

# **Ad Hoc Disease Transmission Advisory Committee: A Report to the OPTN/UNOS Board**

*Dr. Michael Green, MD, MPH, Chair*  
*Dr. Daniel Kaul, MD, Vice Chair*

*November 11-12, 2013*  
*Atlanta, GA*

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

- Released June 19, 2013 after a five year process!
- Much more acceptable than the draft that was circulated for public comment in September 2011.
- Still includes some recommendations that are controversial in the transplant community.

# Why is this an issue?

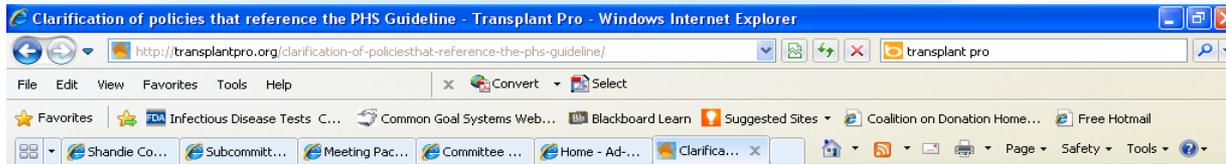
- Final Rule, §121.4:

OPTN Board of Directors is responsible for developing policies **consistent with recommendations** of the Centers for Disease Control and Prevention (CDC) to **test potential organ donors** and **follow transplant recipients** to prevent the spread of infectious disease.

# Current Policy Impacts Addressed by Executive Committee, August 28

- **Policy defines and references PHS Guideline**
  - OPOs may currently use 1994 or 2013 for med-soc evaluation
  - BOD will consider sunset date for this option in Nov
- **Executive Committee did NOT endorse full Guideline- current OPTN policy refers only to med-soc evaluation for identifying donors suspected to be at increased risk for transmitting blood-borne pathogens**
  - No references to specific testing recommendations for donors, candidates, or recipients

# Keeping the Community Updated



A screenshot of the Transplant Pro website. The header features the logo 'Transplant Pro' with the tagline 'Critical news &amp; resources for transplant professionals'. Below the header is a navigation menu with categories: COMMUNITY, POLICY, PATIENT SAFETY, EDUCATION, and RESOURCES. The main content area shows the article title 'Clarification of policies that reference the PHS Guideline' in green text. Below the title, it indicates the date 'SEP 6, 2013' and lists categories: FEATURED, OPOS, PATIENT SAFETY, POLICIES, TRANSPLANT CENTERS. The article text begins with 'The June 19, 2013, release of the PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation, made policy ambiguous...' and mentions 'Step 1 (approved on Aug. 27, 2013)'. At the bottom, it says 'Standardize the nine policies that reference the PHS Guideline and create a new policy (3.1.14)'. The browser's status bar at the bottom shows 'Done, but with errors on page.' and the Windows taskbar with several open Microsoft Office applications.

## Policy Clarifications Resulting from June 19, 2013, Release of the PHS Guideline for Reducing HIV, HBV, and HCV through Organ Transplantation

**Sponsoring Committee:** Ad Hoc Disease Transmission Advisory Committee (DTAC)

**Policies Affected:** 2.2.2.1 (Obtaining the donor's medical/behavioral history), 2.2.3.1, 2.2.3.4, 3.1.14 (PHS Guideline), 4.2 (Requirements for Informed Consent Regarding Risk of Transmissible Disease), 5.4.3 (Vessels), 5.10.2 (Vessel Storage), 12.3.3 (Psychosocial Evaluation of the Living Kidney Donor), 12.3.4 (Medical Evaluation of the Living Kidney Donor), and 12.7.4.3 (Vessels)

**Distributed for Public Comment:** No

**Effective Date:** October 1, 2013

### **Problem Statement**

The PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B (HBV), and Hepatitis C (HCV) Through Organ Transplantation was released on June 19, 2013. This release made current policy ambiguous in terms of identifying "high risk" organ donors that may be at increased risk for transmitting these diseases to organ recipients. Some policy sections reference the 1994 PHS Guideline. Other sections refer simply to the PHS Guideline or the "current" PHS Guideline.

### **Changes**

All references to the PHS Guideline have been updated with uniform language. Programming is underway to update references to "CDC high risk" donors in DonorNet<sup>®</sup> and on the Deceased Donor Registration so that they match terminology used in the 2013 PHS Guideline. The Board of Directors will consider a timeline for implementing use of only the 2013 Guideline during its November 11-12, 2013 meeting.

