

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

June 24-25, 2013

Richmond, VA

New PHS Guideline Update

- Released on-line through Public Health Reports on **June 19**
 - Journal publication release still anticipated July-August
- CDC hosting webinar introduction on **June 25**
 - Must be registered to attend
 - Will be recorded, for viewing at a later date

DTAC will complete page-by-page review to determine if any policy modifications or additions will be appropriate.

Committee Projects Completed

Encephalitis Subcommittee

- Developed standard slide set meant to help members consider and recognize potential risk of CNS infection of unknown etiology
- Accompanies 2012 guidance document

Toxoplasma Education Subcommittee

- Developed new electronic learning module educational tool to raise awareness regarding the importance of screening donors
- Hoping to partner with ISHLT to reach target audience of heart transplant teams

Ongoing Committee Projects

- **Joint DTAC-OPO-Operations and Safety Subcommittee**
 - Addressing policy needs for re-running a match run when serologies change (anticipated Spring 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 may be used (anticipated Spring 2014)
- **Policy Subcommittee**
 - Developing modifications for deceased donor evaluation for public comment in Fall 2013

Ongoing Committee Projects

- Living Donor Policy Subcommittee
 - Partnering with Living Donor Committee to address concerns in current language for infectious disease evaluation of potential living kidney (and liver) donors
 - Developing guidance for other seasonally or geographically endemic diseases
- ✓ Completed WNV Guidance – in time for mosquito season!

Changes in Classification Process for 2012

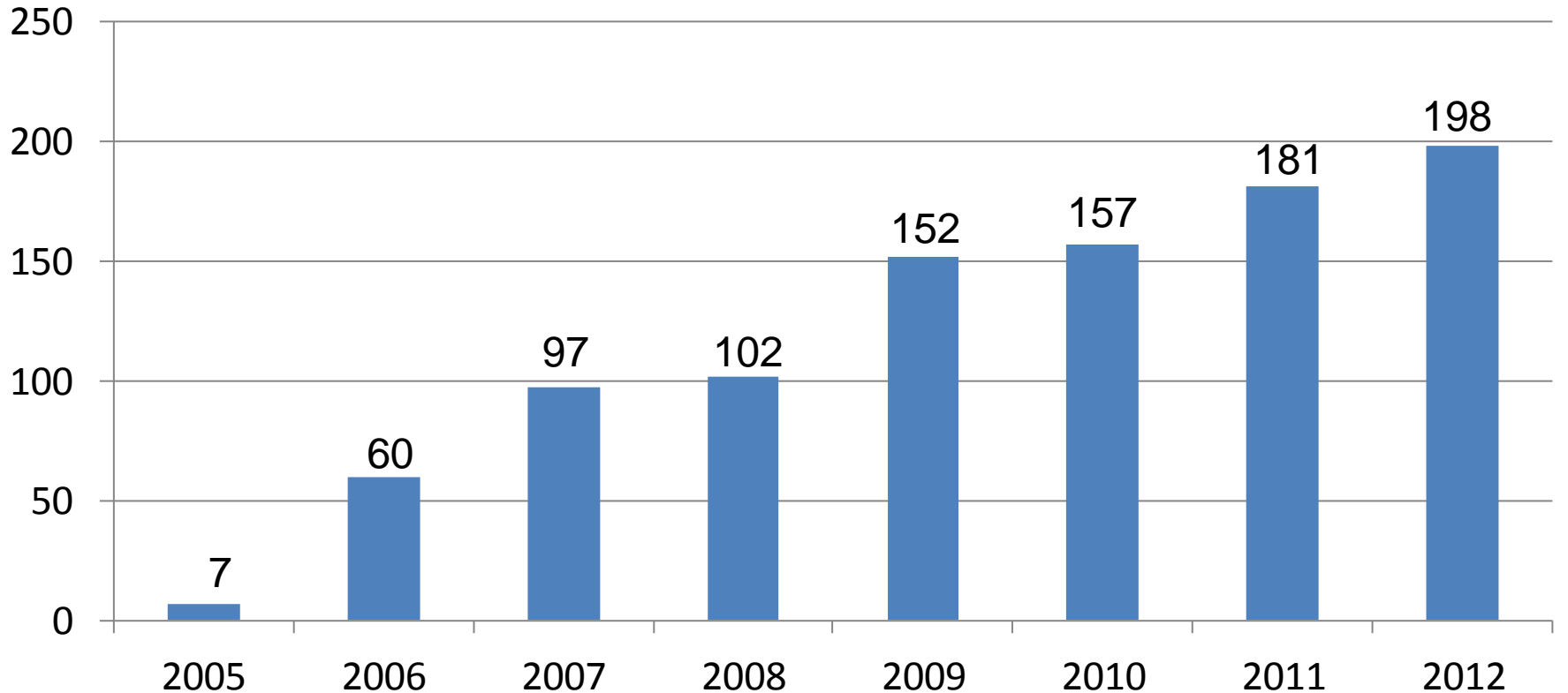
- Intake and case management now housed in Dept of Evaluation and Quality
- Each case classified overall and by EACH organ recipient
 - More useful data that may be helpful in utilizing organs that may have been otherwise discarded based upon trends/patterns
- DTAC members use an algorithm to classify
 - Designed by Dr. Michael Nalesnik, a past vice-chair of the DTAC
 - Ensures consistency in classification of cases

