may have negative consequences

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QAPI

Quality Assessment (QA)

- “A process for ensuring compliance with specifications/requirements/standards to identify indicators for performance monitoring and compliance with standards”

Performance Improvement (PI)

- “An organized, structured process used to identify parts of the transplant program that need addressing due to failure to meet QA expectations and/or results of adverse events”

<https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/downloads/QAPIResourceGuide090810.pdf>
https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_x_otp.pdf

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Transplant Regulations



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https://optn.transplant.hrsa.gov/media/igbbmah/optn_bylaws.pdf [Accessed 4/14/22]

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Transplant QAPI Regulations

Transplant QAPI

OPTN

CMS

➔

D.4 Quality Assessment and Performance Improvement (QAPI) Requirement


A. Transplant hospitals must develop, implement and maintain an ongoing, comprehensive and data-driven QAPI program designed to monitor and evaluate compliance with OPTN requirements and produce measurable process improvement initiatives. The QAPI plan must incorporate all designated transplant programs at the transplant hospital.

B. The hospital must document implementation of all elements of the QAPI plan.

- ✓ Develop a comprehensive, data driven QAPI program
- ✓ Designed to monitor and evaluate compliance with OPTN and produce measurable PI initiatives
- ✓ Must incorporate all transplant programs within the hospital
- ✓ Must document implementation of all elements of the plan

https://optn.transplant.hrsa.gov/media/1gbbmahi/optn_bylaws.pdf [Accessed 4/14/22]

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Transplant QAPI Regulations

Transplant QAPI

OPTN

CMS

➔

Transplant CoP's

- General Requirements
- Data Submission, Clinical Experience, and Outcome Requirements
- Process Requirements
 - 482.90 Patient and Living Donor Selection
 - 482.92 Organ Recovery and Receipt
 - 482.94 Patient and Living Donor Management
 - 482.96 Quality Assessment and Performance Improvement (QAPI)
 - 482.98 Human Resources
 - 482.100 Organ Procurement
 - 482.102 Patient and Living Donor Rights
 - 482.104 Additional Requirements for Kidney Transplant Centers


https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_x_otp.pdf

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Transplant CoP's

Quality Assessment and Performance Improvement (QAPI)

- STANDARD (TAG X099)
 - Transplant Centers must develop, implement, and maintain a written, comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all transplantation services including services provided under contract or arrangement
 - ✓ Transplant specific
 - ✓ Bidirectional flow of information (Transplant QAPI ↔ Hospital QAPI)
 - ✓ Includes participation of transplant program key personnel




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Transplant CoP's

Quality Assessment and Performance Improvement (QAPI)

- 482.96 Standard – Transplant QAPI Program (TAG X099)
- 482.96(a) Components of a QAPI Program (TAG X100)
Performance Improvement (TAG X101)
- 482.96(b) Adverse Events (TAG X102)
- 482.96(b2) Analysis of Adverse Events (TAG X103)
Prevent repeat events (TAG X104)




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Transplant CoP's

Quality Assessment and Performance Improvement (QAPI)

- 482.96 Standard – Transplant QAPI Program (TAG X099)
- 482.96(a) Components of a QAPI Program (TAG X100)
Performance Improvement (TAG X101)
- 482.96(b) Adverse Events (TAG X102)
- 482.96(b2) Analysis of Adverse Events (TAG X103)
Prevent repeat events (TAG X104)




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Transplant CoP's

Quality Assessment and Performance Improvement (QAPI)

- 482.96 Standard – Transplant QAPI Program (TAG X099)
- 482.96(a) Components of a QAPI Program (TAG X100)
Performance Improvement (TAG X101)
- 482.96(b) Adverse Events (TAG X102)
- 482.96(b2) Analysis of Adverse Events (TAG X103)
Prevent repeat events (TAG X104)




```

graph TD
    X099[X099  
Transplant QAPI Program] --- X100((X100  
Components))
    X099 --- X101((X101  
Performance Improvement))
    X099 --- X102((X102  
Adverse Events))
    X099 --- X103((X103  
Analysis))
    X099 --- X104((X104  
Prevention))
  
```

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X099
Transplant QAPI Program

X100
Components

X101
Performance Improvement

X102
Adverse Events

X103
Analysis


X104
Prevention

482.96 (a): Components of a QAPI Program (Tag X100)

- The transplant center's QAPI program must use objective measures to evaluate performance with regards to transplantation activities and outcomes.
 - This standard requires transplant QAPI programs to identify, implement, assess and re-assess objective measures to evaluate and improve both their transplantation outcomes as well as the quality, safety and performance of their transplantation activities, across all phases of transplant and living donation.

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QA – Quality Assessment

- Transplant objective measures
 - ✓ Identify, implement, assess and reassess
 - Define
 - SMART (*specific-measurable-attainable-relevant-timebound*)
 - Categorize
 - **Process**: series of actions or functions during delivery of patient care
 - **Outcome**: measurement or event that is the result of the transplant process

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Example: Transplant Objective Measures

- Process measures
 - Time (days) from waitlisting to transplant
 - Completion rate: discharge education checklist
 - Informed consent obtained



- Define – consent type
 - Transplant
 - Surgical
 - Donor specific
- What is the measure?
 - Consent obtained
 - Form correctly completed
- What is the timepoint?
- What is the frequency?

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Example: Transplant Objective Measures

- Process measures
 - Time (days) from waitlisting to transplant
 - Completion rate: discharge education checklist
 - Informed consent obtained
- Outcome measures
 - Patient and graft survival
 - Hospital length of stay
 - Incidence of CMV viremia after completion of prophylaxis

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Example: Transplant Objective Measures

Phase	Process	Outcome
PRE-transplant/donation		
PERI-transplant/donation	Multidisciplinary team member documentation	
POST-transplant/donation	Action or Function Is the content correct? Occurs at necessary timepoint(s)?	Measurement or Event Did it happen? Frequency of occurrence?

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Example: Transplant Objective Measures

Phase	Process	Outcome
PRE-transplant/donation	✓	✓
PERI-transplant/donation	✓	✓
POST-transplant/donation	✓	✓

Multidisciplinary team member documentation

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Example: Transplant Objective Measures

Phase	Process	Outcome
PRE-transplant/donation	<ul style="list-style-type: none"> Time to obtain financial clearance Time from evaluation to selection Time from listing to transplant SRTR data reviewed 	
PERI-transplant/donation	<ul style="list-style-type: none"> ABO verification Cold ischemia time Informed consent 	
POST-transplant/donation	<ul style="list-style-type: none"> Time to completion of discharge summary Multidisciplinary discharge education completed (all components) 	

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Example: Transplant Objective Measures

Phase	Process	Outcome
PRE-transplant/donation	<ul style="list-style-type: none"> Time to obtain financial clearance Time from evaluation to selection Time from listing to transplant SRTR data reviewed 	<ul style="list-style-type: none"> Waitlist mortality New referral volume Living donor questionnaire completed Incidence of PVT (pulmonary vein thrombosis)
PERI-transplant/donation	<ul style="list-style-type: none"> ABO verification Cold ischemia time Informed consent 	<ul style="list-style-type: none"> Primary graft dysfunction Delayed graft function Unplanned operation
POST-transplant/donation	<ul style="list-style-type: none"> Time to completion of discharge summary Multidisciplinary discharge education completed (all components) 	<ul style="list-style-type: none"> Patient/graft survival Incidence/severity of rejection Hospital readmissions Patient satisfaction

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Example: Transplant Objective Measures

Phase	KIDNEY		LIVER	
	Process	Outcome	Process	Outcome
PRE-transplant/donation	<ul style="list-style-type: none"> Accuracy of 2728 form 	<ul style="list-style-type: none"> 2728 form obtained prior to listing 	<ul style="list-style-type: none"> Functional status assessed at initial evaluation 	<ul style="list-style-type: none"> Percent hospitalized prior to surgery
PERI-transplant/donation				
POST-transplant/donation				

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Active Learning Question #8

- Delayed graft function (DGF) post kidney transplant is what type of objective measure?

- A. Process
B. Outcome

It Depends.....

Process	Outcome
<ul style="list-style-type: none"> Is it assessed? Is it documented? Is it accurate? 	<ul style="list-style-type: none"> Incidence? Incidence in x population?

