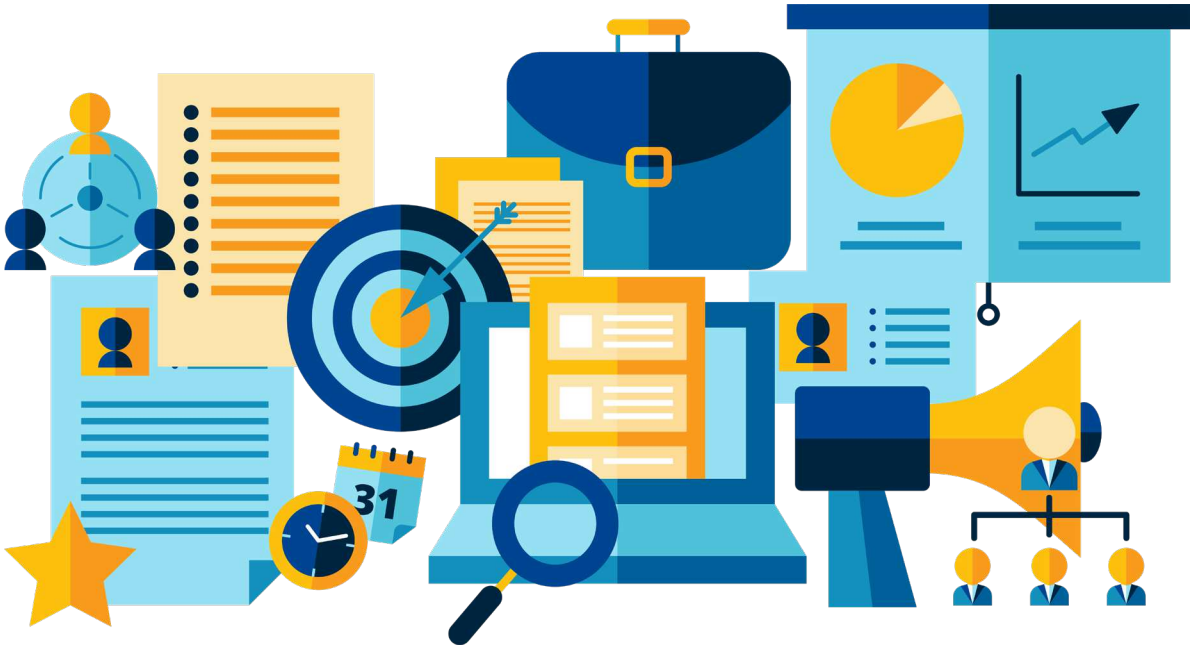
TRANSPLANT QUALITY CORNER
ESSENTIAL QUALITY-FOCUSED TOPICS FOR TRANSPLANTATION
SEPTEMBER 2024 ISSUE 1



UNRAVELING THE COMPLEXITIES OF COMPLIANCE

OPTN Infectious Disease Policy Review

THE Alliance
Equipping a Modern Profession of Lifesavers in Organ Donation & Transplantation

THIS ISSUE

EDITOR'S NOTE

The Transplant Quality Corner presents a series of publications dedicated to enhancing transplant center outcomes through the utilization of the latest metrics, data collection techniques, and monitoring methods. Each publication encompasses an executive summary, background information, essential tools, actionable steps, references, and downloadable resources in the form of a concise one-page summary.

This edition focuses on breaking down the complexities of compliance with a review of the OPTN Infectious Disease Policy.

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We extend our deepest gratitude to our contributors for their tireless efforts in bringing Transplant Quality Corner to life. Their dedication and expertise have been invaluable to the success of this project, and we are truly appreciative of their hard work and commitment.

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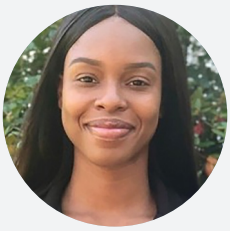

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UNRAVELING THE COMPLEXITIES OF COMPLIANCE

OPTN Infectious Disease Policy Review

In March 2021, the OPTN aligned its policies with the U.S. 2020 Public Health Service (PHS) Guideline for assessing solid organ donors and monitoring transplant recipients for HIV, HBV, and HCV infection, as required by the Final Rule.

