

Ad Hoc Disease Transmission Advisory Committee Report

*OPTN/UNOS Board of Directors Meeting
Dr. Michael Green, MD, MPH, Chair
Dr. Daniel Kaul, MD, Vice Chair
June 23-24, 2014*

PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation

- Document released June 19, 2013 after a five year process!
- Thorough review process, including multiple committees and professional societies.

Joint Subcommittee Composition

OPTN Committees	Professional Societies	Government Ex Officio
DTAC	AOPO	HRSA
Living Donor OPO	AST	FDA
Operations & Safety	ASTS	
	NATCO	SRTR*

* SRTR invited, but did not participate. Representatives received all emails and open invite to attend as desired.

Proposal Development

- Joint Subcommittee completing comprehensive review of Guideline's 34 recommendations to determine:
 - Is the PHS recommendation covered by the Final Rule?
 - Is there policy already in place to address this? Does it need to be changed?
 - Should there be policy in place to address this, or should it remain a PHS recommendation?

Proposal Development

- Strong agreement on addressing the 34 PHS recommendations and subsections within joint subcommittee and DTAC with one exception
- **Split vote on this topic from both groups...**

HCV nucleic acid testing (NAT)

for ALL organ donors

Why is this an issue?

- The Final Rule, §121.4, notes that the OPTN Board of Directors is responsible for developing policies that are **consistent with recommendations** of the Centers for Disease Control and Prevention (CDC) to **test potential organ donors** and **following transplant recipients** to prevent the spread of infectious disease.

DTAC Included HCV NAT Included in its Proposal

- DTAC will be reviewing feedback from public comment, which ended on June 13, 2014.
- Mostly favorable comments overall, but most concerns related to perceived high false positive rate:
 - Effect on some sub-populations (e.g. pediatric donors)
 - How to rule out potential false positive (repeat test?)
 - Access to NAT in all DSAs- delayed donation... lost donors?
 - Allow time for implementation?

Board Feedback Sought...

1. Impact of HCV NAT for all on availability of organs?
2. Operational impact (travel costs/time costs) on OPOs without ready access to NAT locally?
3. Is delaying the HCV NAT requirement piece of this proposal a viable alternative?
4. The Final Rule requires consistency between policy and CDC recommendations, but what if the community is overwhelming against the specific HCV NAT all requirement?

Re-Executing the Match Run

- Joint DTAC-OPO-Operations and Safety Subcommittee
 - Some OPOs making offers prior to receipt of final infectious disease testing results. If test comes back positive, there is possibility that offers would have been made to candidates who wished to be screened from receiving these organ offers
 - Addressing patient safety concern for potential unexpected transmission of disease
 - Considering policy requirement to require re-execution of a match run when infectious disease testing results are positive
 - Working towards Fall 2014 public comment

Living Donor Screening Guidance for Seasonal and Geographically Endemic Infectious Disease