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Transplant PHARMACIST Objective Measures

Phase	Process	Outcome
PRE-transplant/donation		
PERI-transplant/donation		
POST-transplant/donation		

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Transplant PHARMACIST Objective Measures

Phase	Process	Outcome
PRE-transplant/donation	<ul style="list-style-type: none"> • OARRS (PDMP) report reviewed • Dialysis scorecard completed 	
PERI-transplant/donation	<ul style="list-style-type: none"> • Enrolled Self Medication Program (SMP) • Discharge note complete within 12 hours 	
POST-transplant/donation	<ul style="list-style-type: none"> • Pharmacy follow up visit scheduled • BAASIS[®] interview • Tacrolimus CV% 12 month review 	

BAASIS[®] = The Basel Assessment of Adherence to Immunosuppressive Medications Scale, CV = coefficient of variation, OARRS = Ohio automated Rx reporting system; PDMP = prescription drug monitoring program

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Transplant PHARMACIST Objective Measures

Phase	Process	Outcome
PRE-transplant/donation	<ul style="list-style-type: none"> OARRS (PDMP) report reviewed Dialysis scorecard completed 	<ul style="list-style-type: none"> Completion of immunization history documentation Rate adherence assessment completed
PERI-transplant/donation	<ul style="list-style-type: none"> Enrolled Self Medication Program (SMP) Discharge note complete within 12 hours 	<ul style="list-style-type: none"> Recipients enrolled in specialty pharmacy Therapeutic interchange / conversion Pain category (A, B or C)
POST-transplant/donation	<ul style="list-style-type: none"> Pharmacy follow up visit scheduled BAASIS assessment Tacrolimus CV% 12 month review 	<ul style="list-style-type: none"> Incidence/severity of rejection CMV DNA monitoring post prophylaxis completed per protocol Readmissions due to drug toxicities

BAASIS® = The Basel Assessment of Adherence to Immunosuppressive Medications Scale, CV = coefficient of variation, OARRS = Ohio automated Rx reporting system; PDMP = prescription drug monitoring program

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ACTIVE LEARNING: Question #9

- Which of these is the best example of a smart objective measure?
 - Post transplant adherence assessment completion rate
 - Post lung transplant adherence assessment completion rate
 - Post lung transplant 6 month adherence assessment completion rate
 - Post lung transplant 6 month ambulatory adherence assessment completion rate

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ACTIVE LEARNING: Question #9

- Which of these is the best example of a smart objective measure?
 - A. Post transplant adherence assessment completion rate
 - B. Post lung transplant adherence assessment completion rate
 - C. Post lung transplant 6 month adherence assessment completion rate
 - D. Post lung transplant 6 month ambulatory adherence assessment completion rate

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QA Activities

- Identify process and outcome measures (program specific)
- Define objective measures
- Select benchmarks (standards/targets/goals) for objective measures

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Benchmarks

- Quantitative points of reference by which objective measures can be assessed, monitored and compared
- Select an associated benchmark for each objective measure
- Regularly assess/update the benchmark

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Transplant Benchmarks – Source Examples

- Best practices - practice guidelines, protocols/guidelines, care maps
- Compliance with regulations
- Credentialing requirements
- National benchmarks/ industry standards
- Program's own findings, data and/ or independent discovery
- Research, registries/databases
- Various decision aids, such as checklists, reminders, alerts and prompts
- Outcomes of the analysis of adverse events/ sentinel events/ accident reports
- Clinical variances from standards of care
- Response to complaints/results of complaint investigations

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Relating Benchmarks with Objective Measures

Type	Objective Measure	Benchmark	Source(s)
Process	Active candidates on the waitlist (mean per quarter)	≥ 300	<ul style="list-style-type: none"> • UNOS Kidney Benchmark Report • SRTR PSR • Internal data

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Relating Benchmarks with Objective Measures

Type	Objective Measure	Benchmark	Source(s)
Process	Active candidates on the waitlist (mean per quarter)	≥ 300	<ul style="list-style-type: none"> • UNOS Kidney Benchmark Report • SRTR PSR • Internal data
Outcome	Rate of Acute Cellular Rejection (ACR) @ 1 year post RTx	7–12%	<ul style="list-style-type: none"> • OPTN/SRTR 2019 Kidney Annual Data Report • Internal data
		$\leq 7\%$	<ul style="list-style-type: none"> • OPTN/SRTR 2019 Kidney Annual Data Report
		$< 12\%$	<ul style="list-style-type: none"> • Internal data

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QA Activities

- Identify process and outcome measures (program specific)
- Define objective measures
- Select benchmarks (standards/targets/goals) for objective measures
- Develop and implement process for data collection and monitoring

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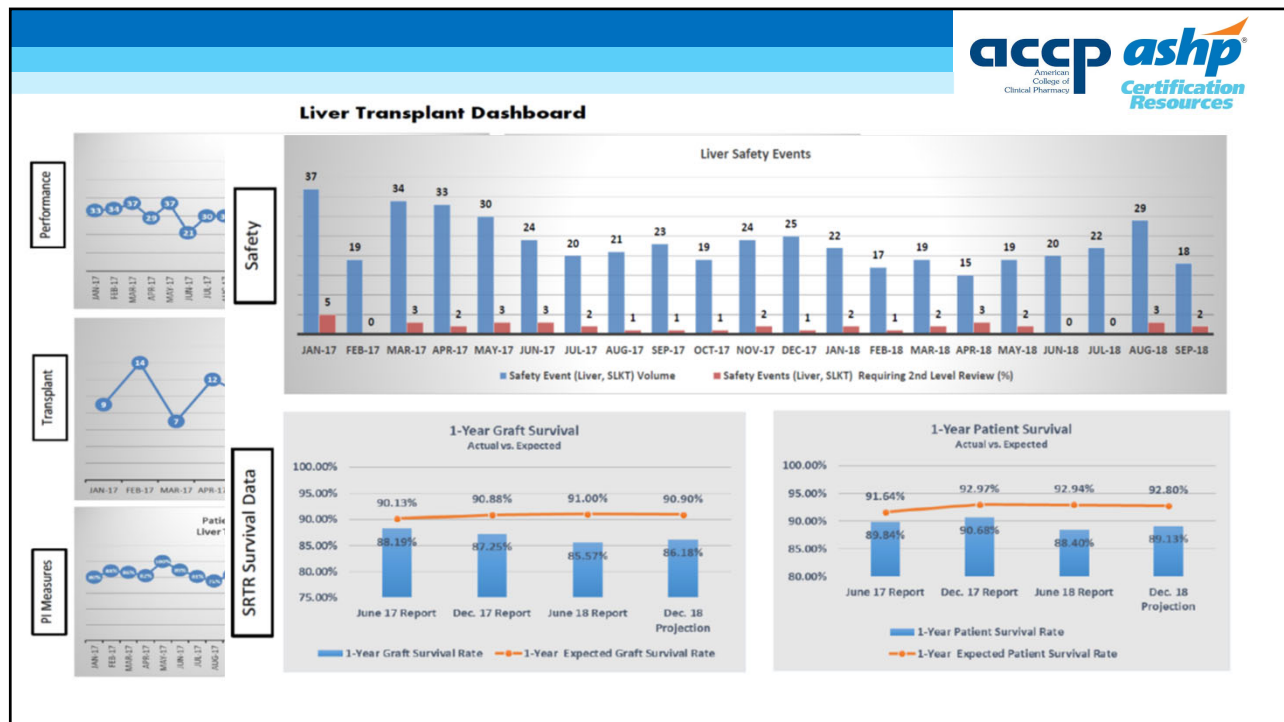
147

Examples (Scorecards, Report Cards, Dashboards)