EDUCATION

POLICY INTERPRETATION | OPTN POLICY 15.2: CANDIDATE PRE-TRANSPLANT TESTING REQUIREMENTS

WHAT	WHEN	EXCEPTIONS	CONSIDERATIONS
Unless testing would violate state or federal laws, all transplant candidates must be tested for: • HIV (per CDC recommended laboratory HIV testing algorithm*See resources) • Hepatitis B surface antigen (HBsAg) • Hepatitis B core antibody (total anti-HBc) • Hepatitis B surface antibody (HBsAb) • Hepatitis C antibody (anti-HCV) • Hepatitis C RNA by NAT	For candidates 12 years or older, blood samples must be collected **during the hospital transplant admission prior to anastomosis of the first organ.** For candidates less than 12 years old on the date of transplant, blood samples can be collected/tested any time before transplant, and does not need to be repeated prior to transplant.	**If candidate is known to be infected with HIV, HBV, or HCV, then testing for the known viral infection(s) is not required.**	*Candidates who test positive for HIV, HBV, or HCV must be offered appropriate counseling by the clinical team. *Blood sample must be collected during required timeframe; but results do not have to be available prior to anastomosis. *When drawing a Hepatitis B core antibody, a TOTAL is required rather than just drawing an IgM or IgG alone. * *Re-testing is needed for patients who experience a "dry-run" (admitted for a transplant, but transplantation doesn't occur) and are discharged- even if readmitted on the same day. Consider a strategy to ensure that candidates who "age out" of the pediatric provision are re-tested upon transplant admission.

HIV: Human immunodeficiency virus; HBV: Hepatitis B Virus; HCV: Hepatitis C Virus; NAT: nucleic acid test; RNA: ribonucleic acid

POLICY INTERPRETATION | OPTN POLICY 15.3.C: REQUIRED POST-TRANSPLANT INFECTIOUS DISEASE TESTING		
WHAT	**WHEN**	**CONSIDERATIONS**
Transplant programs must test all recipients post-transplant for: • HIV RNA by NAT • HBV DNA by NAT • HCV RNA by NAT	Blood sample must be collected for all transplant recipients **at least 28 days, but no later than 56 days** post- transplant.	*Post-transplant testing needs to be **completed even in the event of graft failure**. If a patient is then **re-transplanted**, testing is still required for both transplanted organs. If the required testing windows overlap, one set of testing is sufficient.
Transplant programs must test all liver recipients for: • HBV DNA by NAT	Blood sample must be collected for liver recipients **at least 335 days but no later than 395 days** post-transplant.	

ACTION

1. Improving Compliance Through Changes in Work Flow Processes

a. **Create order sets for pre-transplant testing placed by inpatient transplant team at time of transplant admission**

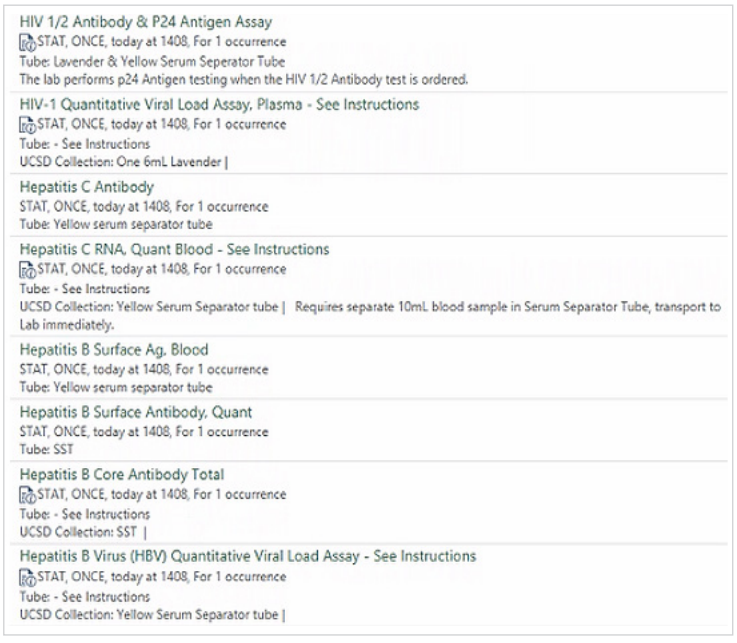
   I. **Pre-check/select labs on admission order sets**

