50th Meeting

HHS Advisory Committee on Blood & Tissue Safety & Availability

April 15-16, 2019

Hubert H. Humphrey Building | Washington, DC
DTAC EXPERIENCE IN DISEASE TRANSMISSION AND OUTCOMES

CAMERON WOLFE, MBBS
Associate Professor of Medicine
Transplant Infectious Disease
DTAC Experience in Disease Transmission and Outcomes

Cameron Wolfe
MBBS(Hons), MPH, FIDSA
Assoc Professor of Medicine
Infectious Diseases Division
Organ Vigilance through DTAC:

• Aims:
  – Rapidly communicate unanticipated potential donor-derived issues to at-risk recipients
  – Evaluate epidemiologic trends; educate transplant community and public about risks/ mitigation
  – Provide a real time alert for CDC and public health about evolving issues
  – Inform policy and national guidelines surrounding transplant safety

• Requirements for reporting disease:
  – OPO:
    • Urgent center notifications of high impact conditions identified post donation (eg: +BC’s, )
    • General notifications of all microbiology, pathology and disease findings
    • Notification to DTAC of any “Pathogens of Special Interest”

  – Transplant Center:
    • Report to DTAC any unanticipated condition felt potentially donor-derived, esp if potential impact on other recipients exists (eg: TB, malignancy, HCV)
Organ Vigilance through DTAC:

Membership:
1 Tx hepatologist
2 Tx pathologist
1 Pulm. Crit Care
3 OPO directors
1 OPO lab director
12 Tx Infectious Dis
1 Tx Coordinator
2 Tx Surgeons

HRSA, CDC, FDA
non-voting members

Transplant Center

DTAC

OPO

CDC

HRSA

FDA

Patient Safety / Member Quality

Transplant

OPTN / UNOS

Government

For an extended description of this chart, please see the description on page 211.
CDC – Public Health led investigations:

Notable Organ Transplant-Transmitted Infections Investigated by Public Health Authorities, 1985 – 2017:

• 1985 - HIV
• 2000 - Hepatitis C (HCV)
• 2001 – Chagas Disease
• 2002 – West Nile Virus (WNV)
• 2003 – Lymphocytic Choriomeningitis Virus (LCMV)
• 2004 – Rabies
• 2005 – LCMV, WNV
• 2006 - Chagas
• 2007 – HIV / HCV

• 2008 - Babesiosis
• 2009 - WNV
• 2010 – Zygomycosis, Coccidiodomycosis, TB
• 2011 – WNV, HCV (organ & tissue)
• 2012 - Microsporidium
• 2013 – Rabies, LCMV, MRSA
• 2014 - Microsporidium
• 2015 – M.tuberculosis, Hep A virus
• 2017 – Eastern Equine Encephalitis Virus (EEEV)
DTAC case evaluation:

For an extended description of this chart, please see the description on page 211.

Table 1. Potential Donor-Derived Disease Transmission as Reported to the OPTN: 2005-2017

<table>
<thead>
<tr>
<th></th>
<th>Reports (Donors)</th>
<th>Recipients Potentially Involved</th>
<th>Recipients with Proven/Probable Transmission</th>
<th>Donor-Derived Disease Attributable Deaths (Recipients)</th>
<th>Liver recipients* with proven or Probable transmissions</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Malignancy</td>
<td>577</td>
<td>1,342</td>
<td>164</td>
<td>43</td>
<td>17</td>
<td>1</td>
<td>26</td>
<td>3</td>
</tr>
<tr>
<td>Viruses*</td>
<td>463</td>
<td>1,463</td>
<td>216</td>
<td>27</td>
<td>26</td>
<td>6</td>
<td>41</td>
<td>14</td>
</tr>
<tr>
<td>Bacteria*</td>
<td>467</td>
<td>1,524</td>
<td>230</td>
<td>21</td>
<td>12</td>
<td>3</td>
<td>39</td>
<td>24</td>
</tr>
<tr>
<td>Fungi*</td>
<td>299</td>
<td>1043</td>
<td>179</td>
<td>26</td>
<td>10</td>
<td>5</td>
<td>18</td>
<td>15</td>
</tr>
<tr>
<td>Mycobacteria*</td>
<td>136</td>
<td>468</td>
<td>35</td>
<td>7</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Parasites†</td>
<td>118</td>
<td>385</td>
<td>103</td>
<td>17</td>
<td>8</td>
<td>6</td>
<td>12</td>
<td>5</td>
</tr>
<tr>
<td>Other Disease</td>
<td>121</td>
<td>402</td>
<td>68</td>
<td>3</td>
<td>8</td>
<td>0</td>
<td>10</td>
<td>6</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1,980</strong></td>
<td><strong>5,688</strong></td>
<td><strong>908 (15.9%)</strong></td>
<td><strong>135</strong></td>
<td><strong>81</strong></td>
<td><strong>21</strong></td>
<td><strong>146</strong></td>
<td><strong>70</strong></td>
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* Organ Specific numbers are only reflective of 2012-2017 data; organ-specific data was not effectively collected prior to this time point.

* Viruses: Adenovirus, HBV, HCV, HEV, HHV-8, HIV, HTLV, Eastern Equine Encephalitis, herpes simplex, influenza, LCMV, Parainfluenza (PIV)-3, Parvovirus B19, rabies, West Nile Virus

* Bacteria: Acinetobacter, Brucella Enterococcus (including VRE), Ehrlichia spp, E. coli, Enterobacter, Gram Positive Bacteria, Klebsiella, Legionella, Listeria, Lyme Disease, Nocardia, Pseudomonas, Rocky Mountain Spotted Fever, Serratia, S. aureus (MRSA), Streptococcus spp, Syphilis, Ureaplasma urealyticum, Veillonella; bacterial meningitis & bacterial emboli

* Fungi: Aspergillus spp, Candida spp, Coccidioides imitis, Cryptococcus neoformans, Histoplasma capsulatum, Scopulariopsis, zygomycetes

* Mycobacteria: Tuberculosis, Non-TB Mycobacteria

† Parasites: Babesia, Balmuthia mandrillaris, Chagas (Trypanosoma cruzi), Naegleria fowleri, schistosomiasis, strongyloidiasis, Toxoplasma

Wolfe, Ison: Clinical Transplantation, 2019
Organ Specific Transmission Data: close up…

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<th>Donor-Derived Disease</th>
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</tr>
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<tbody>
<tr>
<td></td>
<td>Heart recipients</td>
<td>Kidney or Pancreas recipients</td>
</tr>
<tr>
<td>Malignancy</td>
<td>43</td>
<td>3</td>
</tr>
<tr>
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<td>27</td>
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<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Total</td>
<td>135</td>
<td>70</td>
</tr>
</tbody>
</table>

* Organ Specific numbers are not effectively collected prior to this time point. Organ specific infections include: Herpes simplex, influenza, LCMV, parainfluenza (PIV)-3, Paillat’s, Pneumococcus ssp, Poliovirus, Pseudomonas aeruginosa, Rabies, Reovirus, Serratia, S. aureus, Shigella, Staphylococcus aureus, Streptococcus ssp, Toxocara, Tuberculosis, Mycobacterium avium-intracellulare, Mycobacterium leprae, Mycobacterium tuberculosis, and Mycobacterium xanthus.

† Parasites: Babesia, Balamuthia mandrillaris, Chagas (Trypanosoma cruzi), Naegleria fowleri, schistosomiasis, strongyloidiasis, Toxoplasma gondii, and others.
## Malignancy Transmissions over last 10 years:

<table>
<thead>
<tr>
<th>Transmission</th>
<th>Type</th>
<th>Total Reports</th>
<th>Total Proven/Probable (P/P) Donors</th>
<th>Total Recipients from P/P Donors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malignancy</td>
<td>Adenocarcinoma</td>
<td>36</td>
<td>6</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>Breast</td>
<td>15</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Cholangiocarcinoma</td>
<td>3</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Hematological</td>
<td>14</td>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Kaposi's</td>
<td>12</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Liver</td>
<td>11</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Lung</td>
<td>21</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Melanoma</td>
<td>11</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Neuroendocrine</td>
<td>15</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Other Malignancy</td>
<td>94</td>
<td>5</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Renal</td>
<td>146</td>
<td>11</td>
<td>26</td>
</tr>
<tr>
<td></td>
<td>Thyroid</td>
<td>28</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Urothelial</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total Malignancy</strong></td>
<td></td>
<td><strong>409</strong></td>
<td><strong>36</strong></td>
<td><strong>82</strong></td>
</tr>
</tbody>
</table>

Pending publication, 2019
Zika: Changing epidemiology meets variable risk tolerance

• **Transplant Guidelines (HRSA/DTAC)**

  • **At-risk Living donors:**
    - Likely *defer* for at least 28d if not longer
    - Current guidance *does not preclude* using travelers or those living in endemic areas
    - If *proven infection* would *strongly suggest* 6 months *deferral*, akin to FDA tissue guidance

  • **At-risk Deceased donors:**
    - Accepting an organ with a positive Zika test?
      - NAT: Should likely *defer*
      - IgM: less likely to be an issue, and unlikely to be done during donor evaluation
      - Accepting an organ from an asymptomatic recent traveler?
      - Cautiously *accept*, esp if > 28d

• **Tissue/Blood Guidelines (FDA)**

  • **Living donors:**
    - *Ineligible* to donate if sick or travelled or lived in endemic area; or have male sexual partner with same risks – within 6 months.

  • **Deceased donors:**
    - *Ineligible* to donate if diagnosed with zika within 6m
Chagas Disease / West Nile Virus: Emerging problems?

For an extended description of these maps, please see the descriptions on page 212 and 213.
Learning to live with some risk:

1. Changing infectious epidemiology

Donor-Derived West Nile Virus Infection in Solid Organ Transplant Recipients: Report of Four Additional Cases and Review of Clinical, Diagnostic, and Therapeutic Features

Winston, Drew J.1,12; Vikram, Holenarasipur R.2; Rabe, Ingrid B.1; Dhillon, Gundeep5; Mulligan, David2; Hong, Johnny C.1; Busuttil, Ronald W.1; Nowicki, Marek J.5; Mone, Thomas6; Civen, Rachel7; Tecle, Selam A.6; Trivedi, Kavita K.3; Hocevar, Susan N.10; the West Nile Virus Transplant-Associated Transmission Investigation Team

2. Variable geographic risk

Clinical Infectious Diseases

Donor-Related Coccidioidomycosis in Organ Transplant Recipients

Patty W. Wright1,4, Demosthenes Pappagianis2, Mark Wilson1, Ana Louro1, Stephen A. Moser1, Kenneth Komatsu3, and Peter G. Pappas1

3. Imperfect tests; window periods

MMWR

Morbidity and Mortality Weekly Report

HIV Transmitted from a Living Organ Donor --- New York City, 2009

Weekly

March 18, 2011 / 60(10);297-301

4. Imperfect medical / social history

JAMA

The Journal of the American Medical Association

Raccoon Rabies Virus Variant Transmission Through Solid Organ Transplantation FREE
IVDU and HCV

For an extended description of the map, please see the description on page 214.
Donor testing timelines:

13 / 14 cases notable for IVDU or active reported drug use.
Donor testing timelines:

9 / 14 cases had HCV NAT drawn within a 48hr window of hospital arrival

Wolfe et al. ATC, Jun 5, 2018, abstract 569
A therapeutic antiviral revolution:

HIV  HCV  HBV
HIV / HCV / HBV transmissions in the US

**HIV:**

- No reported HIV transmissions in the US since 2009 living-donor transplant in NYC
- No reported HIV transmissions amongst deceased donors in the US since 2007, in Chicago
- Through the HOPE Act (transplantation of HIV+ donors into HIV+ recipients) risk has probably even gone *down further*
  - If donors with ?false-positive tests for HIV are found, they are transplanted safely into HIV +ve recipients.
- So current transplant management protocols appear SAFE in terms of detecting and managing HIV transmission risk

MMWR 2011 Mar 18;60(10):297-301
Less impact on HIV rates from opiate epidemic:

- But not zero…
  - Scott County, rural Indiana
  - Jan 2015 outbreak first recognized
  - By Sept 2016, 205 persons in community of 4,400 were diagnosed with HIV
  - Realistically community remains at a small risk of unanticipated HIV transmission

Campbell, et al; Detailed Transmission Network Analysis of a Large Opiate-Driven Outbreak of HIV Infection in the United States, JID, v216;9, 27 November 2017, 1053–1062
How do considerations of HCV / HIV impact the transplant community?
But what question does the patient face?

Heart Transplant
Lung Transplant

But what question does the patient face? (continued)

Conclusions:

- Donor-derived transmission events remain very rare in the US, although they can be significant.

- OPTN / DTAC can assess real-time changing trends in transplant, disease transmission, and helps explain and mitigate risk.