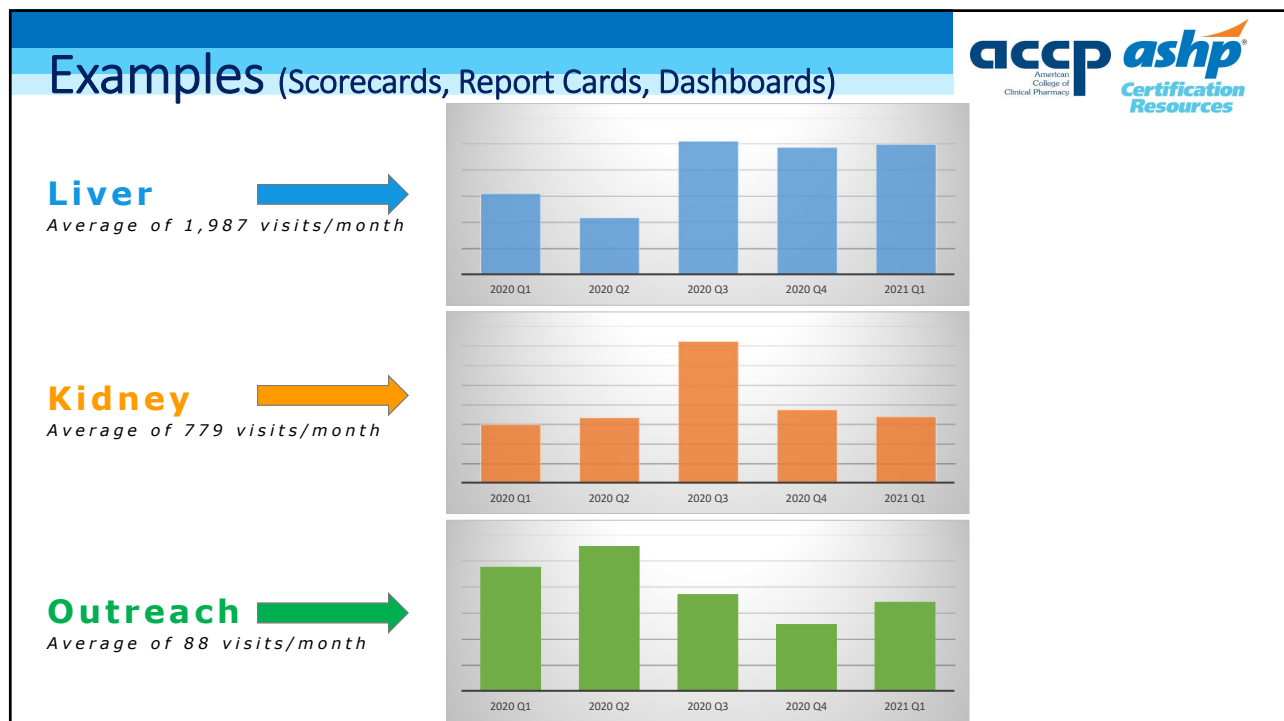
PRE TRANSPLANT PHASE				Owner	Target	Frequency	Jan '20	Feb '20	Mar '20	Apr '20	May '20	June '20
ALL PROGRAMS												
Waitlist Sensitivity												29/29
ABO source documents on file 2x - New Vessels												12
KIDNEY												46
SRTR Reviewed prior to Listing (at Eval)												37
Informed Consent prior to Listing (at Eval)												
2728 Dialysis Start Dates Match - UNO												
Listing Notification Letter Sent within 10 Da												
Evaluation Denial Letters within 10 Da												
Waitlist Removal Letter within 10 Day												
LIVER												
SRTR Reviewed prior to Listing (at Eval)												
Informed Consent prior to Listing (at Eval)												
Listing Notification Letter Sent within 10 Da												
Evaluation Denial Letters within 10 Da												
Waitlist Removal Letter within 10 Day												
PANCREAS												
SRTR Reviewed prior to Listing (at Eval)												
Informed Consent prior to Listing (at Eval)												
Listing Notification Letter Sent within 10 Da												
Evaluation Denial Letters within 10 Da												
Waitlist Removal Letter within 10 Day												
HEART												
Informed Consent prior to Listing (at Eval)												
SRTR Reviewed prior to Listing (at Eval)												
Listing Notification Letter Sent within 10 Da												
Evaluation Denial Letters within 10 Da												
Waitlist Removal Letter within 10 Day												
LIVING DONOR - Kidney												
SRTR Reviewed at Evaluation (beginning)												
Informed Consent at Evaluation												
ILDA Social Work Evaluation (initial)												
ILDA SW Eval (within 12 months prior)												

Transplant Quality & Safety - Performance Improvement															
Category	Transplant Phase			GOAL	Metric/Objective Measure	19-Jul	19-Aug	19-Sep	19-Oct	19-Nov	19-Dec	2020 Average	2019 Target	Status of Goal	
	PRE	PERI	POST												
Ambulatory (Top Clinic)	X		X	Improve and assess overall HA (CLABS) (CAUTI, SSI, C-CHF, MRSA) rates (QDEE)	Hand Washing compliance before and after each patient contact - Kidney program				100%	100%	100%	100%	100%		
					Hand Washing compliance before and after each patient contact - Liver program				90%	93%	92%	92%	100%		
Kidney	X		X	Achieve "Rate hospital 9 or 10" (QDEE)	PG Outpatient survey: Transplant Overall Provider rating of 9 or 10 - Kidney program				94%	91%	93%	93%	83%		
					PG Outpatient survey: Transplant Overall Provider rating of 9 or 10 - Liver program				94%	78%	62%	78%	83%		
Liver	X			Decrease patient care delays	Evaluation to listing (median days)					122	122	120	*		
Liver	X			Improve patient selection	6 minute walk test for all NEW visits										
					Hand grip strength for all NEW visits										
FY15 Q3	13	54%	53.8%	69.2%	52	27.6	10	76.9%	4.0	4.0	1	1.4	0	0.0%	38.2%
FY15 Q4	5	26%	20.0%	80.0%	45	24.5	2	40.0%	3.5	3.0	1	1.5	0	0.0%	16.1%

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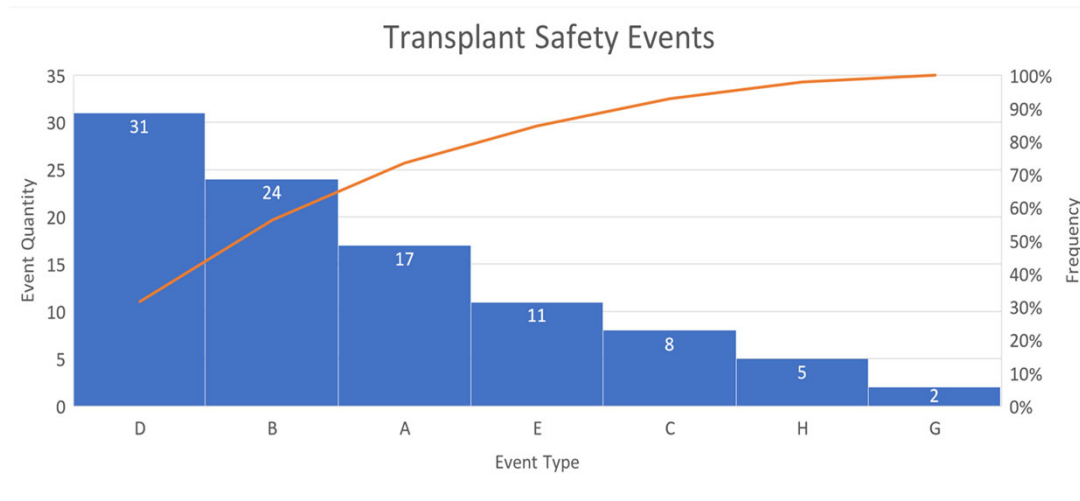


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Examples (Scorecard, Report Card, Dashboard)



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QA Activities

- Identify process and outcome measures (program specific)
- Define objective measures
- Select benchmarks (standards/targets/goals) for objective measures
- Develop and implement process for data collection and monitoring
- Analyze results regularly

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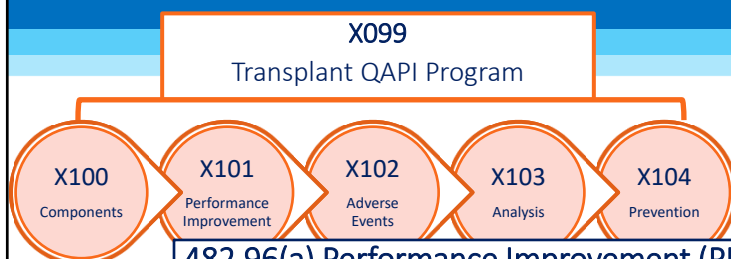
152