   II. **Create lab panel (i.e., Pre-Transplant PHS Labs) that is 'locked-down' to ensure that all testing is completed, and end-users are not able to delete any required testing.**

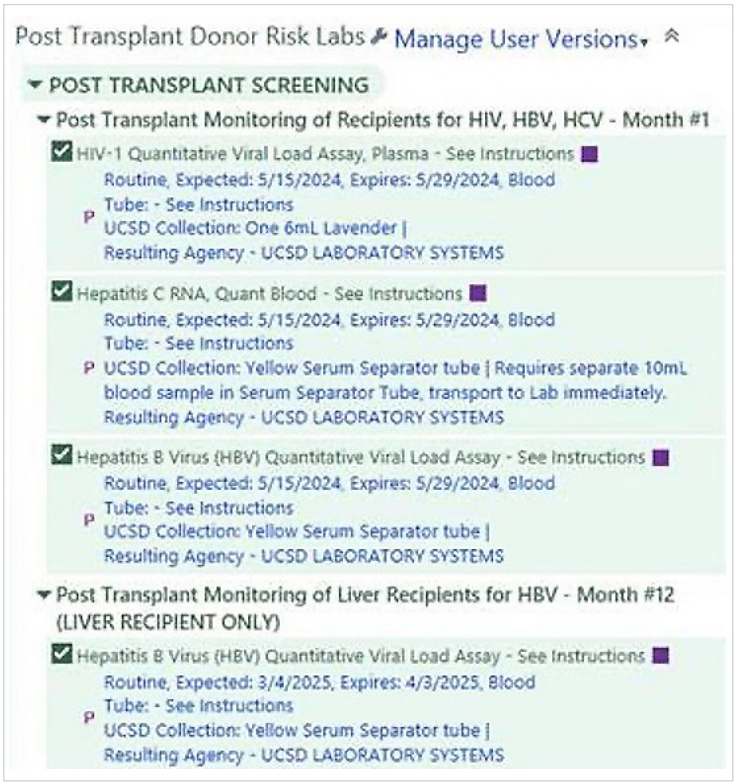
b. **Opportunities to improve post-transplant testing compliance**

   I. **Order Sets: As part of the discharge process, transplant clinician places the post-transplant PHS testing order**

   II. **Create notification process: if the patient is still inpatient during post-transplant testing period. Communication with your inpatient team is key.**



III. Scheduling: Post-transplant team will schedule the patient's follow-up clinic visits, and one visit to correspond to the closest weekday that is at least 28 and no more than 56 days post-transplant.



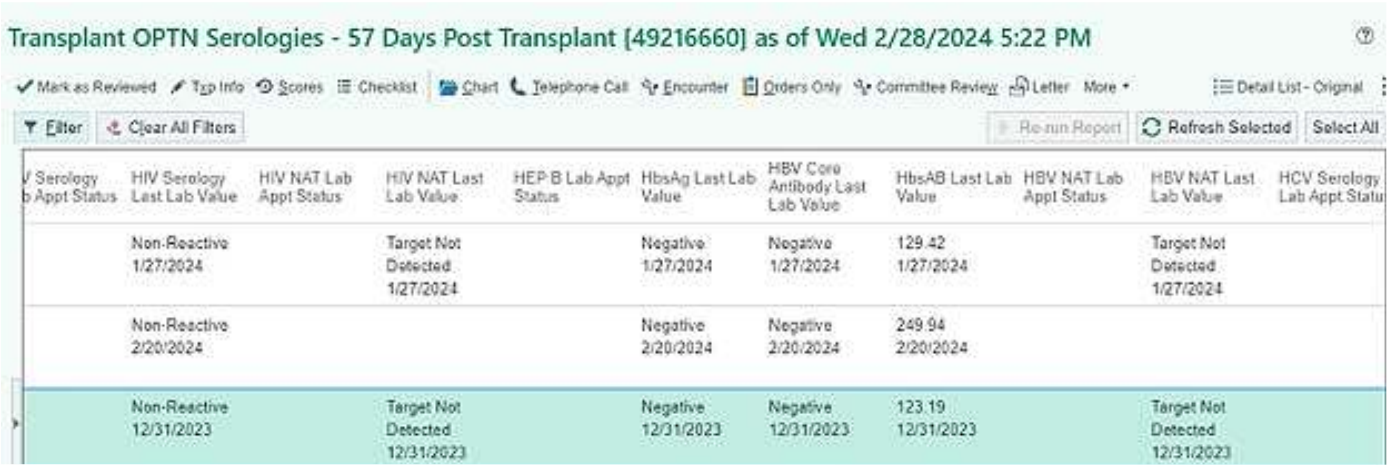
2. Improving Compliance Through Monitoring