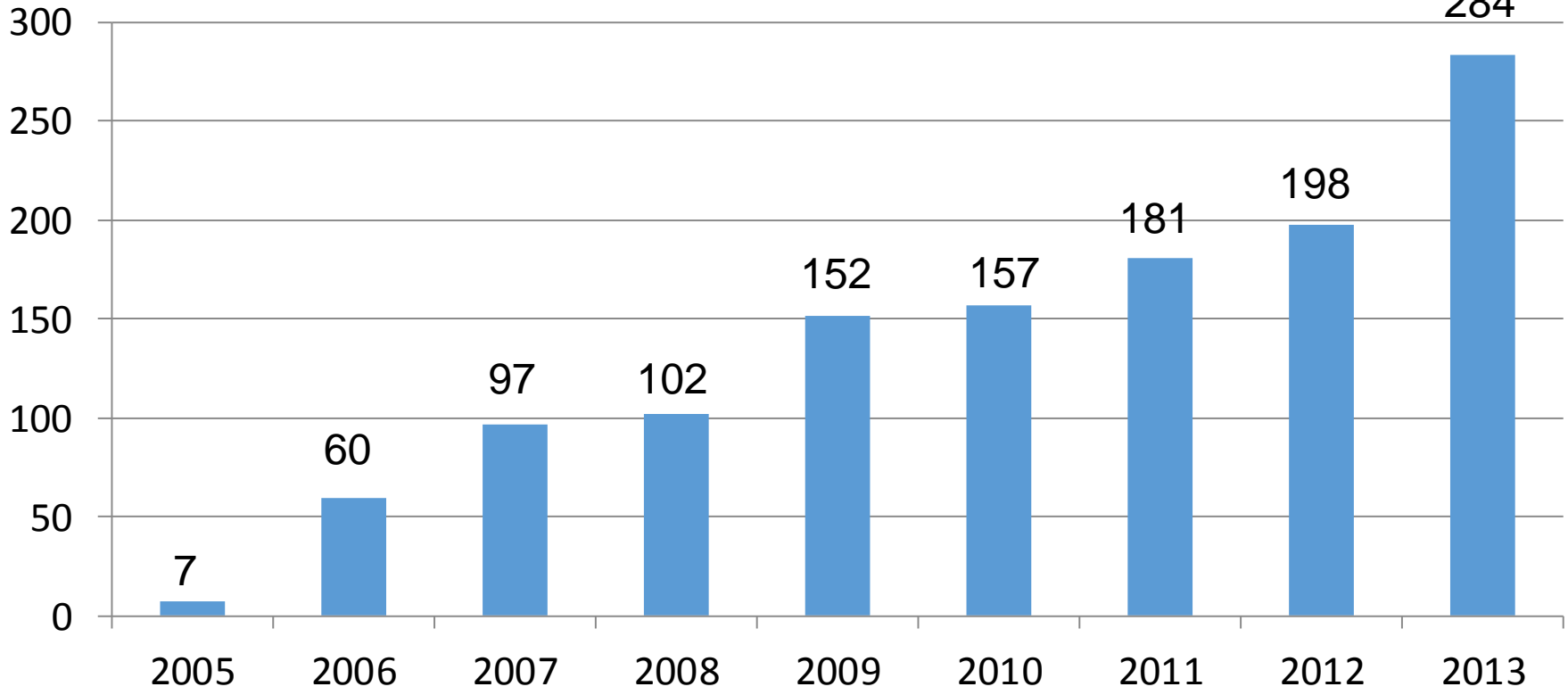
- Subcommittee developing guidance meant to complement changes to living donor medical evaluation policy
- Expected for Board in November 2014
- Will provide overview of diseases seen in DTAC experience: symptoms, endemic areas to consider, risk factors, testing options, etc.

Communicating New Donor Information Learned Post-Transplant

- Failure Mode and Effects Analysis (FMEA) underway to determine potential failure points in current process
- Partnered with OPO, Transplant Coordinators, and Transplant Administrators to gather firsthand input and experience from the community
- Spring 2015 public comment anticipated

Potential Donor Derived Transmission Events (PDDTE)

Number of PDDTE Reviewed by DTAC*, 2005-2013



*Additional reports are submitted, but not reviewed by full DTAC (duplicates, expected transmissions and other unnecessary reporting, etc).

Conclusions

- **Continued increase in PDDTE reporting in 2013!**
 - Percent PDDTE with probable/proven transmission classifications remain low (11% of total cases classified for 2013)
 - Cumulative incidence of probable/proven transmission in donors remains low ($\approx 0.2\%$)
 - Committee beginning to look at overhauling reporting requirements based upon what it has learned over the last 5 years
 - MANY positive donor cultures with no ill recipients
 - Guidance or potential policy modifications may be end result to streamline communication and reporting efforts

DTAC Membership 2013-14

Dr. Mike Green (Chair, Peds TID)

Ms. Donna Ennis (Sr. TX Coord)

Ms. Dianne LaPointe Rudow (TX ad, LD)

Dr. Tom Gross (Peds Hem/Onc)

Dr. Shelley Morris (TID)

Dr. Costi Sifri (TID)

Dr. Mary Klassen-Fischer (Anat Path)

Dr. Martha Pavlakis (Nephrology)

Ms. Kristin Ludrosky (TX Coord)

Dr. Marilyn Menegus (Micro/Immuno)

Dr. Sridhar Basavaraju (CDC*)

Dr. Jim Bowman (HRSA*)

Dr. Pallavi Annambhotla (CDC*)

Dr. Dan Kaul (Vice Chair, TID)

Dr. Ed Dominguez (TID)

Dr. Yuk Law (Peds Cardiac)

Dr. Camille Kotton (TID)

Dr. Cameron Wolfe (TID)

Mr. Dave DeStefano (OPO Dir)

Dr. Walter Bell (Path)

Dr. Tim Pruett (Abd TX Surgeon)

Dr. David Conti (TX Surgeon)

Dr. Scott Biggins (Hepatology)

Dr. Melissa Greenwald (FDA*)

Dr. Bernie Kozlovsky (HRSA*)

* Ex Officio (non voting) members

Questions?

Thank you!

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