Objective Measures – Results Analysis

Type	Objective Measure	Q1	Q2	Q3	Q4	Benchmark	Source(s)
Process	Active candidates on the waitlist (mean per quarter)	275	302	325	311	≥ 300	<ul style="list-style-type: none"> • UNOS Kidney Benchmark Report • SRTR PSR • Internal data

Type	Objective Measure	Q1	Q2	Q3	Q4	Benchmark	Source(s)
Process	Active candidates on the waitlist (mean per quarter)	421	379	352	333	≥ 300	<ul style="list-style-type: none"> • UNOS Kidney Benchmark Report • SRTR PSR • Internal data

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482.96(a) Performance Improvement (PI) (Tag X101)

- The transplant program must take actions that result in PI and track performance to ensure that improvements are sustained.
 - Program must use what it learns from monitoring the objective measures described in Tag X100 to identify and implement actions to improve its performance
 - Program should review the available evidence, if any, for particular PI strategies and implement activities that are most likely to be effective in addressing the specific factors that are contributing to the program's performance.
 - If successful, performance will need to be monitored over time to verify that improvements are sustained.
 - If not, the program will need to re-evaluate, determine an appropriate alternative course of action, and track performance.

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When to consider a PI initiative?

- Objective measure not meeting benchmark/goal
- Unfavorable trend
- Gap analysis
- Safety issue identified
- New or revised internal policy/protocol/guideline/process
- New or revised regulatory requirement
- Regulatory citation
- Complaint / recommendation

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When to consider a PI initiative?

Transplant Examples

- Objective measure not meeting benchmark/goal
Ambulatory hand hygiene compliance
- Safety issue identified
Increase in patient FALL events on the inpatient transplant unit
- New or revised regulatory requirement
Universal recipient infectious risk testing
- Regulatory citation
Untimely TIEDI form submission

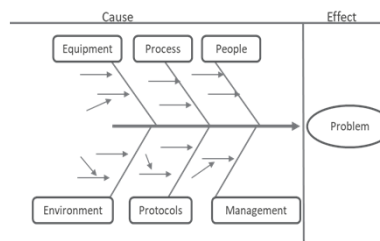
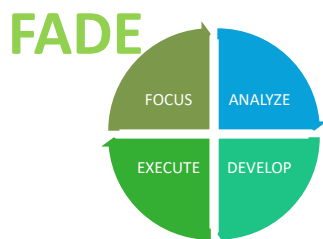
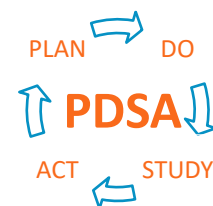
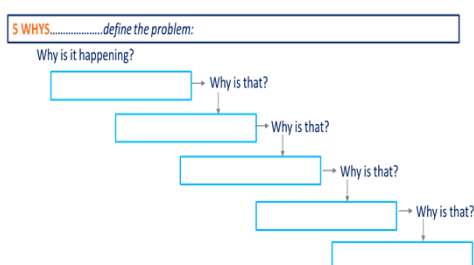
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PI Methods/Tools

- Multiple types available
- Common goal = improvement
- Select based on institution/program preference
 - May vary depending on situation (overall, specific program, personnel etc.)

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Examples

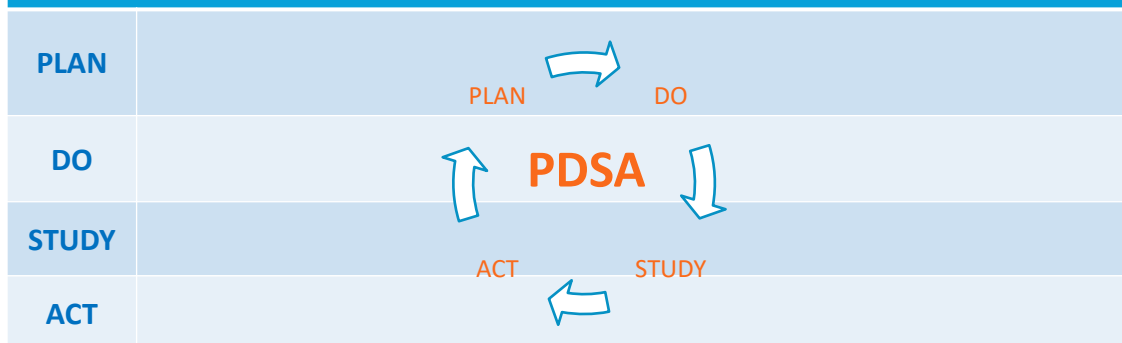


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Example: Performance Improvement

Problem: increase in hospital re-admission events due to hyperglycemia

Early Blood Sugar Management Post Heart Transplantation (HTx)



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Example: Performance Improvement

Problem: increase in hospital re-admission events due to hyperglycemia

Early Blood Sugar Management Post Heart Transplantation (HTx)

PLAN	<ul style="list-style-type: none"> Evaluate current process for blood sugar management in HTx recipients to determine <ul style="list-style-type: none"> a) If it is effective? b) Is there room for improvement?
DO	
STUDY	
ACT	

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Example: Performance Improvement

Problem: increase in hospital re-admission events due to hyperglycemia

Early Blood Sugar Management Post Heart Transplantation (HTx)

PLAN	<ul style="list-style-type: none"> Evaluate current process for blood sugar management in HTx recipients to determine <ol style="list-style-type: none"> If it is effective? Is there room for improvement?
DO	<ul style="list-style-type: none"> Perform retrospective data collection <ol style="list-style-type: none"> HbA1c: @ baseline, 3, 6, 12 months Compliance with HbA1c assessments (% completed): baseline, 3, 6, 12 months
STUDY	
ACT	

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Example: Performance Improvement

Problem: increase in hospital re-admission events due to hyperglycemia

Early Blood Sugar Management Post Heart Transplantation (HTx)

PLAN	<ul style="list-style-type: none"> Evaluate current process for blood sugar management in HTx recipients to determine <ol style="list-style-type: none"> If it is effective? Is there room for improvement?
DO	<ul style="list-style-type: none"> Perform retrospective data collection <ol style="list-style-type: none"> HbA1c: @ baseline, 3, 6, 12 months Compliance with HbA1c assessments (% completed): baseline, 3, 6, 12 months
STUDY	<ul style="list-style-type: none"> Analyze data
ACT	

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Example: Performance Improvement

Problem: increase in hospital re-admission events due to hyperglycemia

HbA1c	Baseline (n=23)	3 months (n=19)	6 months (n=19)	12 months (n=14)
Median	5.9	6.6	6.2	6.0
SD	4.3 - 8.1	4.8 - 9.9	5.5 - 9.0	5.2 - 9.0

HbA1c assessment adherence	Baseline (n=23)	3 months (n=19)	6 months (n=19)	12 months (n=14)
Rate	96% (23/24)	79% (19/24)	79% (19/24)	58% (14/24)
Days	101.7 ± 81.0	191.5 ± 87.6	301.6 ± 87.6	354.7 ± 14

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Example: Performance Improvement

Problem: increase in hospital re-admission events due to hyperglycemia

Early Blood Sugar Management Post Heart Transplantation (HTx)

PLAN	<ul style="list-style-type: none"> Evaluate current process for blood sugar management in HTx recipients to determine <ol style="list-style-type: none"> If it is effective? Is there room for improvement?
DO	<ul style="list-style-type: none"> Perform retrospective data collection <ol style="list-style-type: none"> HbAa1c: @ baseline, 3, 6, 12 months Compliance with HbA1c assessments (% completed): baseline, 3, 6, 12 months
STUDY	<ul style="list-style-type: none"> Analyze data
ACT	<ul style="list-style-type: none"> Continue data collection to obtain larger sample size Categorize recipients BS management according to management group (≤ 3 months post) <ol style="list-style-type: none"> HTx team Endo_{internal} Endo_{external} Primary care None Determine % on insulin or oral therapy @ baseline, 3, 6, 12 months Review in 3 months



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Example: Performance Improvement