a. Leverage Epic EMR: Create checklist task to monitor testing completion

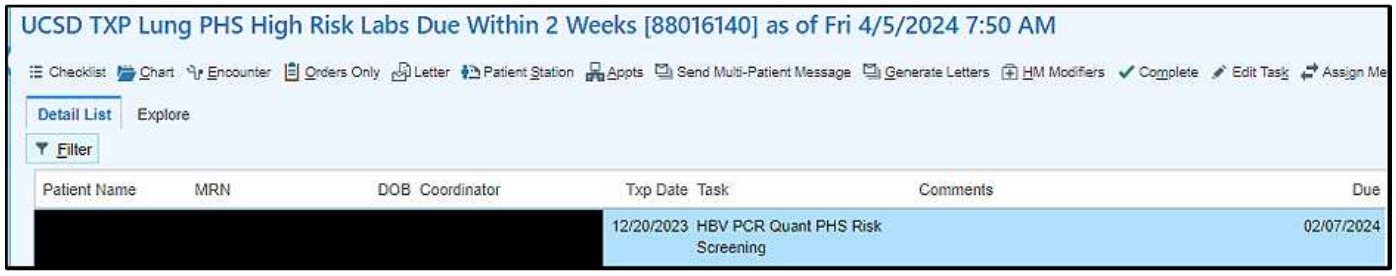
I. Post-transplant Coordinator to create checklist task as soon as the transplant notification is received.

II. The testing order can be linked to the checklist task for auto completion of the task.

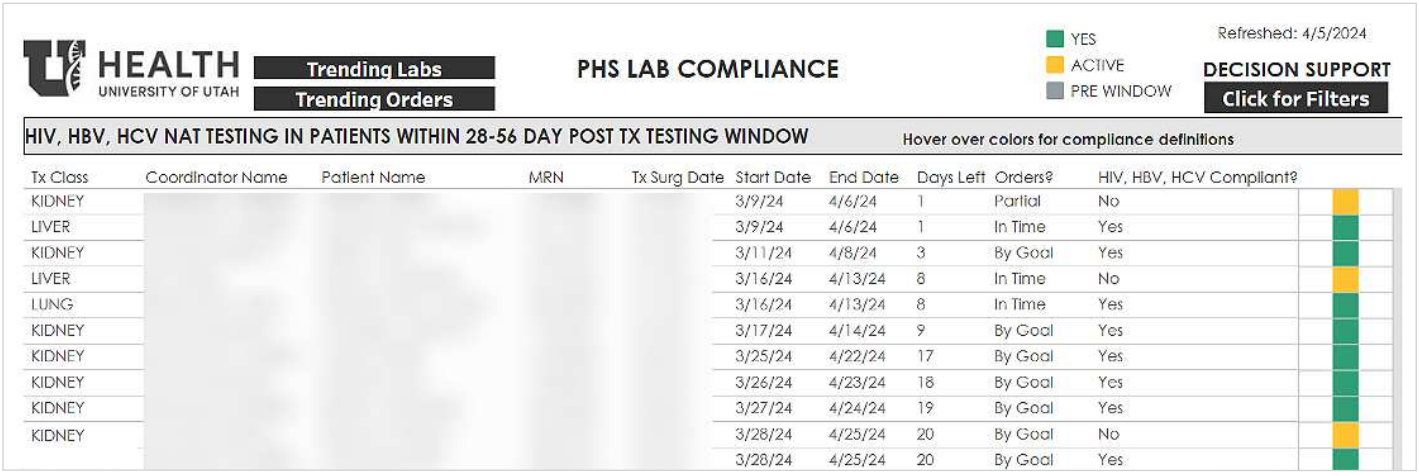
b. Create an automated tracking report- can be utilized by coordinators as part of standard work to monitor completion of ordered labs.