- Risk of the unknown is always balanced in solid organ transplant with the risk of doing nothing…
Questions?
Extra Slides if needed
Policies regarding Organ Vigilance:

- Required testing of donors:
  - Detailed NOK history, focusing on behavioural risks, geographic exposures
  - Required minimum standard testing:
    - HIV
    - HCV NAT
    - HBV serology
    - CMV, EBV, Syphilis
    - Toxoplasma IgG
    - Blood cultures
    - Urine cultures
    - Sputum / bronch cultures

- Additional testing per OPO and transplant center negotiation
  - Strongyloides, Chagas, Coccidioides, West Nile Virus etc
Increased Risk Donor issues vs Graft Issues:

For an accessible description of this image, please see the image description on page 215.
The Antiviral Revolution:

<table>
<thead>
<tr>
<th>Year</th>
<th>Trade Name</th>
<th>Generic Name</th>
<th>Genotypes</th>
<th>Success (SVR rate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>Olysio</td>
<td>Simepravir</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>2013</td>
<td>Sovaldi</td>
<td>Sofosbuvir (+Sim)</td>
<td>1,2,3,4</td>
<td>95-97%</td>
</tr>
<tr>
<td>2014</td>
<td>Harvoni</td>
<td>Ledispasvir / sofosbuvir</td>
<td>1,4,5,6</td>
<td>93-100%</td>
</tr>
<tr>
<td>2014</td>
<td>Viekira Pak</td>
<td>Dasabuvir/ombitsavir/paritaprevir/ R</td>
<td>1</td>
<td>95-96%</td>
</tr>
<tr>
<td>2015</td>
<td>Technivie</td>
<td>Ombitsavir/paritaprevir/R</td>
<td>4</td>
<td>91-100%</td>
</tr>
<tr>
<td>2015</td>
<td>Daklinza</td>
<td>Daclatasvir</td>
<td>3</td>
<td>96-100% (not ESLD)</td>
</tr>
<tr>
<td>2016</td>
<td>Zepatier</td>
<td>Elbasvir/Grazoprevir</td>
<td>1,4</td>
<td>92-100% (inc HD/CKD)</td>
</tr>
<tr>
<td>2016</td>
<td>Epclusa</td>
<td>Sofosbuvir / velpatasvir</td>
<td>1,2,3,4,5,6</td>
<td>95-100%</td>
</tr>
<tr>
<td>2017</td>
<td>Vosevi</td>
<td>Sofosbuvir / velpatasvir/ voxilaprevir</td>
<td>1,2,3,4,5,6</td>
<td>96-98% (in Rx failures)</td>
</tr>
<tr>
<td>2017</td>
<td>Mavyret (8w)</td>
<td>Glecaprevir / pibrentasvir</td>
<td>1,2,3,4,5,6</td>
<td>92-100% (inc HD/CKD)</td>
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</table>
Hepatitis C Ab+ donors: STILL underutilizing…

- 2015-2016: 9290 donors, 94% Ab-NAT-, ~2% Ab+/NAT-, remainder NAT+
  - 165 Ab+/NAT– donors = 134 livers, 80 kidneys, 1 lung, 0 hearts
  - 391 Ab+/NAT+ donors = 280 livers, 203 kidneys, 1 lung, 3 hearts

- Propensity score-matched model:
  - If we used Ab+/NAT-ve donors at the same pace as we do for Ab-/NAT- donors, we’d get an extra:
    - 48 kidney donors,
    - 37 hearts and
    - 15 more lung donors annually

Kling et al, AJT July 2017

US Deceased Donors 2017

<table>
<thead>
<tr>
<th>NAT+</th>
<th>NAT-</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ab+</td>
<td>474</td>
</tr>
<tr>
<td>Ab-</td>
<td>29</td>
</tr>
</tbody>
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US Deceased Donors 2017

False negative NAT?
Spontaneously cleared?
NAT below limit of detection?

False positive NAT?
Infected recently, within serologic eclipse period?
Infected recently, within NAT eclipse period?
Pathogens of special interest- reportable for suspected or confirmed donor or recipient illness

Amebic encephalitis
Anaplasma or Ehrlichiosis
Anthrax
Babesiosis
Brucellosis
California Serogroup Virus Diseases
Chagas
Chikungunya Virus Disease
Coccidioidomycosis/Valley Fever ** Specifically identified by autopsy, biopsy, or cultures. Exclude serology only
Crimean-Congo Hemorrhagic Fever virus
Dengue virus infections
Eastern Equine Encephalitis Virus Disease
Ebola virus
Enterovirus D68
Hantavirus
Hepatitis A
Hepatitis C (acute, past or present)
HIV Infection
Influenza-associated pediatric mortality

Lassa virus
LCMV
Leptospirosis
Listeriosis
Lujo virus
Lyme disease
Malaria
Marburg virus
Measles/Rubeola
Microsporidia
MERS co-V
Mumps
New World Arenaviruses
Pandemic Influenza strains
Plague
Poliomyelitis, paralytic
Poliomyelitis, nonparalytic
Powassan Virus Disease
Q fever (acute, chronic)
Rabies, animal or human
Rubella/ German Measles
Severe Acute Respiratory Syndrome (SARS)-Associated Coronavirus Disease
• Smallpox/Variola

OPTN/UNOS Disease transmission advisory committee
DTAC PERSPECTIVE AND OPINIONS ON NECESSARY CHANGES TO THE PHS GUIDELINE RECOMMENDATIONS

MARIAN MICHAELS, MD, MPH
Professor Pediatrics and Surgery
UPMC Children’s Hospital of Pittsburgh
Pediatric Infectious Diseases
PHS IRD Discussion: OPTN perspective

Marian G Michaels MD MPH
Chair, ad hoc OPTN DTAC
Professor of Pediatrics and Surgery
UPMC Children's Hospital of Pittsburgh
Acknowledgement

This analysis reflects, in part, work performed on behalf of the OPTN.

This work was supported wholly or in part by HRSA contract 234-2005-370011C. The content is the responsibility of the authors alone and does not necessarily reflect the views or policies of the Department of HHS, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government

Disclosures: No conflict of interest
Question 1: Is a new term needed to replace current term ‘PHS Increased Risk Donor’? 

- Yes
  - Term PHS IRD has an unintended negative connotation
  - Although it is superior to prior term “High Risk Donor”

- No consensus on specific new term
  - Recommend consultation with PR or behavioral psychologist

- OPTN DTAC member Informal discussion with psychologist
  - Lucy Cochran (lucy.m.cochran@gmail.com)
  - Cognitive biases may lead person to reject an organ despite probability of better outcome by accepting organ offer
Cognitive Biases

- **Base Rate Fallacy:**
  - Placing more emphasis on specific information versus general information
    - Focus on “increased risk” rather than on “good quality organ” is available

- **Negativity Bias:**
  - When all elements are equal, the potential negative outcome is given greater weight than potential positive or neutral outcome

- **Stigma of Disease:**
  - Perceived stigma of lifestyle leading to a risk for HIV, HCV, HBV

- **Zero Risk Bias:**
  - Preference to completely eliminate one risk (potential HIV, HCV, HBV) at the expense of not recognizing the greater risk (lack of organ availability)

Adapted from Lucy Cochran
Suggestions: Reframe the term and question

- Use more neutral term and offer more choices to make it less threatening

- Give 3 options rather than 2 options
  - **PHS A**: No further testing required based on PHS risk identification
  - **PHS B**: Further testing required based on identified possible risks
    - Behavioral risks or absence of adequate information
    - Equivalent to current PHS IRD
  - **PHS C**: Further testing/℞ required based on Positive donor test
    - Ex: Donor with Positive HCV NAT testing, or HOPE Act recipient
Question 2: Should donors continue to be identified based on risk factors for HIV, HBV, HCV?

- Infections are a risk with transplantation

- OPTN supports education on donor transmission risks not just PHS IRD
  - OPTN Policy 15.3: Informed consent of transmissible disease risk

- However, OPTN also supports maintaining a classification specifically for HIV, HBV, and HCV:
  - To inform transplant center & recipient of need for follow-up testing
  - For transparency to the public
Question 3: Should time be shortened from 12 months?

- Yes
  - We note that the 12 month period was a decrease from the 1994 guidelines which reviewed donor behaviors from the prior 5 years

- Rationale:
  - The 12 month period was instituted prior to all OPOs using nucleic acid tests (NAT)
  - NAT decreases the eclipse period substantially
  - By 2017 NAT used on >99.9% of donors - Abara et al MMWR Jan 2019
  - Accordingly, a protracted period of time no longer required

- Based on data presented by CDC
  - This window or eclipse period is < than 30 days for all three viruses and less than 10 days for HIV and HCV.
CDC data on risk of undetected virus based on time from behavior

Risk of undetected HIV infection among PWID

Risk of undetected HCV infection among PWID with an HCV-positive injecting partner

Risk of undetected HBV infection among donors with 3x the incidence of HBV among MSM

Eclipse period is < 30 days for all three viruses
Question #4: Are there specific criteria which should be eliminated or revised?

OPTN Evaluation of PHIS IRD – 2018

- 2018: 2,904 donors classified as PHS IRD
  - 10% Donors Sampled: (N=290) to assess individual risks
  - Methods: used “free text” narratives provided in DonorNet:
    - Donor admission course
    - Donor highlights
    - Donor Medical/Social History
    - DRAI
  - Limitation: except for hemodilution or death by drugs could not tell the time of the risk behavior
  - 2 donors removed as not truly PHS IRD
    - Leaving Total Sample Size N= 288
Rates of PHS IRD By Region During 2018

Regions
Region 1: Maine, New Hampshire, Massachusetts, Rhode Island, Connecticut
Region 2: Pennsylvania, New Jersey, Washington, DC, Maryland, West Virginia
Region 3: Arkansas, Louisiana, Mississippi, Alabama, Georgia, Florida
Region 4: Oklahoma, Texas
Region 5 California, Nevada, Utah, Arizona, New Mexico
Region 6: Washington, Oregon, Idaho, Montana, Alaska, Hawaii
Region 7: North Dakota, South Dakota, Minnesota, Wisconsin, Illinois
Region 8: Wyoming, Colorado, Nebraska, Kansas, Iowa, Missouri
Region 9: New York, Vermont
Region 10: Michigan, Indiana, Ohio
Region 11: Kentucky, Tennessee, Virginia, North Carolina, South Carolina
Rates of PHS IR Donors By Region 2018: All PHS IRD vs Sample

See map of regions on page 42 to identify which States are located in each region.
PHS IR Donors Demographics: Sample vs Total

<table>
<thead>
<tr>
<th>Description</th>
<th>Sample</th>
<th>All 2018 PHS IRD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N</strong></td>
<td>288</td>
<td>2,904</td>
</tr>
<tr>
<td><strong>Median Age (IQR)</strong></td>
<td>36 (27 – 45)</td>
<td>35 (27—46)</td>
</tr>
<tr>
<td><strong>Pediatric (&lt;12 y.o.) Donors (%)</strong></td>
<td>4 (1.4%)</td>
<td>47 (1.6%)</td>
</tr>
<tr>
<td><strong>Female Donors (%)</strong></td>
<td>92 (31.7%)</td>
<td>944 (32.5%)</td>
</tr>
<tr>
<td><strong>Donor Ethnicity (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>211 (72.3%)</td>
<td>1995 (68.7%)</td>
</tr>
<tr>
<td>Black or African—American</td>
<td>39 (13.4%)</td>
<td>458 (15.8%)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>33 (11.4%)</td>
<td>350 (12.1%)</td>
</tr>
<tr>
<td>Other/Multiracial</td>
<td>5 (1.7%)</td>
<td>101 (3.5%)</td>
</tr>
</tbody>
</table>
Results: PHS IRD Sample from 2018 (N= 288)

- Most deceased donors met only one criterion for increased risk:
Results: Indication for PHS IR Designation  N= 288

For an extended description of this chart, please see the description on page 216.
Results: N=179 donors with 1 Criterion only for PHS IRD

- Incarceration: N=46 (26%)
- IVDA: N=43 (24%)
- Poor Historian: N=22 (12%)
- Hemodialysis: N=22 (12%)
- Hemodilution: N=21 (12%)
- Dx/Rx for STI: N=11 (6%)
- MSM: N=5 (3%)
- Sex with Individual with IVDU: N=3 (2%)
- Sex with Indiv. Known/Susp. with HIV/HBV/HCV: N=3 (2%)
- Sex with Indiv. Who Had Sex for Money/Drugs: N=1 (1%)
- Sex for Money or Drugs: N=1 (1%)
- Child: Born to MO with or IR for HIV/HCV/HBV: N=1 (1%)
- Female Who Had Sex with MSM: N=0 (0%)
- Child: Breastfed by MO with or IR for HIV: N=0 (0%)

For an extended description of this chart, please see the description on page 217.
Hemodialysis and Hemodilution as risks

- Between 2008 and 2018 No transmissions of HIV, HCV, HBV due to hemodialysis or hemodilution as a risk factor

- Hemodilution was associated with transmission in very early transplant era using only Antibody testing not NAT

- Hemodialysis has been associated with confusion
  - Over 80% of dialysis centers test HCV annually and incidence decreased from 0.14 →0.08/100 person years
  - Accordingly, anticipate Donor testing by NAT identifying HCV infected donors who had been on routine hemodialysis
Pediatric Specific issue

- Looking at **all deceased donors** recovered in 2018
- 479 of 10,271 donors were less than 12 years of age
- Among these 479 pediatric donors:
  - 47 (10%) were PHS IRD
  - 28 /47 (60%) PHS IRD classification was due to hemodilution as sole criterion
OPTN Recommendations for Question #4:

- We believe the largest impact on decreasing the number of donors classified as PHS IRD will be based on changing 12 months to a shorter period of time.