- Outpatient rabbit antithymocyte globulin (rATG) administration to reduce hospital length of stay and drug expenditures
 - Assess hospital readmission trends to ensure benefits sustainable
 - Assess rate within 7days of rATG administration
 - Determine degree of readmissions related to rATG adverse drug reactions
 - Outpatient rATG is feasible, safe and did not result in increased readmissions
 - % of overall readmissions ranged from 9-12% (2008-14) and <10% (2014-2016)
 - Outpatient rATG infusions potentially resulting in readmission <4%/year

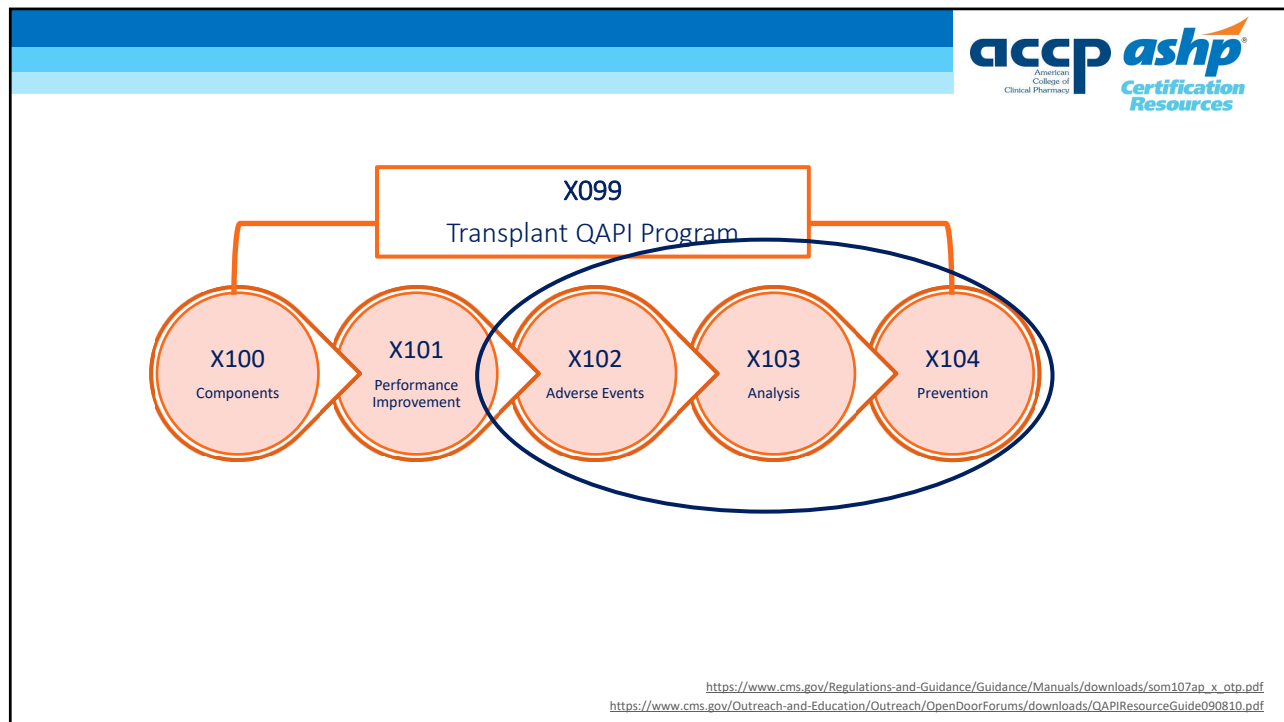
Pharmacotherapy 2018;38(6):620-27

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QAPI Summary

- **Quality Assessment (objective measures)**
 - Identify process and outcome measures (program specific)
 - Define objective measures (Smart)
 - Select benchmarks (standards/targets/goals)
 - Develop and implement process for data collection and monitoring
 - Analyze results regularly
- **Performance Improvement**
 - Identify area(s) not meeting expectations
 - Continuous monitoring
 - Sustained improvement

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X099
Transplant QAPI Program

X100
Components

X101
Performance Improvement

X102
Adverse Events

X103
Analysis

X104
Prevention

482.96(b): Adverse Events (Tag X102)

- A transplant program must establish and implement written policies to address and document adverse events that occur during any phase of an organ transplantation case.
- Policies must address at a minimum, the process for identification, reporting, analysis, and prevention of adverse events

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_x_otp.pdf
<https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/downloads/QAPIResourceGuide090810.pdf>

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X099
Transplant QAPI Program

X100 Components → X101 Performance Improvement → X102 Adverse Events → X103 Analysis → X104 Prevention

482.96(b): Adverse Events (Tag X102)

- A transplant program must establish and implement written policies to address and document adverse events that occur during any phase of an organ transplantation case
 - Policies must address at a minimum the identification, reporting, and prevention of adverse events
 - Policies must include →
 - Clear definition of what the program considers an adverse event incorporating the CMS regulatory definition
 - “An adverse event is defined at 42 CFR §482.70 as “an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof.”
 - Procedures for internal reporting of adverse events in all phases of transplant recipient or living donor care within the hospital
 - Process(es) used for analyzing adverse events in the transplant program
 - Process for developing, evaluating and tracking actions to prevent recurrence
 - Required timeframe for reporting, investigating and analyzing adverse events

Examples of Transplant Adverse Events

- Donor disease transmission
- Death / Graft loss within 3 years
- Medication error
- Missed abnormal result
- Donor readmission within 1 year of donation

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_x_otp.pdf

<https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/downloads/QAPIResourceGuide090810.pdf>

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Transplant Safety Events and Volume Per Month (Total Census)

Legend: Monthly Txp Volume (Epic) (blue bars), Monthly Txp incidents (red line), Monthly Midas incidents (green line)

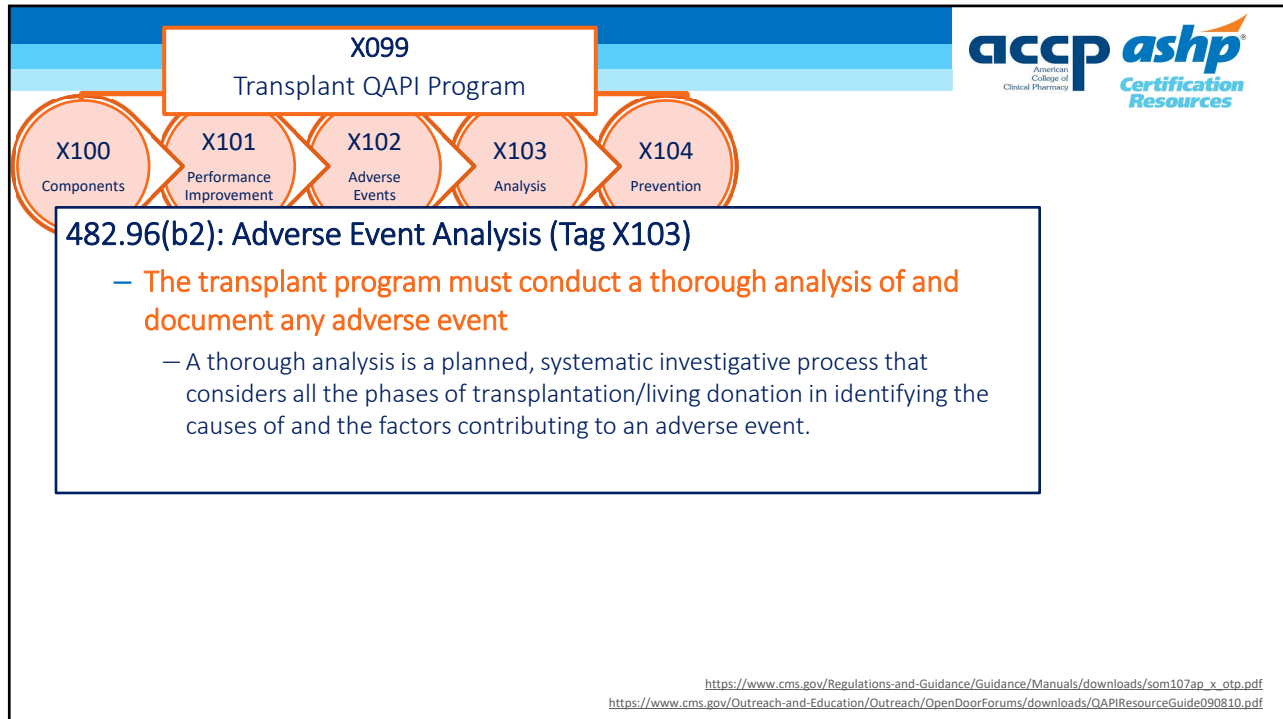
Month	Monthly Txp Volume (Epic)	Monthly Txp incidents	Monthly Midas incidents
Jan-20	1100	55	35
Feb-20	1050	60	40
Mar-20	900	57	27
Apr-20	750	82	35
May-20	700	51	35
Jun-20	950	59	45
Jul-20	1050	50	35
Aug-20	1050	60	45
20-Sep	1050	50	35
20-Oct	1050	50	35
20-Nov	1100	71	45
20-Dec	1000	90	45