Reporting Example of Lab Values & Transplant Date



Reporting Example Based off Utilization of Checklist Tasks



c. Creation of a dashboard to monitor compliance by post-transplant team and quality team

I. Here is an example of a Tableau report built to allow for proactive tracking for required post-transplant testing.

1. Start and end date of testing window and number of days left in testing window are shown.
2. Color coding is utilized to mark patients compliant w/ testing requirements (green), within the testing window but testing not complete (yellow), and patients coming into the testing window (gray).
3. This report can be filtered by transplant organ, transplant coordinator.

3. Compliance is a team effort: Dissemination to transplant teams

a. Maintaining a regular audit schedule that is conducted by the quality team and results are sent out to the transplant center.

b. Identified noncompliance and policy education is sent to nurse managers to review with organ specific teams.

LESSONS LEARNED ON THE JOURNEY TOWARD COMPLIANCE

1. Collaboration and education of all multidisciplinary team members is key

a. Several transplant programs have developed "double-checks" throughout the pre-transplant admission process to ensure labs are collected. Some strategies for consideration:

1. Fast tracking samples to lab to allow enough time for reminder for collection /re-collection if needed
2. Use EMR reports to ensure that all ordered labs have been collected/resulted. If blood sample isn't collected/resulted, coordinate with lab to have labs re-run on extra blood samples from patient collected prior to transplant.
3. Real-time follow up and education with the team when noncompliance is noted, including any residents, fellows, bedside nurse, etc., depending on the circumstance.

b. Some laboratories and payors have testing algorithms and timeframes that prohibit collection and/or coverage for specific tests. These cases may require additional follow-up and education to ensure all testing has been completed.

c. TIEDI Reporting Requirements

REPORTING PRE- AND POST-TRANSPLANT PHS LABS IN TIEDI			
TIEDI FORM	**WHAT TO REPORT**	**WHERE TO REPORT**	**CONSIDERATIONS**
Transplant Recipient Registration (TRR)	Pre-Transplant Testing for All Recipients	**Viral Detection:** HIV Serostatus:* (HIV Antibody) HBV Surface Antibody Total HBV Core Antibody:* HBV Surface Antigen:* HCV Serostatus:*(HCV Antibody) EBV Serostatus:* **NAT Results** HIV NAT:* HBV NAT:* HCV NAT:*	Enter all available pre-transplant testing results. **Not all testing on the TRR is required per OPTN policy.** If testing is not completed put NOT DONE.

REPORTING PRE- AND POST-TRANSPLANT PHS LABS IN TIEDI (CONT.)			
TIEDI FORM	**WHAT TO REPORT**	**WHERE TO REPORT**	**CONSIDERATIONS**
Transplant Recipient Follow-Up (TRF) 6 Month Form	Post-Transplant Testing (28-56 Days) for All Recipients	**Viral Detection:** HIV Serology:* HIV NAT:* HbsAg:* HBV DNA:* HBV Core Antibody:* HCV Serology:* HCV NAT:* **For all recipients, documentation on 6-month TRF should be completed if lab results were within the 28- 56 days post-transplant range. Unlike the TRRs, if testing was outside this range or not completed, select NOT DONE.**	For results that are originally equivocal (or indeterminate): • Repeated testing changes to either positive or negative: change the result to the newer more specific value even though it may be a different test date. • Repeated testing remains equivocal (or indeterminate): record as "UNK/cannot disclose"
Transplant Recipient Follow-Up (TRF) 1 Year Form	Post-Transplant Testing (335-395 Days) for Liver Transplant Recipients	**Viral Detection:** CMV IgG:* CMV IgM:* HIV Serology:* HBV DNA:* HBV Core Antibody:* HCV Serology:* HCV NAT:* **If testing of highlighted field is not completed within the 335-395 days post-transplant testing window, select NOT DONE**	