### **Member Actions**

OPOs may use either the 1994 or the 2013 PHS Guideline for medical-social evaluation questions to determine if a deceased donor is at increased risk for HIV, HBV, or HCV transmission. OPO staff must document in the donor highlights section of DonorNet<sup>®</sup> which

# Step Two:

## Recommendations Review

- 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 recommendations?
- DTAC will review Joint Subcommittee's work to develop a PC proposal that addresses recommended changes to current policy for Spring 2014

# Joint Subcommittee Composition

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

\* SRTR invited, but has not participated to date. Representative receives all emails and open invite to attend as desired.

# Subgroups for Recommendation Review

- Informed Consent (**Emily Blumberg**)
- Risk Assessment (screening) of Living and Deceased Donors (**Mike Souter**)
- Testing of Living and Deceased Donors and Testing of Recipients Pre- and Post-Transplant (**Mike Ison**)
- Collection and Storage of Donor and Recipient Specimens and Tracking and Reporting of HIV, HBV, and HCV (**Lisa Stocks**)

# Working Groups

- All recommendations divided up for group discussion/review
- Some issues were particularly challenging:
  - Recommendation to use either HIV Ag/Ab combined test OR NAT testing for HIV for increased risk donors (PHS recommendation for combo test)
  - Recommendation to perform NAT for HCV for ALL donors OR increased risk donors (PHS recommends universal HCV testing)
- Full Joint Subcommittee met 11/7 to hear work group discussions before finalizing feedback for the DTAC to consider

# Timeline for Review

- **June 19, 2013-** new PHS Guideline released
- **July 2013** – Joint Subcommittee convened and review Process began (ongoing)
- **Aug 2013-** Executive Committee consideration
  - 8/2- Executive Committee updated on progress to date
  - 8/27- Executive Committee approved updated references to PHS Guidance in OPTN policy
- **Nov 2014-** Joint Subcommittee reconvened to review working group recommendations and prepare final summary for DTAC
- **Nov-Dec 2014-** DTAC to finalize proposed policy changes for public comment
- **March 2014-** Spring public comment if other modifications/additions to policy are pursued
- **Nov 2014-** possible BOD consideration

# Keeping Everyone Informed...



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Brian Maynard  
Interim Executive Director & CEO

## MEMORANDUM

**TO:** Alan Langnas, DO, ASTS President  
Carrie Lindower, RN, MBA, CCTC, CPTC, NATCO President  
Dan Salomon, MD, AST President  
Susan Stuart, RN, MPM, AOPO President

**FROM:** Michael Green, MD, MPH, Chair  
Ad Hoc Disease Transmission Advisory Committee (DTAC)

Dan Kaul, MD, Vice Chair, DTAC  
Chair, Joint DTAC-OPO-Operations & Safety-Living Donor  
Subcommittee for PHS Guideline Review