Transplant Events - July thru Sep 2019 (n=113)

Event_No	Facility_Name	Event_Date	Date_Received	MRN	Encounter_Name	Txp Organ	Reviewed/72 hrs	Txp FU	Txp FU details	Location_Name	Event_Type_Name

Other (other)	0
abdominal	0
Heart	0
LVAD	0

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X099
Transplant QAPI Program

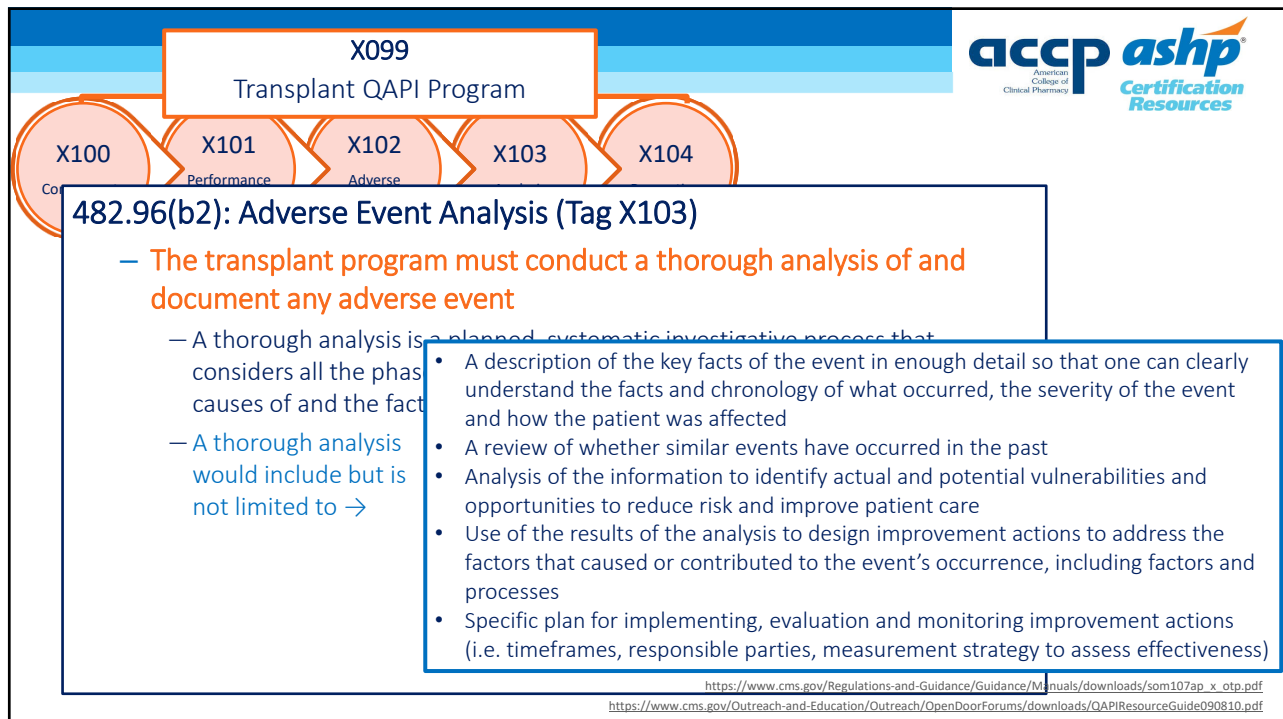
X100 Components X101 Performance Improvement X102 Adverse Events X103 Analysis X104 Prevention

482.96(b2): Adverse Event Analysis (Tag X103)

- The transplant program must conduct a thorough analysis of and document any adverse event
 - A thorough analysis is a planned, systematic investigative process that considers all the phases of transplantation/living donation in identifying the causes of and the factors contributing to an adverse event.

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_x_otp.pdf
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X099
Transplant QAPI Program

X100 Components X101 Performance Improvement X102 Adverse Events X103 Analysis X104 Prevention

482.96(b2): Adverse Event Analysis (Tag X103)

- The transplant program must conduct a thorough analysis of and document any adverse event
 - A thorough analysis is a planned, systematic investigative process that considers all the phases of transplantation/living donation in identifying the causes of and the factors contributing to an adverse event.
 - A thorough analysis would include but is not limited to →
 - A description of the key facts of the event in enough detail so that one can clearly understand the facts and chronology of what occurred, the severity of the event and how the patient was affected
 - A review of whether similar events have occurred in the past
 - Analysis of the information to identify actual and potential vulnerabilities and opportunities to reduce risk and improve patient care
 - Use of the results of the analysis to design improvement actions to address the factors that caused or contributed to the event's occurrence, including factors and processes
 - Specific plan for implementing, evaluation and monitoring improvement actions (i.e. timeframes, responsible parties, measurement strategy to assess effectiveness)

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_x_otp.pdf
<https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/downloads/QAPIResourceGuide090810.pdf>

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Initials	MRN	Organ Transplanted				Date Transplanted				PRE PERI POST
Event Type (circle one)	Death & Graft Loss Graft Loss Other	Event Date	Time to Event (# POD)		Event Location (i.e UCMC, Outside facility, Home, other)		Transplant Phase (circle one)		PRE PERI POST	
Event Cause										

PRE – LTx Evaluation

DOB	Age	Race	Height	Weight(pds)	BMI	Ethnic group
Date Eval start	Date of selection	Date of Listing	Urgent Listing	Attended listing Class		
Date(s) of WL (if applicable)	Marital status	ESLD	Blood Type			
Place of residence	Children	History of diabetes	HbA1c value	HbA1c date		
History of malignancy	Description	History of HCC	Outside Milan	History PVT		
History of abdominal surgeries	Other Comorbidities					
CMV IgG	EBV IgG	HCV Ab	HBSAg	HBCAb	Stress Echo date	
Stress positive	Cardiac consult	Pulm HTN	6 min walk	6 min walk result		
Txp ID evaluation	Comments					
1 st Psychosocial eval	Location	Caregiver(s) @ eval	Psychiatry history?	Narcotics @ listing?		
Support - primary	Support - others					
ETOH/Drug history	Substance Use disorder	Referral/Consults	Advance directives PRE			
Other evaluation comments						

DONOR

UNOS ID	MATCH ID	DOB	Age	Race	Gender	OPO
Height (ft/in)	Weight (lbs)	BMI kg/m ²	KDPI			
Admt date/time	Death date/time	Cross clamp date/time				
Cause of death	Mechanism of injury	Circumstances of death				
Cardiac arrest/downtime	Minutes	CPR Admin	Minutes	DCD		
CMV	EBV IgG	HCV Ab	HBSAg	HBCAb	HBSAb	Blood Type
History of IV Drug Use	Heavy ETOH	PHS	IRD (UCMC defined)			
History of malignancy?	Comments					

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Review Leader:

Review Forum:

Form Completed By:

Patient Name:

Transplant date:

Location (select one): ☐ UCMC ☐ Other

Brief summary of case:

Event type (select all that apply):

☐ Death (circle one: pre, peri or post)
☐ Procedural/Surgical Complication
☐ PNF (primary non function)
☐ Thrombotosis
☐ Bile/Urine/Pancreatic leak / stricture
☐ DGF (delayed graft function)
☐ SGF (slow graft function)
☐ Allograft rejection (circle one: acute, chronic)
☐ Infection
☐ Graft Loss
☐ Other: _____

Contributing Factors and System

Factor	Contributing
Recipient Selection/Waitlist Management	Yes or No
Donor Selection/Donor Management	Yes or No
Surgical/Periopertative	Yes or No
Anesthesia	Yes or No
Medical Management	Yes or No
Postoperative/Follow-up Care	Yes or No
Psychosocial	Yes or No
Dietary	Yes or No
Pharmacological Management	Yes or No
Nonadherence	Yes or No
Communication	Yes or No
Competency/Training	Yes or No
Equipment/Resources	Yes or No
Policies/Procedures/Process	Yes or No
Other	Yes or No

Were there any human factors involved?
(Examples: distraction, communication, fatigue, etc.)
Details: _____

Were there any environmental factors involved?
(Examples: location, lack of systems for organization)
Details: _____

Were there any failures in equipment?
(Examples: design, usability, safeguards, maintenance)
Details: _____

Were there any issues related to policy?
(Examples: effectiveness, usability, implementation)
Details: _____

Were there any organizational issues?
(Examples: lack of programmatic monitoring efforts)
Details: _____

Why did the event happen?