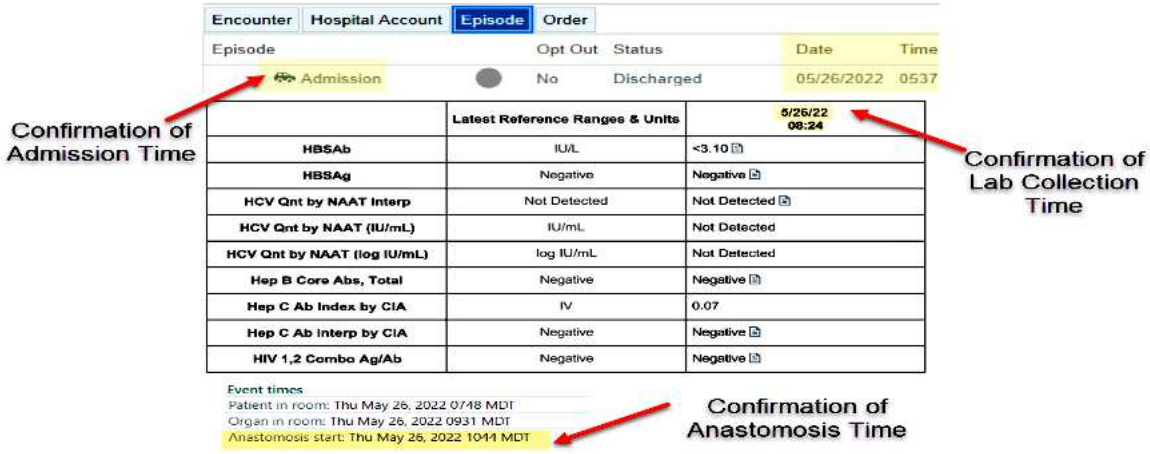
OPTN SURVEY READINESS

1. **Pre-Transplant Testing: Provide documentation that shows required testing was completed after transplant admission & prior to anastomosis of first organ. Documentation Requirements:**

   a. Admission Date and Time

   b. Anastomosis time

   c. Lab Results, including collection time



2. **Post-Transplant Testing: Provide documentation that testing was completed within 28-56 days post-transplant for all recipients and 335-395 days post-transplant for liver recipients.**

	Latest Reference Ranges & Units	07/27/22 12:42
HBSAb	IU/L	20.41
HBSAg	Negative	Negative
HBV Qnt by NAAT (IU/mL)	IU/mL	Not Detected
HBV Qnt by NAAT (log IU/mL)	log IU/mL	Not Detected
HBV Qnt by NAAT Interp	Not Detected	Not Detected
HCV Qnt by NAAT Interp	Not Detected	Detected !
HCV Qnt by NAAT (IU/mL)	IU/mL	19,694,567
HCV Qnt by NAAT (log IU/mL)	log IU/mL	7.29
HIV-1 Qnt by NAAT (log copies/mL)	log cpy/mL	Not Detected
HIV-1 Qnt by NAAT (copies/mL)	cpy/mL	Not Detected
HIV-1 Qnt by NAAT Interp	Not Detected	Not Detected

Confirmation of Lab Collection Time

TOOLS & RESOURCES

- OPTN policies to align with 2020 U.S. Public Health Service Guideline - Toolkit
- CDC PHS Guideline
- CDC Guidelines for Organ Transplants
- OPTN Policies and Evaluation Plan
- Notice of OPTN Policy Changes
- PHS – FAQs
- Lab testing FAQs
- UNOS Connect: search for the PHS Playlist
- CDC Vaccination Schedule 2024
- Hepatitis B Foundation - Vaccination Schedule and Guidelines

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