- Consider eliminating:
  - Hemodialysis
  - Hemodilution
  - Particularly for pediatric donor
OPTN Conclusions:

- Applaud PHS effort to consider changes to PHS IRD
- Believe there is worthiness to continue to have some assessment of risk for HIV, HCV and HBV
- Suggest changing the name to a more neutral term
- Recommend shortening the 12-month time period substantially
- Consider removal of hemodialysis and hemodilution particularly for pediatric population
HIV/HCV IN ORGAN TRANSPLANTATION: CLINICAL TRIALS AND OUTCOMES

CHRISTINE DURAND, MD
Associate Professor of Medicine and Oncology Johns Hopkins University, School of Medicine Division of Infectious Diseases, Transplant Oncology ID Group
HIV and HCV in organ transplantation: clinical trials and outcomes

Christine M. Durand, MD
Associate Professor of Medicine, Transplant Infectious Diseases
HHS Advisory Committee on Blood & Tissue Safety and Availability
April 15, 2019
Outline

• HIV in organ transplantation
  • Biology and epidemiology
  • HIV- donor for HIV+ recipient (HIV D-/R+) transplantation
  • HIV+ donor for HIV+ recipient (HIV D+/R+) transplantation

• HCV in organ transplantation
  • Biology and epidemiology
  • HCV+ donor for HCV+ recipient (HCV D+/R+) transplantation
  • HCV+ donor for HCV- recipient (HCV D+/R-) transplantation
HIV

• Retrovirus, RNA virus, infects CD4 T cells
• Transmitted through blood or sexual contact
• Acute HIV
  • Flu like illness, can be severe with meningitis
  • Natural clearance or cure not reported
• Chronic HIV
  • If left untreated, over 5-15 years progression to AIDS
• Manageable condition with antiretroviral treatment near normal life expectancy
HIV epidemiology

• 1.1 million people with HIV in US
• Since 2012, incidence stable, with estimated 38,700 new cases in 2017

For an extended description of this charts, please see the descriptions on page 218.
# Evolution of HIV treatment

<table>
<thead>
<tr>
<th>Year</th>
<th>Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>'85-'89</td>
<td>1987 Zidovudine (NRTI)</td>
</tr>
</tbody>
</table>
| '90-'94 | 1991 Didanosine (NRTI)  
1992 Zalcitabine (NRTI)  
1994 Stavudine (NRTI) |
| '95-'99 | 1995 Lamivudine (NRTI)  
Saquinavir (PI)  
1996 Indinavir (PI)  
Nevirapine (NNRTI)  
Ritonavir (PI)  
1997 Combivir (FDC)  
Delavirdine (NNRTI)  
Nelfinavir (PI)  
1998 Abacavir (NRTI)  
Efavirenz (NNRTI)  
1999 Amprenavir (PI) |
| '00-'04 | 2000 Didanosine EC (NRTI)  
Kaletra (FDC)  
Trizivir (FDC)  
2001 Tenofovir DF (NRTI)  
2003 Emtricitabine (NRTI)  
Enfuvirtide (PI)  
Fosamprenavir (PI)  
2004 Epzicom (FDC)  
Truvada (FDC) |
| '05-'09 | 2005 Tipranavir (PI)  
2006 Atripla (FDC)  
Darunavir (PI)  
2007 Maraviroc (CA)  
Raltegravir (INSTI)  
2008 Etravirine (NNRTI) |
| '10-'14 | 2011 Complera (FDC)  
Nevirapine XR (NNRTI)  
Rilpivirine (NNRTI)  
2012 Strivolid (FDC)  
2013 Dolutegravir (INSTI)  
2014 Cobicistat (PE)  
Elvitegravir (INSTI)  
Truumeq (FDC) |
| '15-'18 | 2015 Evotaz (FDC)  
Genvoya (FDC)  
Prezempix (FDC)  
2016 Descovy (FDC)  
Odefsey (FDC)  
2017 Juluca (FDC)  
2018 Biktarvy (FDC)  
Cimduo (FDC)  
Delstrigo (FDC)  
Doravirine (NNRTI)  
Ibalizumab (PAI)  
Symfandi (FDC)  
Symfandi Lo (FDC)  
Symtuza (FDC) |

7 drug classes, > 25 drugs

- **NRTI** – nucleoside reverse transcriptase inhibitor
- **PI** – protease inhibitor
- **NNRTI** – non-nucleoside reverse transcriptase inhibitor
- **FI** – Fusion inhibitor
- **CA** – CCR5 antagonist
- **INSTI** – integrase strand transferase inhibitor
- **PAI** – post attachment inhibitor

**FDC** – Fixed dose combination

https://aidsinfo.nih.gov

For an extended description of this image, please see the descriptions on page 219.
Early experience of HIV transplant

- 1980’s unintentional HIV D+ and HIV R+ transplants
  - n=18 (all organs) Univ Pittsburgh, 6 month survival 50%¹

- 1988 National Organ Transplant Act amendment bans acquisition of organs from individuals with HIV

- 1990’s intentional HIV D-/R+ transplants (pre-highly active antiretroviral therapy), inferior outcomes
  - n=32, kidney, SRTR, 3 yr survival 83%, graft survival 53%²

- HIV in a donor or a recipient was a contraindication

HIV D-/R+ in era of effective ART

2003-2009 HIV Transplant Recipient (HIV TR) Study
HIV D-/R+ in era of effective ART
2003-2009 HIV Transplant Recipient (HIV TR) Study

Kidney n=150

Survival
1 yr: 95%
3 yr: 91%

Graft survival
1 yr: 90%
3 yr: 77%

For an extended description of these graphs, please see the descriptions on page 220.

Stock PG/Roland M NEJM 2010.
HIV D-/R+ in era of effective ART

2003-2009 HIV Transplant Recipient (HIV TR) Study

Kidney
n=150

Survival
1 yr: 95%
3 yr: 91%

Graft survival
1 yr: 90%
3 yr: 77%

Liver
HIV/HCV  HCV
n=89  n=235

Patient survival
1 yr: 76%  92%
3 yr: 60%  79%

Graft survival
1 yr: 72%  88%
3 yr: 53%  74%

For an extended description of these graphs, please see the descriptions on page 221.

Stock PG/Roland M NEJM 2010.

Terrault/Stock Liver Transp 2012
National real-world data confirms

- 1431 HIV+ kidney transplant candidates 2001-2012
- Relative risk of mortality 79% lower for transplant vs dialysis

Locke JE/Segev DL. Ann Surgery, 2017
National real-world data confirms

- 1431 HIV+ kidney transplant candidates 2001-2012
- Relative risk of mortality 79% lower for transplant vs dialysis

Locke JE/Segev DL. Ann Surgery, 2017

- 180 HIV+ liver transplant recipients matched 1:10 HIV-
- HIV monoinfected recipients in modern era did not have increased hazard of death

Locke JE/Segev DL. Transplantation, 2016
HIV and transplant in modern era

- National organ shortage remains
- HIV+ candidates on waitlist have disproportionate mortality compared to HIV-
- Novel donor sources needed
S Africa: HIV D+/R+ kidney transplant

Table 1. Clinical Characteristics of HIV-Positive Recipients of a Transplant from an HIV-Positive Donor.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Patient 1</th>
<th>Patient 2</th>
<th>Patient 3</th>
<th>Patient 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>47</td>
<td>56</td>
<td>37</td>
<td>29</td>
</tr>
<tr>
<td>Sex</td>
<td>Male</td>
<td>Male</td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>Diagnosis on renal biopsy</td>
<td>HIV-associated nephropathy</td>
<td>HIV-associated nephropathy and hypertensive nephropathy</td>
<td>Malignant hypertension</td>
<td>HIV-associated nephropathy</td>
</tr>
<tr>
<td>Creatinine (liter)</td>
<td>678</td>
<td>582</td>
<td>1712</td>
<td>725</td>
</tr>
<tr>
<td>CD4 count (cells/mm)</td>
<td>288</td>
<td>258</td>
<td>132</td>
<td>147</td>
</tr>
<tr>
<td>HIV viral load (copies/ml)</td>
<td>≤50</td>
<td>≤50</td>
<td>≤50</td>
<td>≤50</td>
</tr>
<tr>
<td>Antiretroviral regimen</td>
<td>Tenofovir, lamivudine, and lopinavir-ritonavir</td>
<td>Stavudine, lamivudine, and efavirenz</td>
<td>Stavudine, lamivudine, and efavirenz</td>
<td>Zidovudine, lamivudine, and nevirapine</td>
</tr>
</tbody>
</table>

Figure 1. Graft and Patient Survival among 27 Human Immunodeficiency Virus (HIV)-Positive Patients Who Received Kidney Transplants from HIV-Positive Donors.
Potential of HIV+ donor pool

- 300-500 potential HIV+ donors every year in US
- Someone on the waiting list is likely to benefit from them

Estimating the Potential Pool of HIV-Infected Deceased Organ Donors in the United States


*Department of Surgery, Johns Hopkins School of Medicine, Baltimore, MD
**Department of Surgery, Georgetown University School of Medicine, Washington, DC
***Department of Medicine, Johns Hopkins University School of Medicine, Baltimore, MD
****Department of Epidemiology, Johns Hopkins School of Public Health, Baltimore, MD

National Organ Transplant Act of 1984; OPTN, Organ Procurement and Transplantation Network; NIS, Nationwide Inpatient Sample; AHRQ, Agency for Healthcare Research and Quality; HCUP, Healthcare Cost and Utilization Project; CCS, Clinical Classification Software.

Received 03 December 2010, revised 24 January 2011 and accepted for publication 09 February 2011

Introduction
Due to superior medical management of human immuno-

An Assessment of HIV-Infected Patients Dying in Care for Deceased Organ Donation in a United States Urban Center

A. Richterman†, D. Sawinski‡, P. P. Reese†, D. H. Lee§, H. Claus¶, R. D. Hasz**, A. Thomasson†, D. S. Goldberg†, P. L. Abt‡, K. A. Forde†, R. D. Bloom, S. L. Doll, K. A. Brady§ and E. A. Blumberg‡

†Department of Medicine, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA
‡Department of Medicine, Drexel University, Philadelphia, PA
¶Department of Medicine, Temple University, Philadelphia, PA
§Gift of Life Donor Program, Philadelphia, PA

Received 17 December 2014, revised 05 February 2015 and accepted for publication 05 March 2015

Introduction
HIV Organ Policy Equity Act 2013
HIV D+/R+: **Research Only for Now**

- Potential risks:
  - HIV superinfection from donor to recipient
  - HIV associated organ disease in allograft
  - Increased rejection
  - Increased infections

- NIH Safeguards and Research Criteria
HIV D+/R+: **Research Only** for Now

- The HOPE Act states, “not later than 4 years after the date of enactment and annually thereafter, the Secretary shall review the results of scientific research in conjunction with the OPTN to determine whether the results warrant revision of the standards of quality.”

- IRB approved protocol

- Organ Procurement Transplantation Network - open variance and annual safety reports
• Multicenter effort to determine if HIV D+/R+ transplantation in US is safe and effective

• Pilot/Parent kidney and liver study, opened in 2016

• NIH funded U01 trials for kidney and liver, opened in 2018 and 2019, respectively

Kidney: U01AI134591 NCT03500315
Liver: U01AI138897 NCT03408106
Johns Hopkins March 2016
First HIV D+/R+ kidney and liver transplants
HOPE in 2019: 31 transplant centers

Barnes Jewish Hospital, St Louis
Columbia University
Duke University
Emory University
Georgetown University
Hahnemann University
Indiana University Health
Jackson Memorial Miami
Johns Hopkins Hospital
Montefiore Medical Center
Mount Sinai Medical Center
Massachusetts General
Methodist Dallas Medical
Montefiore
New York University Medical
Northwestern Memorial
Ochsner Foundation Hospital
Rush University
Saint Barnabas Medical Center
University of Alabama
University of California SF
University of Cincinnati
University of Colorado
University of Illinois
University of Maryland
University of Minnesota
University of Pittsburgh
University of Virginia Medical Center
VCU Medical Center
Weill Cornell Medical Center
Yale New Haven Hospital

See map of regions on page 42 to identify which States are located in each region.

31 transplant centers
46/58 organ procurement organizations
Study Design
Eligible HIV+ kidney or liver candidates

UNOS organ offers per availability
“Natural randomization”

- HIV+ Candidate Criteria
  - No opportunistic infections
  - Kidney CD4 > 200 cells
  - Liver CD4 > 100 cells

- HIV+ Donor Criteria
  - No active opportunistic infections
  - Any HIV VL or CD4 count
  - Study team must describe effective ART for recipient
Organs from deceased donors with false-positive HIV screening tests: An unexpected benefit of the HOPE act

- Donors tested for both HIV antibody (Ab) and nucleic acid test (NAT)
- Designed to capture acute infection HIV Ab-/NAT+
- Assays have false positive rates Ab>NAT
- Screen > 20,000 donor/yr, false-positive rate 0.1-0.3%
- ≈50-100 HIV false positive donors/year

Durand CM/Segev DL, AJT, 2018
Study Endpoints

• Patient survival
• Graft survival
• Rejection
• Graft function
• HIV related organ disease
• HIV breakthrough or failure
• HIV resistance
• Opportunistic infections
• Cancer incidence
• HIV superinfection in blood and tissues
• HIV anatomic sanctuaries
• HIV reservoirs over time
• Quality of life
• Patient reported outcomes
First three years of HOPE in Action
HOPE donors and transplants

<table>
<thead>
<tr>
<th>Donor</th>
<th>HIV</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>True Positive</td>
<td></td>
<td>3</td>
<td>7</td>
<td>19</td>
<td>4</td>
<td>33</td>
</tr>
<tr>
<td>False Positive</td>
<td></td>
<td>6</td>
<td>2</td>
<td>14</td>
<td>1</td>
<td>23</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>9</td>
<td>9</td>
<td>33</td>
<td>4</td>
<td>56</td>
</tr>
</tbody>
</table>

For an extended description of these graphs, please see the descriptions on page 222.
HOPE Pilot Study*

HIV+ kidney or liver transplant candidates

Consented for study
N = 338

Eligible to receive deceased donor transplant
N = 159

Received deceased donor transplant
N = 96

Removed from study 7 withdrew consent
- 3 removed per transplant team decision
- 56 moved onto U01 trial
- 17 died on the waitlist