Ongoing Educational Efforts

- Guidance documents
- Manuscripts
- Abstracts and professional meeting presentations
 - ATC
 - NATCO
 - ISHLT
 - ICAAC

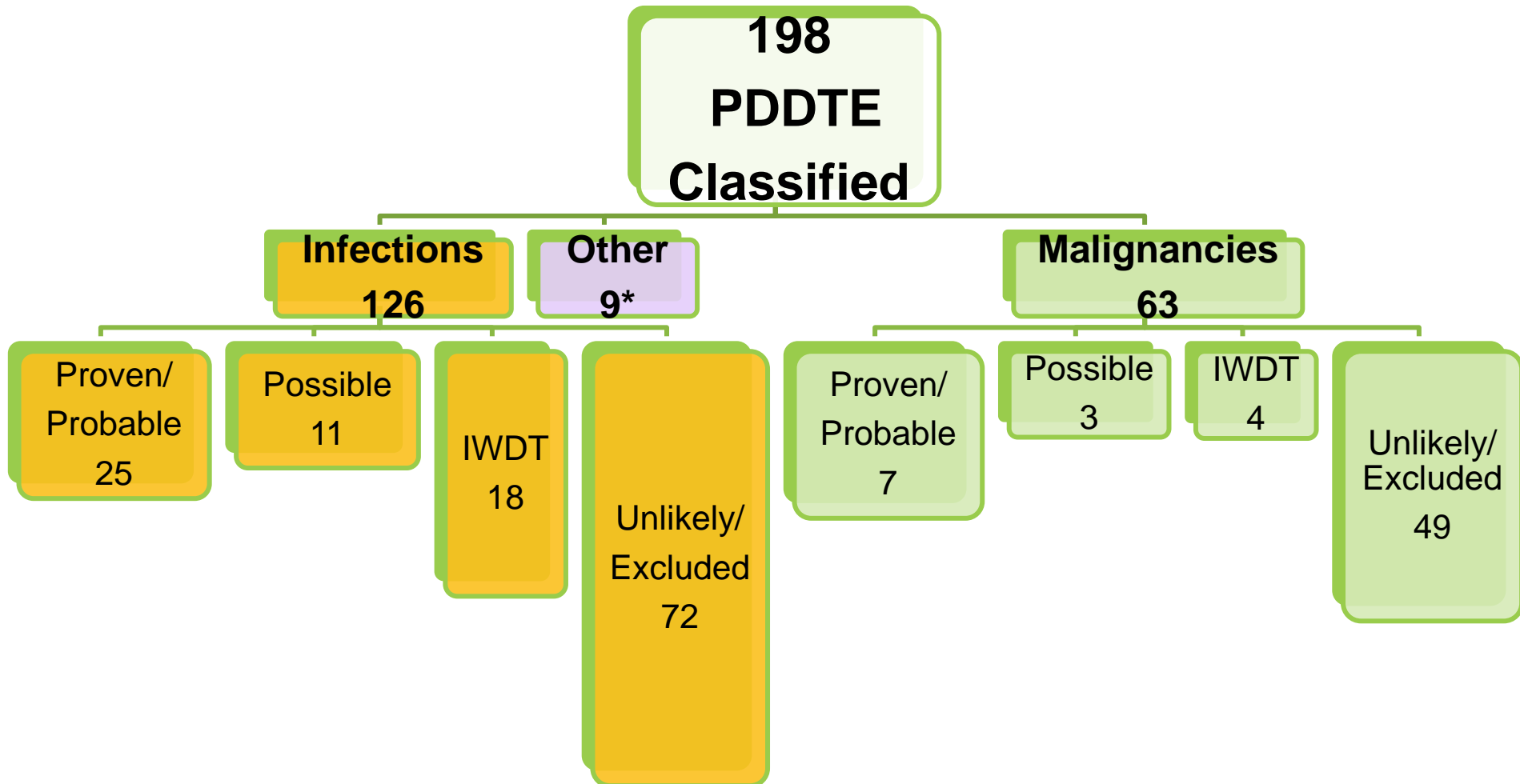
Potential Donor Derived Transmission Events (PDDTE)