Your sentence event recap

Why? _____
 Why? _____
 Why? _____
 Why? _____
 Why? _____

[Root causes (to determine if truly a root cause, ask yourself: if you removed this root cause, would this event or problem have been prevented?)]

Peer Review Outcome:

☐ NOT Preventable
☐ Possibly Preventable
☐ Preventable

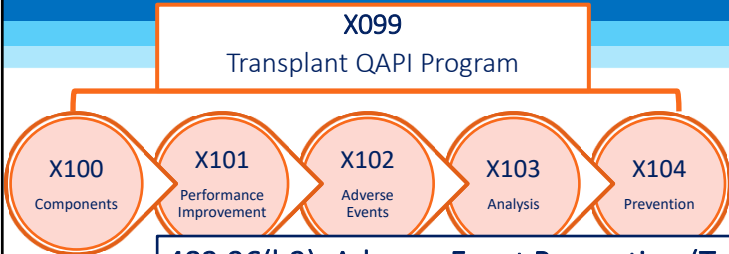

Review Conclusions:

☐ Agree with management - variation does not represent a problem (*disease process and/or known complications of care*)
☐ Management could be questioned but is within the standards of care
☐ Management and/or quality concern has been identified
☐ A SERIOUS management and/or quality concern that is outside the usual standards of care has been identified

Case Disposition and Follow-Up (select all that apply):

☐ No Action required
☐ Action Plan required
☐ Send to Transplant QAPI
☐ QUALITY IMPROVEMENT opportunity identified
☐ POLICIES/PROCEDURE/PROCESS issue identified
☐ EDUCATIONAL opportunity identified
☐ TREND to be used for dept. benchmarking; no issues identified
☐ Refer to Hospital Quality/Patient Safety
☐ Other: _____

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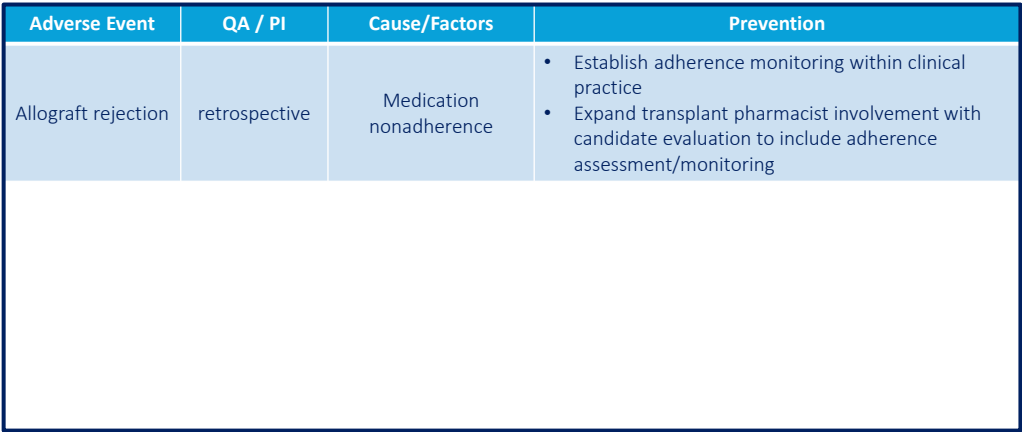

482.96(b2): Adverse Event Prevention (Tag X104)

- The transplant program must utilize the analysis to effect changes in the program's policies and practices to prevent repeat incidents
 - It's expected that the changes would be permanent so that the adverse event is not repeated, and that the transplant program would monitor that the change had been fully implemented

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_x_otp.pdf

<https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/downloads/QAPIResourceGuide090810.pdf>

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¹ AJT 2013;13:796-801

² Drug Healthcare and Patient Safety 2020;12:229-35

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Examples: Adverse Event Management

Adverse Event	QA / PI	Cause/Factors	Prevention
Allograft rejection	retrospective	Medication nonadherence	<ul style="list-style-type: none"> Establish adherence monitoring within clinical practice Expand transplant pharmacist involvement with candidate evaluation to include adherence assessment/monitoring
Medication errors ^{1,2}	retrospective	Discharge medication reconciliation; Inadequate medication lists	<ul style="list-style-type: none"> Discharge process to involve pharmacist Pharmacist-drive medication reconciliation

¹ AJT 2013;13:796-801² Drug Healthcare and Patient Safety 2020;12:229-35

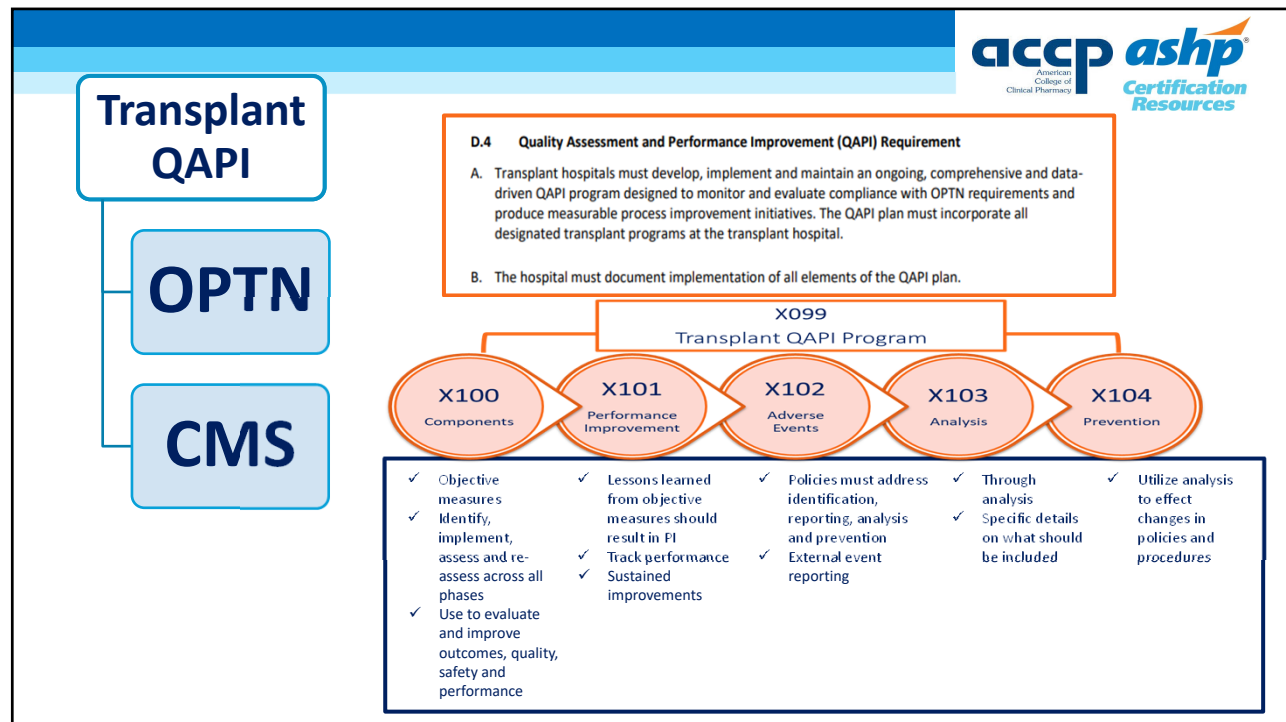
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Examples: Adverse Event Management