HIV D-/R+
N = 63

HIV D+/R+
N = 33

*Does not include U01 transplants or studies outside of JHU pilot
# Consented candidates (N=338)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Organ consented to receive</strong></td>
<td></td>
</tr>
<tr>
<td>Kidney</td>
<td>273 (80.8%)</td>
</tr>
<tr>
<td>Liver</td>
<td>54 (16.0%)</td>
</tr>
<tr>
<td>Kidney/Liver</td>
<td>9 (2.7%)</td>
</tr>
<tr>
<td>Kidney/Pancreas</td>
<td>2 (0.6%)</td>
</tr>
<tr>
<td><strong>Age at consent, median (IQR)</strong></td>
<td>53 (44, 59)</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td>83 (24.6%)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
</tr>
<tr>
<td>White/Caucasian</td>
<td>91 (26.9%)</td>
</tr>
<tr>
<td>Black/African American</td>
<td>241 (71.3%)</td>
</tr>
<tr>
<td>Asian</td>
<td>3 (0.9%)</td>
</tr>
<tr>
<td>American Indian</td>
<td>1 (0.3%)</td>
</tr>
<tr>
<td>Missing</td>
<td>2 (0.6%)</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>37 (10.9%)</td>
</tr>
<tr>
<td>Non-Hispanic/Latino</td>
<td>299 (88.5%)</td>
</tr>
<tr>
<td>Missing</td>
<td>2 (0.6%)</td>
</tr>
</tbody>
</table>
## HOPE deceased donors (N=71)

<table>
<thead>
<tr>
<th>Factor</th>
<th>HIVD-</th>
<th>HIVFP</th>
<th>HIVD+</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>36</td>
<td>14</td>
<td>21</td>
<td>-</td>
</tr>
<tr>
<td><strong>Organs used</strong></td>
<td>&lt;N&gt;</td>
<td>&lt;N&gt;</td>
<td>&lt;N&gt;</td>
<td>&lt;N&gt;</td>
</tr>
<tr>
<td>Kidney(s)-only</td>
<td>27 (75%)</td>
<td>6 (43%)</td>
<td>4 (19%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Liver-only</td>
<td>5 (14%)</td>
<td>2 (14%)</td>
<td>6 (29%)</td>
<td>-</td>
</tr>
<tr>
<td>Both</td>
<td>4 (11%)</td>
<td>6 (43%)</td>
<td>11 (52%)</td>
<td>-</td>
</tr>
<tr>
<td>Age, median (IQR)</td>
<td>31.5 (27, 39.5)</td>
<td>29.5 (20, 41)</td>
<td>32 (27, 42)</td>
<td>0.7</td>
</tr>
<tr>
<td>Male sex</td>
<td>22 (61%)</td>
<td>9 (64%)</td>
<td>15 (71%)</td>
<td>0.8</td>
</tr>
<tr>
<td>Race</td>
<td>&lt;N&gt;</td>
<td>&lt;N&gt;</td>
<td>&lt;N&gt;</td>
<td>0.5</td>
</tr>
<tr>
<td>White/Caucasian</td>
<td>20 (56%)</td>
<td>7 (50%)</td>
<td>8 (38%)</td>
<td>-</td>
</tr>
<tr>
<td>Black/African American</td>
<td>12 (33%)</td>
<td>4 (29%)</td>
<td>11 (52%)</td>
<td>-</td>
</tr>
<tr>
<td>Asian</td>
<td>1 (3%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>-</td>
</tr>
<tr>
<td>Hawaiian</td>
<td>1 (3%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>-</td>
</tr>
<tr>
<td>Other</td>
<td>2 (6%)</td>
<td>3 (21%)</td>
<td>2 (10%)</td>
<td>-</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>&lt;N&gt;</td>
<td>&lt;N&gt;</td>
<td>&lt;N&gt;</td>
<td>0.2</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>2 (6%)</td>
<td>3 (21%)</td>
<td>2 (10%)</td>
<td>-</td>
</tr>
<tr>
<td>Not Specified/Unknown</td>
<td>34 (94%)</td>
<td>11 (79%)</td>
<td>19 (90%)</td>
<td>-</td>
</tr>
</tbody>
</table>
**HOPE deceased donors (N=71)**

<table>
<thead>
<tr>
<th>Factor</th>
<th>HIVD-</th>
<th>HIVFP</th>
<th>HIVD+</th>
<th>p-value</th>
</tr>
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<tbody>
<tr>
<td>-</td>
<td>36</td>
<td>14</td>
<td>21</td>
<td>-</td>
</tr>
<tr>
<td>Organs used</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Kidney(s)-only</td>
<td>27 (75%)</td>
<td>6 (43%)</td>
<td>4 (19%)</td>
<td>-</td>
</tr>
<tr>
<td>Liver-only</td>
<td>5 (14%)</td>
<td>2 (14%)</td>
<td>6 (29%)</td>
<td>-</td>
</tr>
<tr>
<td>Both</td>
<td>4 (11%)</td>
<td>6 (43%)</td>
<td>11 (52%)</td>
<td>-</td>
</tr>
<tr>
<td>Age, median (IQR)</td>
<td>31.5 (27, 39.5)</td>
<td>29.5 (20, 41)</td>
<td>32 (27, 42)</td>
<td>0.7</td>
</tr>
<tr>
<td>Male sex</td>
<td>22 (61%)</td>
<td>9 (64%)</td>
<td>15 (71%)</td>
<td>0.8</td>
</tr>
<tr>
<td>Race</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>0.5</td>
</tr>
<tr>
<td>White/Caucasian</td>
<td>20 (56%)</td>
<td>7 (50%)</td>
<td>8 (38%)</td>
<td>-</td>
</tr>
<tr>
<td>Black/African American</td>
<td>12 (33%)</td>
<td>4 (29%)</td>
<td>11 (52%)</td>
<td>-</td>
</tr>
<tr>
<td>Asian</td>
<td>1 (3%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>-</td>
</tr>
<tr>
<td>Hawaiian</td>
<td>1 (3%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>-</td>
</tr>
<tr>
<td>Other</td>
<td>2 (6%)</td>
<td>3 (21%)</td>
<td>2 (10%)</td>
<td>-</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>0.2</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>2 (6%)</td>
<td>3 (21%)</td>
<td>2 (10%)</td>
<td>-</td>
</tr>
<tr>
<td>Not Specified/Unknown</td>
<td>34 (94%)</td>
<td>11 (79%)</td>
<td>19 (90%)</td>
<td></td>
</tr>
</tbody>
</table>
# HOPE deceased donors (N=71)

<table>
<thead>
<tr>
<th>Factor</th>
<th>HIVD-</th>
<th>HIVFP</th>
<th>HIVD+</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>36</td>
<td>14</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>BMI, med (IQR)</td>
<td>25.7</td>
<td>26.2</td>
<td>23.1</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td>(23.0, 30.0)</td>
<td>(22.1, 34.2)</td>
<td>(21.5, 26.0)</td>
<td></td>
</tr>
<tr>
<td>Donation after Cardiac Death</td>
<td>1 (3%)</td>
<td>3 (21%)</td>
<td>0 (0%)</td>
<td>0.03</td>
</tr>
<tr>
<td>Intravenous drug use</td>
<td>15 (42%)</td>
<td>1 (7%)</td>
<td>2 (10%)</td>
<td>0.01</td>
</tr>
<tr>
<td>Cause of Death</td>
<td></td>
<td></td>
<td></td>
<td>0.1</td>
</tr>
<tr>
<td>Anoxia</td>
<td>21 (58%)</td>
<td>3 (21%)</td>
<td>11 (52%)</td>
<td></td>
</tr>
<tr>
<td>Cerebrovascular/Stroke</td>
<td>4 (11%)</td>
<td>4 (29%)</td>
<td>4 (19%)</td>
<td></td>
</tr>
<tr>
<td>Head Trauma</td>
<td>11 (31%)</td>
<td>6 (43%)</td>
<td>6 (29%)</td>
<td></td>
</tr>
<tr>
<td>Other; specify</td>
<td>0 (0%)</td>
<td>1 (7%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>History of hypertension</td>
<td>4 (11%)</td>
<td>4 (29%)</td>
<td>5 (24%)</td>
<td>0.3</td>
</tr>
<tr>
<td>History of cancer</td>
<td>0 (0%)</td>
<td>1 (7%)</td>
<td>1 (5%)</td>
<td>0.2</td>
</tr>
<tr>
<td>Creatinine (mg/dL), med (IQR)</td>
<td>1 (.75, 1.51)</td>
<td>.915 (.9, 1)</td>
<td>1 (.9, 1.3)</td>
<td>0.5</td>
</tr>
<tr>
<td>KDPI, median (IQR)</td>
<td>40.5 (29, 54)</td>
<td>30.5 (21, 73)</td>
<td>38 (28, 63)</td>
<td>0.5</td>
</tr>
</tbody>
</table>

KDPI; Kidney donor profile index; percentile score from 0-100
BMI; body mass index
Infectious disease characteristics of donors (n=71)

<table>
<thead>
<tr>
<th>Factor</th>
<th>HIVD- (N=36)</th>
<th>HIVFP (N=14)</th>
<th>HIVD+ (N=21)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-HIV I/II</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Negative</td>
<td>36 (100%)</td>
<td>1 (7%)</td>
<td>0 (0%)</td>
<td>-</td>
</tr>
<tr>
<td>Positive</td>
<td>0 (0%)</td>
<td>13 (93%)</td>
<td>21 (100%)</td>
<td>-</td>
</tr>
<tr>
<td>HIV NAT reactive</td>
<td>0 (0%)</td>
<td>1 (7%)</td>
<td>14 (67%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>HIV viral load</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Detectable</td>
<td>NA</td>
<td>-</td>
<td>11 (52%)</td>
<td>-</td>
</tr>
<tr>
<td>HIV viral load, med (range)</td>
<td>-</td>
<td>-</td>
<td>30220 (475-3074276)</td>
<td>-</td>
</tr>
<tr>
<td>CD4 count</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Median (range)</td>
<td>-</td>
<td>-</td>
<td>293 (26-1683)</td>
<td>-</td>
</tr>
<tr>
<td>Not reported</td>
<td>-</td>
<td>-</td>
<td>2 (10%)</td>
<td>-</td>
</tr>
<tr>
<td>Anti-HCV</td>
<td>11 (31%)</td>
<td>0 (0%)</td>
<td>1 (5%)</td>
<td>0.008</td>
</tr>
<tr>
<td>HCV NAT</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>0.03</td>
</tr>
<tr>
<td>Negative</td>
<td>26 (72%)</td>
<td>14 (100%)</td>
<td>19 (90%)</td>
<td>-</td>
</tr>
<tr>
<td>Positive</td>
<td>10 (28%)</td>
<td>0 (0%)</td>
<td>2 (10%)</td>
<td>-</td>
</tr>
<tr>
<td>HBV NAT</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>0.2</td>
</tr>
<tr>
<td>Negative</td>
<td>36 (100%)</td>
<td>14 (100%)</td>
<td>20 (95%)</td>
<td>-</td>
</tr>
<tr>
<td>Positive</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1 (5%)</td>
<td>-</td>
</tr>
<tr>
<td>Anti-HBcAb</td>
<td>3 (8%)</td>
<td>0 (0%)</td>
<td>2 (10%)</td>
<td>0.7</td>
</tr>
</tbody>
</table>
# Infectious disease characteristics of donors (n=71)

<table>
<thead>
<tr>
<th>Factor</th>
<th>HIVD- (N=36)</th>
<th>HIVFP (N=14)</th>
<th>HIVD+ (N=21)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-HIV I/II</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>&lt;0.001</td>
</tr>
<tr>
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<td>36 (100%)</td>
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<td>0 (0%)</td>
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</tr>
<tr>
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<td>0 (0%)</td>
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<td>&lt;0.001</td>
</tr>
<tr>
<td>HIV viral load</td>
<td>NA</td>
<td>-</td>
<td>11 (52%)</td>
<td>-</td>
</tr>
<tr>
<td>HIV viral load, med (range)</td>
<td>-</td>
<td>-</td>
<td>30220 (475-3074276)</td>
<td>-</td>
</tr>
<tr>
<td>CD4 count</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Median (range)</td>
<td>-</td>
<td>-</td>
<td>293 (26-1683)</td>
<td>-</td>
</tr>
<tr>
<td>Not reported</td>
<td>-</td>
<td>-</td>
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</tr>
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<td>Anti-HCV</td>
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<td>0 (0%)</td>
<td>1 (5%)</td>
<td>0.008</td>
</tr>
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<td>HCV NAT</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>0.03</td>
</tr>
<tr>
<td>Negative</td>
<td>26 (72%)</td>
<td>14 (100%)</td>
<td>19 (90%)</td>
<td>-</td>
</tr>
<tr>
<td>Positive</td>
<td>10 (28%)</td>
<td>0 (0%)</td>
<td>2 (10%)</td>
<td>-</td>
</tr>
<tr>
<td>HBV NAT</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>0.2</td>
</tr>
<tr>
<td>Negative</td>
<td>36 (100%)</td>
<td>14 (100%)</td>
<td>20 (95%)</td>
<td>-</td>
</tr>
<tr>
<td>Positive</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1 (5%)</td>
<td>-</td>
</tr>
<tr>
<td>Anti-HBcAb</td>
<td>3 (8%)</td>
<td>0 (0%)</td>
<td>2 (10%)</td>
<td>0.7</td>
</tr>
</tbody>
</table>
## Infectious disease characteristics of donors (n=71)