Number of PDDTE Reviewed by DTAC*, 2005-2012



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

2012 Potential Donor Derived Transmission Events Classified by DTAC



* Nine Other (Non-Infection/Non-Malignancy) reported events classified as 1 Probable, 1 IWDT, and 7 Unlikely/Exclude.

Proven/Probable (PP) Transmissions for 2012 Cases

| | Total Reports | Total PP Cases | Number of Transplants by Organ Type PP Recip/Total Recip From PP Cases | | | | | Total PP Recip/Total Recip From PP Cases | Total Deaths From Disease |
|---------------------|---------------|----------------|---|--------------|-------------|--------------|---------------------------|--|---------------------------|
| | | | Kidney | Liver | Heart | Lung | Other Organs (IN, KP, PA) | | |
| Malignancy | 63 | 7 | 4/4 | 3/5 | 0/1 | 2/2 | 0/0 | 9/12 | 3 |
| Bacteria | 44 | 8 | 3/9 | 1/6 | 1/3 | 4/6 | 0/1 | 9/25 | 3 |
| Fungus | 31 | 4 | 3/5 | 0/1 | 1/2 | 2/3 | 0/0 | 6/11 | 3 |
| Virus | 39 | 6 | 4/8 | 2/5 | 2/3 | 2/2 | 0/0 | 10/18 | 1 |
| Parasite and Amoeba | 12 | 7 | 4/9 | 4/6 | 3/3 | 0/0 | 1/1 | 12/19 | 3 |
| TOTAL | 189 | 32 | 18/35 | 10/23 | 7/12 | 10/13 | 2/3 | 47/86 | 13 |

Note: There were nine additional non-infection/non-malignancy cases of which one was classified as proven/probable, with no deaths.

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Cumulative Incidence of Disease Transmission: PDDTE Reported Through 2012 Involving Donors Recovered 2008-2011

| | Deceased Donors | Living Donors | Deceased and Living Combined |
|---|-----------------|---------------|------------------------------|
| Donors recovered | 32080 | 25408 | 57488 |
| N (%) with PDDTE through 2012 | 575 (1.8%) | 18 (0.07%) | 593 (1.0%) |
| N (%) with prov/prob PDDTE through 2012 | 107 (0.3%) | 5 (0.02%) | 112 (0.2%) |
| Total recipients transplanted | 88214 | 25408 | 113622 |
| N (%) recipients with prov/prob disease | 135 (0.2%) | 4 (0.02%) | 139 (0.1%) |
| N (%) recipient deaths due to prov/prob disease | 28 (0.03%) | 1 (0.004%) | 29 (0.03%) |

Conclusions

- Continued increase in PDDTE reporting in 2012
 - Percent PDDTE with P/P transmissions remains low (17%)
- Cumulative incidence of P/P transmission in donors remains low (0.2%)
- Analysis of individual recipients identified parasites/amoeba as having highest transmission rate to exposed recipients (63%) with associated mortality
- Attention to outcome of individual recipients may:
 - Potentially predict whether all “exposed” recipients are at equal risk of transmission
 - Enhance our ability to develop strategies to reduce adverse events related to PDDTE

DTAC Membership 2012-13

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. Shimon Kusne (TID)
Dr. Rachel Miller (TID)
Dr. Mary Klassen-Fischer (Anat Path)
Dr. Martha Pavlakis (Nephrology)
Dr. Philip Ruiz (Pathology)
Dr. Nicole Siparsky (TX Surgeon)
Dr. Marilyn Menegus (Micro/Immunology)
Dr. Emily Blumberg (Ex Officio)
Dr. Jim Bowman (HRSA)
Dr. Bernie Kozlovsky (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 (Pathology)
Dr. Tim Pruett (Abd TX Surgeon)
Dr. Michael Souter (OPO Med Dir)
Ms. Linda Weiss (OPO Lab Dir)
Dr. Scott Biggins (Hepatology)
Dr. Sridar Basavaraju (CDC)
Dr. Melissa Greenwald (FDA)
Ms. Raelene Skerda (HRSA)

Questions?

Thank you!

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