**RE:** Update on 2013 PHS Guideline Review

**DATE:** October 21, 2013

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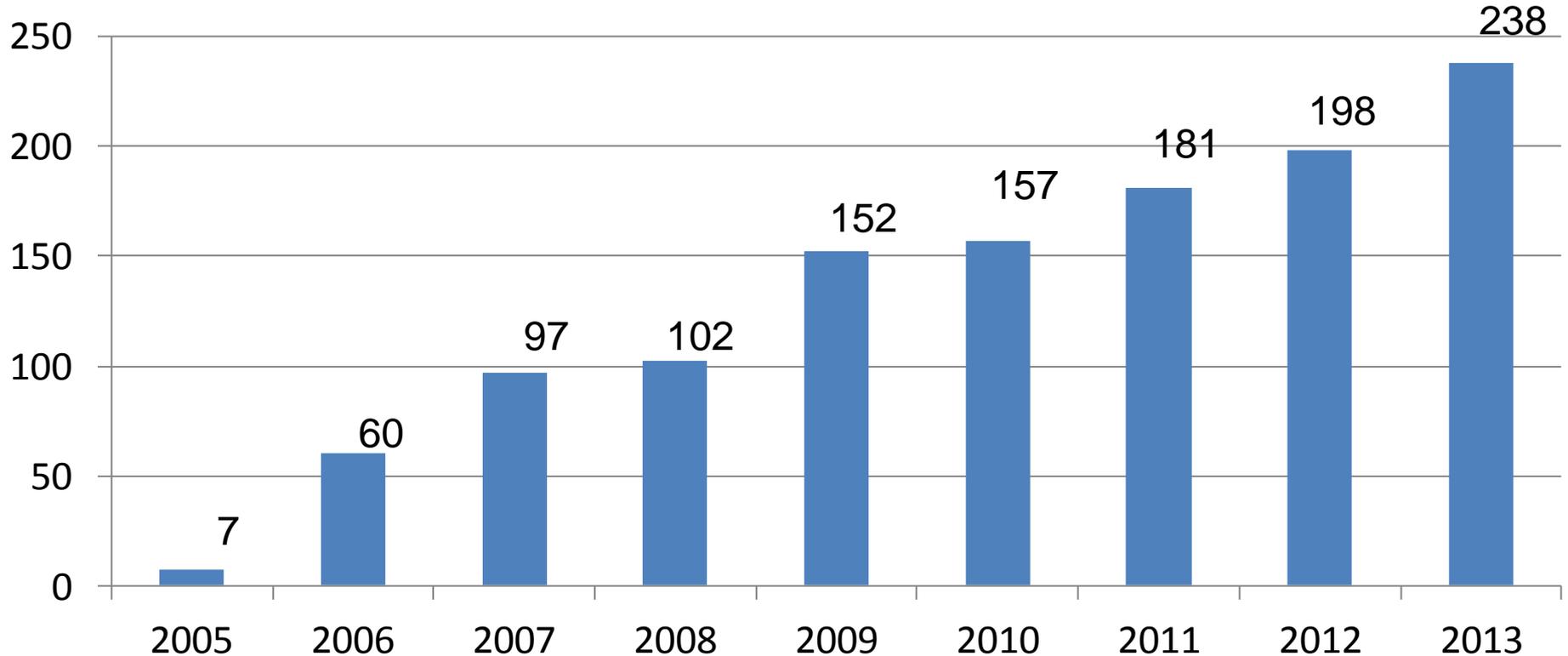
I would like to take this opportunity to bring you all up to date on where we are in the process of reviewing the 2013 PHS Guideline. A recent [Transplant Pro article](#) was released to update the general transplant community on this project. The UNOS liaisons to your societies also reached out to you regarding recent modifications to current policy referencing the PHS Guideline and identification of increased risk donors through medical-social evaluation questions. This memo will not focus on specific decisions and proposed policy changes in response to individual recommendations, as the review is still ongoing. Rather our purpose is to let you know where we are currently with this effort.

As a reminder, the Joint Subcommittee responsible for the initial review and proposed policy recommendations includes representation from multiple UNOS committees (DTAC,

# What else is DTAC Doing?

# Potential Donor Derived Transmission Events (PDDTE)

Number of PDDTE Reviewed by DTAC\*, 2005-2013<sup>B</sup>



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

<sup>B</sup> Cases reviewed and posted through Nov 7, 2013

# What else is DTAC Doing?

- Developing strategies to address increasing potential donor-derived disease transmission case volume
- Ongoing work by multiple Joint Subcommittees on other projects
- Ongoing educational 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. 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!**

**Dr. Michael Green**

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*Special thanks to Sarah Taranto, Kimberly Parker and  
Cassandra Meekins, as well as the entire Committee!*

OPTN



# Ongoing Committee Projects

- **Joint DTAC-OPO-Operations and Safety Subcommittee**
  - Addressing policy needs for re-running a match run when serologies change (anticipated 2014 public comment)
- **Joint DTAC-OPO Subcommittee**
  - Communicating new donor information learned post-transplant
  - education vs. policy change still being discussed- a survey of OPOs and centers requested
- **Policy Subcommittee**
  - Current public comment proposal for modifications to deceased donor screening requirements

# Ongoing Committee Projects

- Living Donor Policy Subcommittee
  - Partnered with Living Donor Committee to address concerns in current language for infectious disease evaluation of potential living donors
  - Developing guidance for other seasonally or geographically endemic diseases (June 2014)

# Ongoing Educational Efforts

- Guidance documents
- Manuscripts
- Abstracts and professional meeting presentations
  - AOPO
  - World Transplant Congress
  - NATCO
  - ISHLT
  - ICAAC

# Conclusions

- **Continued increase in PDDTE reporting in 2013!**
  - Percent PDDTE with probable/proven transmission classifications remain low (14% of total cases classified to date 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
    - Guidance or potential policy modifications may be end result to streamline communication and reporting efforts