<table>
<thead>
<tr>
<th>Factor</th>
<th>HIVD- (N=36)</th>
<th>HIVFP (N=14)</th>
<th>HIVD+ (N=21)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-HIV I/II</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Negative</td>
<td>36 (100%)</td>
<td>1 (7%)</td>
<td>0 (0%)</td>
<td>-</td>
</tr>
<tr>
<td>Positive</td>
<td>0 (0%)</td>
<td>13 (93%)</td>
<td>21 (100%)</td>
<td>-</td>
</tr>
<tr>
<td>HIV NAT reactive</td>
<td>0 (0%)</td>
<td>1 (7%)</td>
<td>14 (67%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>HIV viral load</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Detectable</td>
<td>NA</td>
<td>-</td>
<td>11 (52%)</td>
<td>-</td>
</tr>
<tr>
<td>HIV viral load, med (range)</td>
<td>-</td>
<td>-</td>
<td>30220 (475-3074276)</td>
<td>-</td>
</tr>
<tr>
<td>CD4 count</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Median (range)</td>
<td>-</td>
<td>-</td>
<td>293 (26-1683)</td>
<td>-</td>
</tr>
<tr>
<td>Not reported</td>
<td>-</td>
<td>-</td>
<td>2 (10%)</td>
<td>-</td>
</tr>
<tr>
<td>Anti-HCV</td>
<td>11 (31%)</td>
<td>0 (0%)</td>
<td>1 (5%)</td>
<td>0.008</td>
</tr>
<tr>
<td>HCV NAT</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>0.03</td>
</tr>
<tr>
<td>Negative</td>
<td>26 (72%)</td>
<td>14 (100%)</td>
<td>19 (90%)</td>
<td>-</td>
</tr>
<tr>
<td>Positive</td>
<td>10 (28%)</td>
<td>0 (0%)</td>
<td>2 (10%)</td>
<td>-</td>
</tr>
<tr>
<td>HBV NAT</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>0.2</td>
</tr>
<tr>
<td>Negative</td>
<td>36 (100%)</td>
<td>14 (100%)</td>
<td>20 (95%)</td>
<td>-</td>
</tr>
<tr>
<td>Positive</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1 (5%)</td>
<td>-</td>
</tr>
<tr>
<td>Anti-HBcAb</td>
<td>3 (8%)</td>
<td>0 (0%)</td>
<td>2 (10%)</td>
<td>0.7</td>
</tr>
</tbody>
</table>
### HIV+ kidney-only transplant recipients (N=63)

<table>
<thead>
<tr>
<th>Factor</th>
<th>HIVD-/R+</th>
<th>HIVD+/R+</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>46</td>
<td>17</td>
<td>-</td>
</tr>
<tr>
<td>Age at transplant, median (IQR)</td>
<td>52.5 (41, 56)</td>
<td>52 (45, 56)</td>
<td>0.5</td>
</tr>
<tr>
<td>Female sex</td>
<td>15 (33%)</td>
<td>4 (24%)</td>
<td>0.6</td>
</tr>
<tr>
<td>Race</td>
<td>-</td>
<td>-</td>
<td>0.08</td>
</tr>
<tr>
<td>Caucasian/White</td>
<td>3 (7%)</td>
<td>3 (18%)</td>
<td>-</td>
</tr>
<tr>
<td>African American/Black</td>
<td>43 (93%)</td>
<td>13 (76%)</td>
<td>-</td>
</tr>
<tr>
<td>Asian</td>
<td>0 (0%)</td>
<td>1 (6%)</td>
<td>-</td>
</tr>
<tr>
<td>Hispanic or Latino ethnicity</td>
<td>2 (4%)</td>
<td>1 (6%)</td>
<td>-</td>
</tr>
<tr>
<td>Primary cause of renal failure</td>
<td>-</td>
<td>-</td>
<td>0.1</td>
</tr>
<tr>
<td>HIV-Associated Renal Disease</td>
<td>17 (37%)</td>
<td>3 (18%)</td>
<td>-</td>
</tr>
<tr>
<td>Diabetes/Hypertension</td>
<td>18 (39%)</td>
<td>7 (41%)</td>
<td>-</td>
</tr>
<tr>
<td>Glomerulonephritis</td>
<td>0 (0%)</td>
<td>1 (6%)</td>
<td>-</td>
</tr>
<tr>
<td>IgA Nephrosclerosis</td>
<td>0 (0%)</td>
<td>1 (6%)</td>
<td>-</td>
</tr>
<tr>
<td>Other</td>
<td>11 (24%)</td>
<td>5 (29%)</td>
<td>-</td>
</tr>
<tr>
<td>Induction Immunosuppression</td>
<td>-</td>
<td>-</td>
<td>0.1</td>
</tr>
<tr>
<td>ATG</td>
<td>17 (37%)</td>
<td>2 (12%)</td>
<td>-</td>
</tr>
<tr>
<td>Basiliximab</td>
<td>27 (59%)</td>
<td>15 (88%)</td>
<td>-</td>
</tr>
<tr>
<td>Other</td>
<td>2 (4%)</td>
<td>0 (0%)</td>
<td>-</td>
</tr>
</tbody>
</table>
# HIV+ kidney-only transplant recipients

## Infectious disease characteristics

<table>
<thead>
<tr>
<th>Factor</th>
<th>HIVD-/R+</th>
<th>HIVD+/R+</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>46</td>
<td>17</td>
<td>-</td>
</tr>
<tr>
<td>HIV RNA used for eligibility</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Undetectable defined as &lt; 200 copies</strong></td>
<td>46 (100%)</td>
<td>17 (100%)</td>
<td>-</td>
</tr>
<tr>
<td>CD4 count used for eligibility, median (IQR)</td>
<td>506 (318, 667)</td>
<td>504 (409, 622)</td>
<td>0.90</td>
</tr>
<tr>
<td>HCV Ab+</td>
<td>12 (26%)</td>
<td>2 (12%)</td>
<td>0.3</td>
</tr>
<tr>
<td>Log$_{10}$ HCV RNA (if detected), median (IQR)</td>
<td>5.7 (1.5, 6.6)</td>
<td>6.3 (6.3, 6.3)</td>
<td>0.5</td>
</tr>
</tbody>
</table>
### HIV+ liver transplant recipients (N=33)

<table>
<thead>
<tr>
<th>Factor</th>
<th>HIVD-/R+</th>
<th>HIVD+/R+</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>17</td>
<td>16</td>
<td>-</td>
</tr>
<tr>
<td>Age at transplant, median (IQR)</td>
<td>55 (46, 60)</td>
<td>61 (53, 63)</td>
<td>0.09</td>
</tr>
<tr>
<td>Female gender</td>
<td>5 (29%)</td>
<td>3 (19%)</td>
<td>0.7</td>
</tr>
<tr>
<td>Race</td>
<td>-</td>
<td>-</td>
<td>0.6</td>
</tr>
<tr>
<td>White/Caucasian</td>
<td>9 (53%)</td>
<td>11 (69%)</td>
<td>-</td>
</tr>
<tr>
<td>Black/African American</td>
<td>7 (41%)</td>
<td>5 (31%)</td>
<td>-</td>
</tr>
<tr>
<td>American Indian</td>
<td>1 (6%)</td>
<td>0 (0%)</td>
<td>-</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>-</td>
<td>-</td>
<td>0.7</td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>3 (18%)</td>
<td>4 (25%)</td>
<td>-</td>
</tr>
<tr>
<td>Not Hispanic or Latino</td>
<td>14 (82%)</td>
<td>12 (75%)</td>
<td>-</td>
</tr>
<tr>
<td>Indication for transplant</td>
<td>-</td>
<td>-</td>
<td>0.7</td>
</tr>
<tr>
<td>HCV</td>
<td>8 (47%)</td>
<td>10 (63%)</td>
<td>-</td>
</tr>
<tr>
<td>HCC alone</td>
<td>1 (6%)</td>
<td>1 (6%)</td>
<td>-</td>
</tr>
<tr>
<td>HepB</td>
<td>4 (24%)</td>
<td>1 (6%)</td>
<td>-</td>
</tr>
<tr>
<td>NASH</td>
<td>2 (12%)</td>
<td>1 (6%)</td>
<td>-</td>
</tr>
<tr>
<td>Other/Cryptogenic/Idiopathic</td>
<td>2 (12%)</td>
<td>3 (19%)</td>
<td>-</td>
</tr>
</tbody>
</table>
HIV+ liver transplant recipients
Infectious disease characteristics

<table>
<thead>
<tr>
<th>Factor</th>
<th>HIVD-/R+</th>
<th>HIVD+/R+</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>17</td>
<td>16</td>
<td>-</td>
</tr>
<tr>
<td>HIV RNA used for eligibility</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Undetectable</td>
<td>17 (100%)</td>
<td>16 (100%)</td>
<td>-</td>
</tr>
<tr>
<td>CD4 count used for eligibility, median (IQR)</td>
<td>314 (156, 461)</td>
<td>262 (154, 392)</td>
<td>0.6</td>
</tr>
<tr>
<td>HCV Ab+</td>
<td>9 (53%)</td>
<td>11 (69%)</td>
<td>0.5</td>
</tr>
<tr>
<td>Log10 HCV RNA (if detected), median (IQR)</td>
<td>1.2 (1.2, 7.1)</td>
<td>1.2 (1.2, 6.0)</td>
<td>0.3</td>
</tr>
</tbody>
</table>
HIV D+/R+ to date and future plans

HOPE in Action Pilot

- 63 deceased donor kidney and 33 liver transplants
- Excellent survival for those transplanted (deaths on waitlist)
- Excellent graft survival to date
- Rare HIV breakthroughs due to non-adherence
- Opportunistic infections in ≈20%, generally CMV and candida esophagitis
- Rejection common in kidney, associated with induction immunosuppression

HOPE in Action NIAID U01 trials

- Kidney: 40 transplants in year 1 (target 160 transplants over study)
- Liver: initiated in January 2019 (target 80 transplants over study)
Outline

• HIV in organ transplantation
  • Biology and epidemiology
  • HIV- donor for HIV+ recipient (HIV D-/R+) transplantation
  • HIV+ donor for HIV+ recipient (HIV D+/R+) transplantation

• HCV in organ transplantation
  • Biology and epidemiology
  • HCV+ donor for HCV+ recipient (HCV D+/R+) transplantation
  • HCV+ donor for HCV- recipient (HCV D+/R-) transplantation
Hepatitis C virus (HCV) biology

- RNA virus, infects liver hepatocytes
- Transmitted primarily through blood contact
- Acute HCV
  - Flu-like illness, rarely severe presentation
  - 2/3 individuals clear infection spontaneously
  - Can be severe in acute post-transplant setting, complications such as fibrosing cholestatic HCV
- Chronic HCV
  - 1/3 individuals develop chronic disease
  - Minimal symptoms over decades can progress to cirrhosis, liver failure, liver cancer
Hepatitis C virus (HCV) biology

- RNA virus, infects liver hepatocytes
- Transmitted primarily through blood contact
- Acute HCV
  - Flu-like illness, rarely severe presentation
  - 2/3 individuals clear infection spontaneously
  - Can be severe in acute post-transplant setting, complications such as fibrosing cholestatic HCV
- Chronic HCV
  - 1/3 individuals develop chronic disease
  - Minimal symptoms over decades can progress to cirrhosis, liver failure, liver cancer
- **Curable infection** (unlike CMV, EBV, HIV)
HCV epidemiology

• 2.4 million people living with HCV in US
• Since 2010, incidence continues to increase with estimated 41,200 new cases in 2016

For extended description of these figures, please see the descriptions on page 223.
HCV treatment

• 1989: Injectable interferon (IFN)
• 1998: Oral ribavirin
• 2011: early direct acting antivirals (DAAs)
• 2014: all oral DAA combinations

• Cure = sustained virologic response (SVR) 12 weeks after treatment

For extended description of this chart, please see the descriptions on page 224.
HCV testing

• HCV antibody (Ab) – immune response to infection, persists after clearance or cure
• HCV nucleic acid test (NAT) – viral particles in blood, sign of active disease and transmission risk

• HCV Ab-/NAT- uninfected
• HCV Ab+/NAT+ chronic HCV infection
• HCV Ab+/NAT- cleared/cured HCV or false positive Ab
• HCV Ab-/NAT+ acute HCV or false positive NAT
# DAAs in transplant recipients

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Design</th>
<th>Patient Population</th>
<th>Direct Acting Antiviral (DAA)</th>
<th>Genotype</th>
<th>SVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAGELLAN-2 Reau et al, 2018</td>
<td>Phase 3, open label, multicenter trial</td>
<td>N=100 Chronically infected HCV liver and kidney (N=20) TXP patients</td>
<td>Glecaprevir/pibrentasvir x 12 weeks</td>
<td>1-6</td>
<td>12 weeks: 99%</td>
</tr>
<tr>
<td>Colombo et al, 2016</td>
<td>Randomized, phase 2, open label, multicenter trial</td>
<td>N=114 Chronically infected HCV kidney TXP patients</td>
<td>Ledipasvir/sofosbuvir x 12 or 24 weeks</td>
<td>1 or 4</td>
<td>12 weeks: 100% 24 weeks: 100%</td>
</tr>
<tr>
<td>Saxena et al, 2017</td>
<td>Retrospective, multicenter, longitudinal treatment cohort</td>
<td>N=443 Chronically infected HCV liver, kidney (N= 60), and combined liver and kidney TXP patients</td>
<td>Ledipasvir/sofosbuvir ± ribavirin Sofosbuvir + Daclatasvir ± ribavirin Ombitasvir/paritaprevir/ritonavir + dasabuvir ± ribavirin</td>
<td>1-6</td>
<td>12 weeks: Liver: 96.6% Kidney: 94.5% SLK: 90.9%</td>
</tr>
</tbody>
</table>

Saxena V et al, Hepatology. 2017  

TXP: Transplant  
SVR: Sustained virologic response
HCV D+/R+ transplantation

- HCV prevalence among transplant candidates:
  - Liver (≈ 40%)\(^1\) > kidney (≈10%)\(^2\) >> heart or lung
- HCV D+/R+ liver transplant common; many studies showing similar patient and graft survival\(^1,3\)
- HCV D+/R+ kidney transplant common; studies showing survival benefit and shorter wait times\(^4\)
- HCV D+/R+ rare in heart\(^4\) and lung transplant due to decreased survival and coronary vasculopathy

1. Bowring/Durand, AJT 2017
2. Bowring/Durand, Transplantation 2018
4. Bloom/Reddy, AJT 2005
5. Gasink/Lautenbach, JAMA 2006
Increasing number and quality of HCV+ donor organs over time