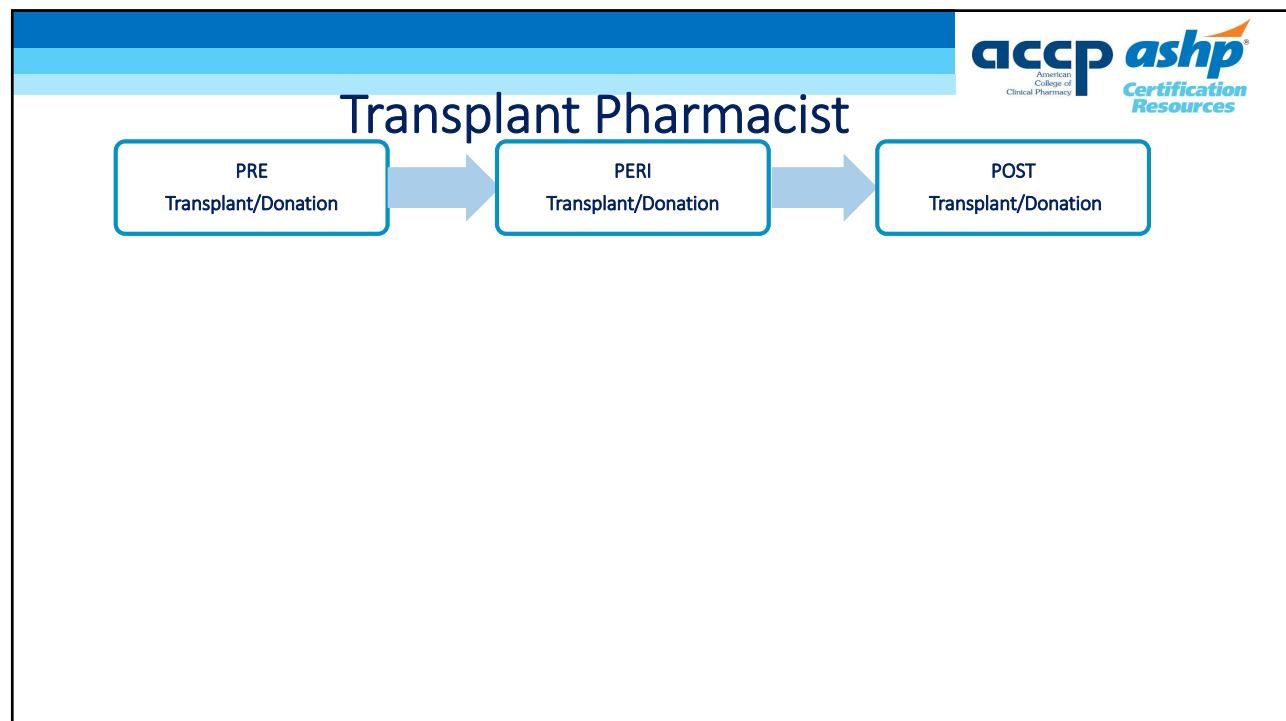
Adverse Event	QA / PI	Cause/Factors	Prevention
Allograft rejection	retrospective	Medication nonadherence	<ul style="list-style-type: none"> Establish adherence monitoring within clinical practice Expand transplant pharmacist involvement with candidate evaluation to include adherence assessment/monitoring
Medication errors ^{1,2}	retrospective	Discharge medication reconciliation; Inadequate medication lists	<ul style="list-style-type: none"> Discharge process to involve pharmacist Pharmacist-drive medication reconciliation
Donor Disease Transmission (CMV, HCV, HBV)	prospective	Discordant transplants (donor + / recipient -)	<ul style="list-style-type: none"> Expand prophylaxis / treatment protocols to include new categories Develop guideline for donor result(s) review/monitoring/action Addition of infectious disease risk assessment

¹ AJT 2013;13:796-801² Drug Healthcare and Patient Safety 2020;12:229-35

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Transplant Pharmacist

C. Clinical Transplant Pharmacist

Each transplant program should identify at least one Clinical Transplant Pharmacist on staff who will provide pharmaceutical expertise to transplant recipients. The Clinical Transplant Pharmacist should be a member of the transplant team, providing comprehensive pharmaceutical care to transplant recipients.

The Transplant Pharmacist will work with patients and their families, and members of the transplant team, including physicians, surgeons, nurses, clinical coordinators, social workers, financial coordinators and administrative personnel. The Transplant Pharmacist should be a licensed pharmacist with experience in transplant pharmacotherapy.

482.98 (e) – Transplant Team

- The transplant program must identify a multi-disciplinary transplant team and describe the responsibilities of each member of the team.
- The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and **pharmacology**.

482.90	TAG X051	Patient Selection
482.94(a)	TAG X082	Care via Multidisciplinary Team
482.94 (b1)	TAG X084	Waiting List Management
482.94(c3)	TAG X090	Care planning/documentation during transplant phase
482.94(cii)	TAG X091	Discharge planning/documentation during discharge phase
482.98 (e)	TAG X125	Transplant Team (responsibilities, qualification, training)

D.4 Quality Assessment and Performance Improvement (QAPI) Requirement

A. Transplant hospitals must develop, implement and maintain an ongoing, comprehensive and data-driven QAPI program designed to monitor and evaluate compliance with OPTN requirements and produce measurable process improvement initiatives. The QAPI plan must incorporate all designated transplant programs at the transplant hospital.

B. The hospital must document implementation of all elements of the QAPI plan.

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Key TakeAways

- Transplant regulations are NOT prescriptive.
- Transplant program policies should describe the composition, qualifications and responsibilities of transplant pharmacists in accordance with transplant regulations, practice standards and institutional policies and procedures.
 - Actions must equal written policies
 - Too many details may have negative consequences
- Transplant pharmacists are qualified to contribute to transplant QAPI initiatives (including QA, PI and adverse event management) and should seek opportunities to participate in QAPI activities to enhance the safety and effectiveness of medication use process within the SOT population.
- Transplant pharmacist involvement in collaborative relationships with the members of the multidisciplinary transplant team across all phases of care will continue to enhance and promote quality patient care across the continuum.

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Key References

- **National Organ Transplantation Act (NOTA)**
 - Available at: <https://www.livingdonorassistance.org/Documents/NOTA.pdf>
- **Scientific Registry of Transplant Recipients (SRTR)**
 - Available at: <https://www.srtr.org/>
- **United Network for Organ Sharing (UNOS)**
 - Available at: <https://unos.org/>
- **Organ Procurement Transplant Network (OPTN)** - <https://optn.transplant.hrsa.gov/>
 - **Organ procurement and transplantation network (OPTN) Policies**
Available at: https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf (course content based on those effective as of 4/11/22)
 - **Organ procurement and transplantation network (OPTN) Bylaws**
Available at: https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf (course content based on those effective as of 12/6/21)
- **Department of Health and Human Services, Center for Medicare and Medicaid Services (CMS)**
 - **Transplant**
 - Available at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Transplant>
 - **Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants; Final Rule**
Available at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Downloads/trancenterreg2007.pdf>
 - **State Operations Manual Appendix X – Guidance to Surveyors: Organ Transplant Programs (Rev. 200, Issued: 02-21-20)**
Available at: https://www.cms.gov/Regulations-and-Guidance/Manuals/downloads/som107ap_x_otp.pdf
 - **Quality Assessment and Performance Improvement (QAPI) Programs. Resource Guide for Transplant Surveyors 9/8/10.**
Available at: <https://www.cms.gov/outreach-and-education/outreach/opendoorforums/downloads/qapiresourceguide090810.pdf>
 - **A Conceptual Framework for Medicare Requirements for Quality Assessment and Performance Improvement in Solid Organ Transplant Programs**
Available at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Downloads/Five-Aspects-Transplant-QAPI.pdf>

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Transplant Regulations and Performance Improvement

Tiffany E. Kaiser, Pharm.D., M.S., FCCP
Director, Solid Organ Transplant Quality
University of Cincinnati
Cincinnati, Ohio

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