- Opioid overdose death donors now account for > 1 out of 8 deceased donors in US
- Over 30% of overdose donors were HCV Ab+ in 2017
- HCV Ab+ donors more likely to be younger with fewer comorbidities
- Outcomes of transplants from overdose death donor organs same or better than trauma death donors

For extended description of this chart, please see the descriptions on page 225.
But HCV+ organs remain underutilized 3/1/15-1/31/18

Slide courtesy of David Goldberg, OPTN data
True potential is likely larger

- “Donor” defined by UNOS as individual who had organs recovered for transplant
- Does not include donors not referred, not evaluated or not approached for donation
- Does not include donors after circulatory death
- Does not include single organ donors
HCV D+/R-: historical perspective

• Kidney: 118 HCV D+/R- (single center, 1991-2007)¹
  • Select candidates with “poor life expectancy”
  • Median survival: 5.3 years, 10 year: 22.6%
  • 93 deaths: 24% cardiac, 16% nephropathy, 4% liver failure

1. Singh/Pirsch, Clin Transplant 2012
2. Gasink/Lautenbach, JAMA 2006
HCV D+/R-: historical perspective

• Kidney: 118 HCV D+/R- (single center, 1991-2007)\(^1\)
  • Select candidates with “poor life expectancy”
  • Median survival: 5.3 years, 10 year: 22.6%
  • 93 deaths: 24% cardiac, 16% nephropathy, 4% liver failure

• Heart: 222 HCV D+/R- (multicenter, 1994-2003)\(^2\)
  • National registry data, according to institutional standards
  • 2 fold higher risk of death
  • More likely to die of liver disease or coronary vasculopathy

---

1. Singh/Pirsch, Clin Transplant 2012
2. Gasink/Lautenbach, JAMA 2006
HCV D+/R-: in era of DAAs

Transplanting Hepatitis C–Positive Kidneys
Peter P. Reese, M.D., M.S.C.E., Peter L. Abt, M.D., Emily A. Blumberg, M.D., and David S. Goldberg, M.D., M.S.C.E.

The scarcity of kidneys for transplantation and high mortality among patients on the waiting list have led some patients to accept kidney transplants that carry elevated risks of transmitting infections or cancer. In certain cases, such as the transmission of cytomegalovirus, physicians can anticipate these events and institute long-term dialysis, but it's available to an ever-smaller percentage of patients. In many regions of the United States, average waiting times for a kidney transplant exceed 5 years, especially for patients with blood type O or B, for whom there's a large imbalance between organ supply and demand. Average more than 6546 kidneys, only 2402 (37%) were transplanted; 91% of the recipients had documented HCV infection. The other kidneys were discarded, although most were of good quality (according to the Kidney Donor Profile Index, a widely used transplant metric). These discarded kidneys could have benefited more than 4000
THINKER: Transmit and Treat

- HCV D+/R- kidney transplant, n=10
  - Genotype 1a only
- Treatment initiated if transmission: 100%
- Treated with GZR/EBR for 12 weeks
- All patients cured
- Median wait: 58 days

Goldberg/Reese NEJM 2017
EXPANDER: Prophylaxis

- HCV D+/R- kidney transplant n= 10
  - Genotypes 1a, 2, 3, mixed
- DAAs pre- and post-exposure prophylaxis
- Prophylaxis GZR/EBR +/- SOF for 12-16 weeks
- No chronic HCV
- Median wait: 30 days

5 patients never viremic
10/10 no chronic HCV

Durand/Desai Ann Intern Med 2018
HCV D+/R- trials in heart and lung

USHER – Transmit and Treat

- n=10 heart transplants
- Treatment initiated if transmission: 100% day 3
- Treated with GZR/EBR for 12-16 weeks +/- RBV
- 9 patients cured, 1 died due acute rejection
HCV D+/R- trials in heart and lung

USHER – Transmit and Treat
- n=10 heart transplants
- Treatment initiated if transmission: 100% day 3
- Treated with GZR/EBR for 12-16 weeks +/- RBV
- 9 patients cured, 1 died due acute rejection

DONATE HCV – Post-prophylaxis
- n=36 lung, n=8 heart transplants
- 6 hours after transplant received post-exposure prophylaxis
- Prophylaxis SOF/VEL for 4 weeks
- No chronic HCV, increased rejection

Reese/Goldberg AJT 2018
Wooley/Baden NEJM 2019
Moving into clinical practice

• Multiple observational studies of the “transmit and treat” approach
  – Schlendorf (Vanderbilt): 9 HCV D+/R- heart transplants
  – Kwong (Stanford): 10 HCV D+/R- liver transplants
  – Aslam (UCSD): 12 HCV D+/R- heart transplant
  – Alonso (Utah): 10 HCV D+/R- liver transplants

1. Schlendorf/Lindenfeld JHLT 2018
2. Kwong/Kwo AJT 2018
3. Aslam, abstract IHLTS 2018
4. Alonso, abstract ASTS 2017
Complications of HCV D+/R-

• Some reports suggest increased allograft rejection\textsuperscript{1,2}
• HCV treatment failure
  – THINKER: n=1 viral breakthrough with initial therapy, required intensification of therapy and prolonged duration, cured
  – Toronto trial of HCV D+/R- lung transplant: 3/13 viral relapse, including severe case with fibrosing cholestatic HCV, on intensified treatment for prolonged duration, ongoing\textsuperscript{4}
• Long term outcomes
• Logistical issues – insurance coverage of DAAs, administration via nasogastric tubes

1. Kwong/Kwo AJT 2018
2. Wooley/Baden NEJM 2019
3. Reese/Goldbert AJT 2018
4. Feld/Cyprel abstract AASLD 2018, updated data personal communication
Remaining questions

Prophylaxis vs Transmit and Treat

- Prevent any HCV related complications such as fibrosing cholestatic HCV, rejection
- Avoid any risk of transmission to others

- Ensure recipients can take oral medications, stable renal function
- More real-world for DAA coverage
Remaining questions

Prophylaxis vs Transmit and Treat

- Prevent any HCV related complications such as fibrosing cholestatic HCV, rejection
- Avoid any risk of transmission to others

Clinical care vs Research only

- Increased access to transplant
- Standard with CMV, HBV, EBV

- Ensure recipients can take oral medications, stable renal function
- More real-world for DAA coverage

Pro: Use of Hepatitis C Virus–Positive Donors Should Be Considered Standard of Care

Con: Use of Hepatitis C Virus–Positive Donors Should Be Restricted to Research Protocols

Grace S. Lee, M.D., M.S.M.E.,* Judith A. Anesi, M.D.,† Behdad D. Besharatian, M.D.,† Therese Bittermann, M.D., M.S.C.E.,† Stephanie Hamel, Pharm.D.,‡ and David S. Goldberg, M.D., M.S.C.E.§
Summary

• Novel strategies to expand donor pool are needed
• Landscape of HIV and HCV treatment has evolved altering risk-benefit for those on the waitlist
• New frontiers of HIV D+/R+ transplant and HCV D-/R+ transplant are under investigation with encouraging early results
Thank you for your attention
BREAK
ETHICS OF INFORMED CONSENT OF RECIPIENTS OF IRD ORGANS

PETER REESE, MD
Associate Professor of Medicine Center for Clinical Epidemiology and Biostatistics
University of Pennsylvania
ETHICS OF INFORMED CONSENT OF POTENTIAL RECIPIENTS OF IRD ORGANS

Peter P. Reese, MD, MSCE
Associate Professor of Medicine & Epidemiology
University of Pennsylvania
Ethical principles at the bedside: transplanting IRD organs

- **Beneficence:** Most organ transplant candidates have a substantial risk of death or other harms while on the wait-list
  - The physician’s duty is to actively seek ways to improve patient health with guidance that balances potential risk and benefit
  - “Do no harm” is an oversimplification that should be avoided

- **Respect for Autonomy:** Patients deserve to be able to make decisions about transplantation consistent with their values
  - They need information presented in a way they can understand – thorough but not overwhelming
  - The setting of the decision ought to avoid coercion or other conditions that limit patient ability to make a decision
Bedside ethics: All organ transplants carry risks

- **Those risks** include disease transmission with infections and/or cancer, as well as harms from transplant medications and surgery.

- **Informed consent** enables physicians to balance the duties of beneficence and respect for autonomy.

- **What is ideal?**
  - Patients should have time to consider the decision and ask for clarification.
  - A clinician should try to actively clear up misunderstanding.
  - A clinician should elicit patient preferences where necessary.
  - The main process of consenting should take place when patients are on the waiting list and when there is not the time pressure of an organ offer.

Barriers to autonomy in current practice

- A long gap in time may elapse between patient education on the waiting list and organ offer.

- Patient education on the waiting list may be overwhelming due to center interest in satisfying regulatory burden and legal concerns.

- Organ offer
  - Specific education about IRD organs may be rushed and emotionally charged.
  - Patients may feel that they have no real choice.

- In some settings, the patient may be no longer able to make an informed decision and so surrogates must decide about organ acceptance.
  - e.g., liver transplantation and hepatic encephalopathy.
Ethics for policy-makers: Problems with the allocation of IRD organs

- **Utility**
  - On the one hand, these valuable IRD organs are at risk of discard
  - On the other, organ donation depends on public trust and disease transmission could undermine trust

- **Equity**
  - It is unclear that these organs are being allocated to patients in an equitable way
Serious utility problem: Many viable organs are declined or discarded

- **EXAMPLE: KIDNEYS**
- About 3,000 kidneys per year are discarded
- IRD status is associated with a greater probability of turning down a kidney offer
  - **Adjusted odds ratio for organ turndown: 2.49**
    - Cohen ... Reese. *American Journal of Transplantation*. 2018
- Consequences of turning down a kidney offer
  - 43% of patients who turned down their first offer later got a transplant
  - Among those patients who get a transplant
    - Wait longer
    - 56% accept a kidney of similar or lower quality than the initial offer
  - Cohen ... Reese. *American Journal of Transplantation*. 2019
These rejected or lost organs would extend life for many patients

**EXAMPLE: KIDNEYS**

- Simulation of outcomes across the spectrum of kidney quality and patient characteristics
  - Chow ... Segev. *American Journal of Transplantation*. 2013
- Model integrated death risks from dialysis, post-transplantation and related to rare complications of HIV and hepatitis C virus infection from transplantation
  - Notably, estimates of HCV infection risk would now be much lower if contemporary data were used because of better antiviral therapy
    - As a result: Outcomes for IRD transplant would be better today
- Model integrates anticipated time until a non-IRD transplant
Survival outcomes for different recipients with IRD transplant

For an extended description of these charts, please see the image description on page 226.
Contemporary relevance
More and more organs from IRDs:
Donor deaths to due opioid overdose
Other relevant considerations

- Hepatitis C virus infection is curable, even with transplant immunosuppression
  - Donor derived, de novo hepatitis C virus infection (D+/R-)
    - 100% cure rates in the trial setting
      - THINKER (n=45) and EXPANDER (n=10) trials in 2018: kidney transplantation
      - USHER (n=10) and DONATE C (n=35) trials in 2019: thoracic transplantation
    - 100% cure reported with accidental transmission
      - Halleck et al. NEJM. 2017. German case series
- HCV transmission with transplant may less risky than CMV
- Donor-derived, de novo HIV infection could be emotionally devastating and impair quality of life
  - Yet, treatment outcomes for HIV-infected transplant recipients appear to be quite good
  - Achieving viral control generally feasible
Do cognitive biases cause transplant doctors to refuse IRD kidneys?
Do cognitive biases cause transplant doctors to refuse IRD kidneys?

- **Fear of sins of commission**
  - For many people, it feels worse to do something that leads to a bad outcome...
    - e.g., accept a kidney that has complications
    - Or “I gave that patient an infection”
  - ... than to do nothing and have a bad outcome on the waiting list
    - e.g., refuse a kidney from an injection drug user for a wait-listed patient

- Yet, turning down organs needlessly (sin of omission) also harms the patient
  - Transplant physician still stands in the causal chain responsible for the death
Do cognitive biases cause transplant doctors to refuse IRD kidneys?

- Availability heuristic
  - Many transplant staff can picture the patient with a post-operative complication, but ...
  - In some cases, they rarely see the patient who suffers on the waiting list
  - Therefore, it is harder for transplant staff to hold themselves as primarily responsible for the health outcomes of waitlisted patients ...
    - ... instead the primary medical physicians do, while rounding in dialysis unit or managing left ventricular assist devices for heart failure patients
Do cognitive biases cause doctors and patients to refuse kidneys?

- Overweighting small probabilities
  - Well described by cognitive psychologists
  - Some patients hear statistics about HIV transmission such as “1 in 1000” and worry much more than, say, the 5% risk of dying every year on dialysis
  - Transplant physicians may share this problem

- Cognitive flaw, not a preference
What do patients say about IRD organs?

- Qualitative study of 162 kidney transplant candidates at a single center
- Semi-structured interviews for patients returning to center for 1 and 3-year waiting list re-evaluation
- Many patients believed that IRDs would be in poor health because of having chronic diseases such as diabetes, hypertension, or cancer (n = 71)
  - “I have been reading, I have more chance, am better off, if the donor don’t smoke or drink.”
    - [African American man, 48 years old]
  - “I would assume some type of technical problems [with the organ] and that the organ might not last.”
    - [African American man, 37 years old]
How do patients weigh the importance of IRD status?

- Conjoint analysis – the goal is to figure out how important individual factors are to a decision; the factors are **CONsidered JOINTly**.

- Cross-sectional study of adult kidney transplant candidates at the University of Pennsylvania.

- All candidates had undergone center education

- Participants considered 12 kidney offers in which we varied 3 things
  - Risk of HIV infection: 1/1500 vs. 1/10,000
  - Expected waiting time for a kidney: 1, 3 or 5 years
  - Donor age as a surrogate for kidney quality: 18 or 55 years

How do patients weigh the importance of IRD status?

- 24% rejected IRD kidneys under all circumstances
- 59% accepted IRD kidneys under some circumstances
- 17% always accepted IRD kidneys

## Factors associated with accepting a kidney

<table>
<thead>
<tr>
<th>Decision element</th>
<th>Odds Ratio</th>
<th>Confidence interval</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 year waiting time to transplant if this offer declined</td>
<td>4.20</td>
<td>2.97, 5.94</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>3 year waiting time to transplant if this offer declined</td>
<td>3.50</td>
<td>2.57, 4.75</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Respondent on dialysis</td>
<td>2.88</td>
<td>1.71, 4.84</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Lower risk of HIV infection (1/10,000 vs. 1/1500)</td>
<td>2.12</td>
<td>1.61, 2.81</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Better kidney quality (18 year old vs 55 yo donor)</td>
<td>1.78</td>
<td>1.43, 2.23</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Participant older age</td>
<td>1.28</td>
<td>1.02, 1.63</td>
<td>0.04</td>
</tr>
</tbody>
</table>
Explanations for why tiny HIV transmission risks strongly influence decisions

- The problem of stigma associated with HIV
- Low understanding
  - Confusion of low quality organ with disease transmission
    - Gordon et al. *Clinical Transplantation*. 2012
- Cognitive bias
  - Overweighting small probabilities
- Patient preferences and judgments
  - Lack of trust in the medical system
  - Acceptable status quo
    - Example: Adaptation to dialysis
Potential areas to align ethics and practice

- Shift the burden of informed consent to the waiting list and away from the moment of organ offer
  - Informed consent should take place at regular intervals, not a 1-time event
  - At the time of organ offer, only minimal specific information about donor characteristics is necessary if a patient has prospectively agreed to accept an IRD organ

- Shift the language toward the most relevant comparison (no transplant) and away from the hypothetical ideal (a different, lower risk, better transplant)
  - “increased risk” is not optimal language
Potential areas to align ethics and practice

- Endorse best practices in patient education
  - Practices should address cognitive biases
- Regulations should transparently explain how change in practice aligns with ethical principles
- Endorse appropriate use of good tools in terms of patient and physician education
  - IRD organ risk calculator that predicts survival with accepting or rejecting an organ offer
    - Chow...Segev. *American Journal of Transplantation*. 2013
Concerns about public trust

- A relevant issue for maintaining organ donation rates
  - Example: Germany’s organ donation rate fell after physicians accused of manipulating waitlist priority

- Yet, robust informed consent at the time of wait-listing ought to be as good in maintaining public trust as consent in a hurry at the time of organ offer

- Similar surveillance for donor-derived blood borne viruses for all organ recipients would be simpler and logical, given that differences in risk are very small between IRD and non-IRDs
Proposals worthy of discussion

- Informed consent on the waiting list might also include informing patients (and referring doctors) about the number and quality of organs turned down for that candidate.

Goals

- Promote patient autonomy
- Better align physician and patient understanding about access to transplantation

Potential risk

- Patients might distrust physician decision-making
Conclusions

- Beneficence means integrating risks and benefits for each patient at the bedside
  - “Do no harm” is not a useful concept for waitlisted patients
- Informed consent for IRD organs is best implemented while the patient is on the waiting list, not at the time of organ offer
- Best practices for informed consent should address the following challenges
  - IRD organs may be declined due to patient preferences or lack of understanding
  - IRD organs may also be declined due to cognitive biases on the part of physicians or patients
Conclusions

- Ethics for policy-makers and transplant leaders
  - Organ discard and turndown rates are too high
  - The transplant community and policy-makers have a duty to maximize the benefits of the precious resource of IRD organs by reducing discards of viable organs
Acknowledgements

• HHS Advisory Committee on Blood & Tissue Safety & Availability for this invitation

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The Greenwall Foundation
OPO EXPERIENCE: HOW ARE IR DONORS IDENTIFIED, LIMITATIONS OF NEXT OF KIN INTERVIEW, TRANSMISSION OF INFORMATION TO RECIPIENT CENTERS

RICHARD HASZ, MFS
Vice President, Clinical Services
Gift of Life Donor Program
HHS Advisory Committee on Blood & Tissue Safety & Availability (ACBTSA)

OPO Experience with PHS Increased Risk Donors

Richard Hasz
VP, Clinical Services, Gift of Life Donor Program
Gift of Life Donor Program
Philadelphia, Pennsylvania USA

- Non-Profit OPO/Tissue Recovery/Eye Bank
- Established in 1974
- Federally designated OPO (by Medicare) for eastern PA, Southern NJ & Delaware
  - 129 Acute Care Hospitals
  - 15 Transplant Centers, 43 Programs
  - 11 Million Population
- 615 organ donors in 2018, resulting in 1,671 transplants; highest volume in the U.S. – over 50 donors/MM; 1,368 bone recoveries; 2,173 cornea recoveries and 2,458 tissue recoveries
- Over 39,000 organs for transplantation and over 550,000 tissue allografts
- Accredited by: Association of Organ Procurement Organizations (AOPO); American Assoc. of Tissue Banks (AATB) & Eye Bank Assoc. of America (EBAA); UNOS/OPTN member OPO
58 OPO Donation Service Areas in the U.S.

326.9 million people – 10,721 Deceased Donors (2018)
6,833 Living Donors (2018)
39,690 Transplants (2018)

OPO Data
Population Bases from 1.4 Million to 19.5 Million
Deceased Donors Recovered ranged from 42 to 615 Donors
Donors per million (DPM) ranged from 20.0 to 59.1; U.S. Average 34.6
Based upon GLDP data through December 31, 2018.
Organs Transplanted from GLD PHS
Increased Risk Organ Donors

Increased Risk? Yes (21%)
Increased Risk? No (79%)

2005: 11% Yes, 89% No
2006: 18% Yes, 82% No
2007: 12% Yes, 88% No
2008: 9% Yes, 91% No
2009: 10% Yes, 90% No
2010: 10% Yes, 90% No
2011: 14% Yes, 86% No
2012: 14% Yes, 86% No
2013: 17% Yes, 83% No
2014: 31% Yes, 69% No
2015: 28% Yes, 72% No
2016: 37% Yes, 63% No
2017: 36% Yes, 64% No
2018: 34% Yes, 66% No

Recovery Year
GLDP PHS Increased Risk Organ Donors Recovered 2005 – 2018 By Cause of Death

<table>
<thead>
<tr>
<th>Cause of Death</th>
<th>PHS Increased Risk?</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes (n=1358)</td>
<td></td>
<td>No (n=5028)</td>
</tr>
<tr>
<td>Anoxia</td>
<td>888 (65%)</td>
<td>1752</td>
<td>(35%)</td>
</tr>
<tr>
<td>Head Tauma</td>
<td>268 (20%)</td>
<td>1298</td>
<td>(26%)</td>
</tr>
<tr>
<td>CVA/Stroke</td>
<td>199 (15%)</td>
<td>1912</td>
<td>(38%)</td>
</tr>
<tr>
<td>CNS Tumor</td>
<td>0 (0%)</td>
<td>22</td>
<td>(0.4%)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (0.2%)</td>
<td>44</td>
<td>(1%)</td>
</tr>
<tr>
<td>All COD</td>
<td>1358 (100%)</td>
<td>5028</td>
<td>(100%)</td>
</tr>
</tbody>
</table>
Number of Deceased Donors Recovered by Year and PHS Increased Risk Status 2008 – 2018

Increased Risk Donor

<table>
<thead>
<tr>
<th>Year of Donor Recovery</th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>8.1%</td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>8.4%</td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>9.0%</td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>10.4%</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>11.9%</td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td>13.4%</td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>20.7%</td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td>22.2%</td>
<td></td>
</tr>
<tr>
<td>2016</td>
<td>24.9%</td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td>26.3%</td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td>27.1%</td>
<td></td>
</tr>
</tbody>
</table>

Number of Deceased Donors Recovered
% PHS High Risk Donors by DSA 1/1/2015 – 12/31/2016

For an extended description of this map, please see the description on page 227.
% PHS High Risk Donors by DSA 1/1/2017 – 12/31/2018

N=5,608
Mean=27%

For an extended description of this map, please see the description on page 228.
% HCV Seropositive Donors by DSA 1/1/2015 – 12/31/2016

N=888
6.5%

For an extended description of this map, please see the description on page 229
% HCV Seropositive Donors by DSA 1/1/2017 12/31/2018

N=1,633
Mean=8%

For an extended description of this map, please see the description on page 230.
Determination of Increased Risk Donors

- Medical Social History Questionnaire
- Specimen Qualification
- Hemodialysis
Medical Social History Questionnaire

- Finding the right person to ask
- Reliability of the information provided
- Applying definitions correctly
GLDP Medical Social History Assessments

Prior to beginning the interview:

I want to advise you that some of the history questions are of a sensitive and personal nature. They are similar to those asked when someone donates blood and we are required to ask every question. For the purpose of this questionnaire, sexual activity is defined as any sexual contact including vaginal, anal, and oral sex. I will read each question, provide any explanations that you may need to thoroughly understand the question, and ask that you answer to the best of your knowledge with a “Yes” or “No.”

Do you feel you know the deceased well enough to answer questions regarding the medical/social history?

Yes ☐ No ☐

At the end of the interview:

50. Regarding these questions, are there other people, including healthcare professionals, who may provide additional information?

Yes ☐ No ☐

50a. Name(s) and contact information:

After the interview:

Medical Social History Assessments

<table>
<thead>
<tr>
<th>Date/Time Added</th>
<th>Person Interviewed</th>
<th>Relationship to Potential Donor</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>02/19/2019 10:18:24 (756)</td>
<td>Carolyn Farmer</td>
<td>Mother</td>
<td>Complete - Full</td>
</tr>
<tr>
<td>02/19/2019 13:19:50 (757)</td>
<td></td>
<td></td>
<td>In Progress - Full</td>
</tr>
</tbody>
</table>

Add New Full Assessment | Add New Supplemental Assessment | Review Edited Questions | Review Yes Questions
SEXUAL HISTORY

Next, I will ask you about his sexual history. As a reminder, sexual activity refers to any method of sexual contact including vaginal, anal, and oral.

28. In the past 12 months has he been newly diagnosed or been treated for syphilis, gonorrhea, chlamydia, or genital ulcers?
   - Yes  - No

   If 28. is yes, donor is PHS high risk.
   28a. Which one was it?
   28b. When?
   28c. Was it treated?  - Yes  - No

29. In the past 5 years was he sexually active, even once?
   - Yes  - No

   If no, proceed to question 30.
   If yes, complete the following questions (29a. to 29g.)

   29a. In the past 5 years, did he have sex in exchange for money or drugs?  - Yes  - No

   If no, proceed to question 29b.

   If yes, 29a(i). Did he have sex in exchange for money or drugs in the preceding 12 months?

   If 29a(i). is yes, donor is PHS high risk, complete question 29a(ii).
   29a(ii). When?

   (N/A) Donor is Female

29b. MALE DONOR only: In the past 5 years, did he have sex with another male?  - Yes  - No

   If no or N/A, proceed to question 29c.

   If yes, 29b(i). Did he have sex with another male in the preceding 12 months?  - Yes  - No

   If 29b(i). is yes, donor is PHS high risk, complete question 29b(ii).
29d. In the preceding 12 months, did he have sex with a person who has had sex in exchange for money or drugs?  

If no, proceed to question 29e.

If yes, 29d(i). Did that sexual partner have sex in exchange for money or drugs in the past 5 years?  

If no, proceed to question 29e.

If yes, 29d(ii). Did that sexual partner have sex in exchange for money or drugs in the preceding 12 months?  

If 29d(ii). is yes, donor is PHS high risk.

29e. In the preceding 12 months, did he have sex with a person who injected drugs by intravenous, intramuscular, or subcutaneous route for nonmedical reasons?  

If no, proceed to question 29f.

If yes, 29e(i). Did that sexual partner inject drugs by intravenous, intramuscular, or subcutaneous route for nonmedical reasons in the past 5 years?  

If no, proceed to question 29f.

If yes, 29e(ii). Did that sexual partner inject drugs by intravenous, intramuscular, or subcutaneous route for nonmedical reasons in the preceding 12 months?  

If 29e(ii). is yes, donor is PHS high risk.
### GLDP PHS Increased Risk Organ Donors Recovered 2005 - 2018

<table>
<thead>
<tr>
<th>Med Soc Interview w/</th>
<th>PHS Increased Risk?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes (n=1358)</td>
</tr>
<tr>
<td>Parents</td>
<td>735  54%</td>
</tr>
<tr>
<td>Spouse</td>
<td>178   13%</td>
</tr>
<tr>
<td>Children</td>
<td>164   12%</td>
</tr>
<tr>
<td>Sibling</td>
<td>159   12%</td>
</tr>
<tr>
<td>Other</td>
<td>122   9%</td>
</tr>
<tr>
<td>All</td>
<td>1358  100%</td>
</tr>
</tbody>
</table>
Specimen Qualification

- Hemodilution Calculation
- Timing of Specimen Collection
GLDP PHS Increased Risk System Alerts

Specimen: Sample For Infectious Disease Testing Qualification

Calculate Specimen

<table>
<thead>
<tr>
<th>Total A=</th>
<th>Total B=</th>
<th>Total C=</th>
</tr>
</thead>
<tbody>
<tr>
<td>3150</td>
<td>1950</td>
<td>73</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total B+C=</th>
<th>Is B+C&gt; TPV?</th>
<th>Total A+B+C=</th>
</tr>
</thead>
<tbody>
<tr>
<td>2023</td>
<td>Yes</td>
<td>5173</td>
</tr>
</tbody>
</table>

Is Specimen One Qualified?

- Yes
- No

If no, are other blood specimens available for infectious disease testing?

- Yes
- No

Calculation Legend

Total A = Blood Products transfused 48 hours prior to draw or asystole
Total B = Colloids infused 48 hours prior to draw or asystole
Total C = Crystalloids infused 1 hour prior to draw or asystole

Is A+B+C>TBV?

- Yes
- No

This Specimen is not qualified, Find a qualified Specimen

For Verified Plasma Dilution Only

Is this sample intended to be sent for infectious disease testing?

- Yes
- No

The donor is considered CDC high risk.

Confirm Date/Time of Asystole or Date/Time of Draw

- 11/22/2017 06:20

GLDP Sample ID Number

- 11212017-0941

ABO Subtype Qualification: Did the patient receive any PRBCs prior to the date and time of draw?

- Yes
- No

This sample does not qualify for ABO subtyping

Infectious Disease Specimen Sent To Designated Laboratory for Testing and Serum Archive

- Yes

Was HLA specimen drawn at this time?

- Yes
- No

- Run
- Hold

Save

Print ID Labels

Print HLA Labels
**22.** Did she EVER use or take drugs, such as steroids, cocaine, amphetamines, or anything NOT prescribed by her doctor?

**22a.** If yes, document details of all non-medical drug use in the grid below and complete question 22b.

### Non-Medical Drugs

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Duration of Use?</th>
<th>When Last Used?</th>
<th>Method of Use</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>cocaine</td>
<td>2 yrs</td>
<td>today</td>
<td>Snorted ✓</td>
<td></td>
</tr>
<tr>
<td>heroin</td>
<td>2 yrs</td>
<td>today</td>
<td>Injected ✓ ✓</td>
<td></td>
</tr>
</tbody>
</table>

**22b.** In the past five years, did she inject drugs by intravenous, intramuscular, or subcutaneous route for non-medical reasons?

22b(i). If yes, document all in the table above.

22b(ii). If yes, was it in the preceding 12 months?

*If 22b(ii) is yes, donor is PHS high risk.*
Unanticipated donor-derived transmissions 2013-2017

14 Donors with NAT negative “eclipse window” HCV transmissions

Donor Terminal Hospitalization Timeline

- IVDU
- DU*
- Sex with HCV+ partner

Legend:
- Ab- / NAT - donor
- Ab+ / NAT - donor
- DU* = Drug use, IV use history unknown

Timeline:
- Admission
- HCV NAT drawn
- Cross-Clamp
15d. Dialysis?
   ☐ Yes  ☐ No
   If yes to dialysis, 15d(i). check type(s). ☐ Hemodialysis ☐ Peritoneal Dialysis

   15d(i)a. If hemodialysis, did this occur in the preceding 12 months?
   ☐ Yes  ☐ No

   If 15d(i)a. is yes, donor is PHS high risk.

   15d(ii). Explain why and how long he received dialysis treatment

27. In the past 12 months was he in lockup, jail, prison, or any juvenile correctional facility for more than 72 consecutive hours?
   ☐ Yes  ☐ No

   If 27. is yes, donor is PHS high risk.

   27a. How long? 1.5 weeks

   27b. Where? Juvenile Correction
No Increased Risk Categories Identified

Check all that apply

- In the absence of a medical history & behavioral risk assessment interview, the donor will be considered to be in an increased risk category. Authorization for donation is included in the donor record.
- When a deceased potential organ donor's blood specimen is hemodiluted, the donor should be considered at increased risk for HIV, HBV, and HCV infection because the donor's risk for infection is unknown.

This donor has been determined by medical history & behavioral risk assessment to meet one or more of the PHS criteria for increased risk (See item(s) below):

- People who have had sex with a person known or suspected to have HIV, HBV, or HCV infection in the preceding 12 months
- Men who have had sex with men (MSM) in the preceding 12 months
- Women who have had sex with a man with a history of MSM behavior in the preceding 12 months
- People who have had sex in exchange for money or drugs in the preceding 12 months
- People who have had sex with a person who had sex in exchange for money or drugs in the preceding 12 months
- People who have had sex with a person who injected drugs by intravenous, intramuscular, or subcutaneous route for nonmedical reasons in the preceding 12 months
- A child who is ≤18 months of age and born to a mother known to be infected with, or at increased risk for, HIV, HBV, or HCV infection
- A child who has been breastfed within the preceding 12 months and the mother is known to be infected with, or at increased risk for, HIV infection
- People who have injected drugs by intravenous, intramuscular, or subcutaneous route for nonmedical reasons in the preceding 12 months
- People who have been in lockup, jail, prison, or a juvenile correctional facility for more than 72 consecutive hours in the preceding 12 months
- People who have been newly diagnosed with, or have been treated for, syphilis, gonorrhea, Chlamydia, or genital ulcers in the preceding 12 months

Donors who meet the following criterion should be identified as being at increased risk for recent HCV infection only:

- People who have been on hemodialysis in the preceding 12 months
### GLDP Donors by PHS Categories
#### Donors Recovered 2017 - 2018

<table>
<thead>
<tr>
<th>PHS Increased Risk Category</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Increased Risk Categories Identified</td>
<td>363</td>
<td>406</td>
</tr>
<tr>
<td>People who have injected drugs by intravenous, intramuscular, or subcutaneous route for nonmedical reasons in the preceding 12 months</td>
<td>125</td>
<td>116</td>
</tr>
<tr>
<td>People who have been in lockup, jail, prison, or a juvenile correctional facility for more than 72 consecutive hours in the preceding 12 months</td>
<td>84</td>
<td>75</td>
</tr>
<tr>
<td>People who have had sex with a person who injected drugs by intravenous, intramuscular, or subcutaneous route for nonmedical reasons in the preceding 12 months</td>
<td>72</td>
<td>48</td>
</tr>
<tr>
<td>People who have had sex with a person who had sex in exchange for money or drugs in the preceding 12 months</td>
<td>33</td>
<td>27</td>
</tr>
<tr>
<td>People who have had sex in exchange for money or drugs in the preceding 12 months</td>
<td>29</td>
<td>20</td>
</tr>
<tr>
<td>People who have had sex with a person known or suspected to have HIV, HBV, or HCV infection in the preceding 12 months</td>
<td>22</td>
<td>13</td>
</tr>
<tr>
<td>People who have been on hemodialysis in the preceding 12 months</td>
<td>18</td>
<td>13</td>
</tr>
<tr>
<td>Blood specimen is hemodiluted</td>
<td>6</td>
<td>18</td>
</tr>
<tr>
<td>People who have been newly diagnosed with, or have been treated for, syphilis, gonorrhea, Chlamydia, or genital ulcers in the preceding 12 months</td>
<td>15</td>
<td>7</td>
</tr>
<tr>
<td>Men who have had sex with men (MSM) in the preceding 12 months</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>Absence of a medical history &amp; behavioral risk assessment interview</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Women who have had sex with a man with a history of MSM behavior in the preceding 12 months</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td><strong>All Donors</strong></td>
<td><strong>565</strong></td>
<td><strong>615</strong></td>
</tr>
</tbody>
</table>
### GLDP Donor Demographic Profile

**Donors Recovered 2005 - 2018**

<table>
<thead>
<tr>
<th>Demographic</th>
<th>PHS Increased Risk?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes (n=1358)</td>
</tr>
<tr>
<td>Average Age (Yrs)</td>
<td>36</td>
</tr>
<tr>
<td>Race</td>
<td>75% White</td>
</tr>
<tr>
<td>Sex</td>
<td>68% Male</td>
</tr>
<tr>
<td>Cause of Death</td>
<td>65% Anoxia</td>
</tr>
<tr>
<td>Manner of Death</td>
<td>42% Drug OD</td>
</tr>
<tr>
<td>Med Soc By</td>
<td>54% Parents</td>
</tr>
</tbody>
</table>
Communication with Transplant Centers

- DonorNet
- Pre-recovery time out
- Organ offer (3rd party screeners)
**Sonar Highlights:**

- High risk criteria: CBF due to track marks seen on physical assessment.
- Patient has had 2 exams and CBF of the brain death. Family requested OR no sooner than 3/20/2019 1200.
- Prior transcranial Doppler (TCD) exam revealed low flow in the right hemisphere.

Initial Referral Information: On 3/17/2019, patient was admitted with signs of heroin withdrawal. EMS gave Narcan, epi, and CBF. Patient was alert, responsive, and had normal TCD exam at 30 min. However, patient has noted mild confusion. MRI reveals no acute findings.

Admission Comments: 3/20/2019 PM admitted to 3/20/2019 after being turned around by ER. Patient has a history of chronic alcohol and drug abuse. Patient has been in and out of treatment facilities for alcohol and drug abuse. Patient has a history of significant medical problems, including chronic pain. Patient has a history of cardiac and pulmonary disease.

**SICU STUDIES**

There are no DICOM images associated with this donor.

**Medical & Social History**

<table>
<thead>
<tr>
<th>History of diabetes</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of cancer</td>
<td>NO</td>
</tr>
<tr>
<td>History of hypertension</td>
<td>YES, 5-10 years</td>
</tr>
<tr>
<td>Compliant with treatment</td>
<td>YES</td>
</tr>
<tr>
<td>History of coronary artery disease (CAD)</td>
<td>NO</td>
</tr>
<tr>
<td>Previous gastrointestinal disease</td>
<td>NO</td>
</tr>
<tr>
<td>Chest trauma</td>
<td>NO</td>
</tr>
<tr>
<td>Opiate use (10+ pack years)</td>
<td>YES</td>
</tr>
<tr>
<td>And continued use</td>
<td>YES</td>
</tr>
<tr>
<td>Vasoconstrictor use</td>
<td>NO</td>
</tr>
<tr>
<td>Vasoconstrictor use</td>
<td>NO</td>
</tr>
<tr>
<td>Alcohol use</td>
<td>YES</td>
</tr>
<tr>
<td>Vasoconstrictor use</td>
<td>YES</td>
</tr>
</tbody>
</table>

According to the OPI/IP policy, the donor has risk factors for blood-borne disease transmission:

- Smoked for 25+ years, quit 10 years ago, cigarettes: 10-15/day.
-第二段
- Worked in sales, seen Philadelphia, had tattoo on arm and feet professionally, 1x 32000,
- Travel to Bahamas 2012 for 7 day vacation.
- Due to opioid withdrawal on March 20, 2019, patient was given a small dose of methadone, 32000, and discharged.
- Second and third doses of methadone were given on March 21, 2019.
- On March 22, 2019, patient was discharged with a prescription for methadone.
GIFT OF LIFE DONOR PROGRAM
REVIEWS AND RECEIPT OF DONOR INFORMATION

Patient Name: 
UNOS# AGDAZ13

By affixing my signature in the space provided, I am certifying in good faith that I have reviewed and agree with the documentation for this organ donor. I understand that the documentation and information includes, but is not limited to:

1. Donor UNOS ID
2. Donor blood type, and subtype if used for allocation
3. Intended Recipient blood type and subtype as indicated on Organ Donor Verification Form, except for kidneys.
4. Recipient' known compatibility or incompatibility as indicated on Organ Donor Verification Form, except for kidneys.
5. Pronouncement of Death (except for DCD donor)
6. Authorization for Donation and Medical-Social History
7. Infectious Disease profile results

(If a single surgeon is to recover multiple organs, please indicate by marking "same as ________" for each recovered organ.)

<table>
<thead>
<tr>
<th>Heart Surgeon</th>
<th>Printed Name</th>
<th>Signature</th>
<th>Date</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>R-Lung Surgeon</td>
<td>Printed Name</td>
<td>Signature</td>
<td>Date</td>
<td>Time</td>
</tr>
<tr>
<td>L-Lung Surgeon</td>
<td>Printed Name</td>
<td>Signature</td>
<td>Date</td>
<td>Time</td>
</tr>
<tr>
<td>Liver Surgeon</td>
<td>Printed Name</td>
<td>Signature</td>
<td>Date 04/10/2019 Time 21:19</td>
<td></td>
</tr>
<tr>
<td>Segmented Liver Surgeon</td>
<td>Printed Name</td>
<td>Signature</td>
<td>Date</td>
<td>Time</td>
</tr>
<tr>
<td>Pancreas Surgeon</td>
<td>Printed Name</td>
<td>Signature</td>
<td>Date</td>
<td>Time</td>
</tr>
<tr>
<td>Intestine Surgeon</td>
<td>Printed Name</td>
<td>Signature</td>
<td>Date</td>
<td>Time</td>
</tr>
<tr>
<td>Right Kidney Surgeon</td>
<td>Printed Name</td>
<td>Signature</td>
<td>Date 04/12/19 Time 21:19</td>
<td></td>
</tr>
<tr>
<td>Left Kidney Surgeon</td>
<td>Printed Name</td>
<td>Signature</td>
<td>Date 04/12/19 Time 21:19</td>
<td></td>
</tr>
<tr>
<td>VCA Surgeon</td>
<td>Printed Name</td>
<td>Signature</td>
<td>Date</td>
<td>Time</td>
</tr>
</tbody>
</table>

Credentials verified for all surgeons* performing recovery.
* (Credentialled surgeons are qualified healthcare professionals for blood type reporting and verification.)

All perfusion solution lot # and expiration dates used during case have been given to the CLDP Perfusionist.

As the responsible primary OPO coordinator, I have provided said documentation explained above for receipt and/or review by aforementioned surgeons who have attached their signatures.

OPO Coordinator: 
Date 04/12/19 Time 21:20
Document/ DE-05-003B Rev 1
3684 Organs Transplanted from 1358 GLDP PHS Increased Risk Organ Donors 2005-2018

Kidney (n=1869)  Liver (n=932)  Heart (n=367)  Lung (n=419)  Pancreas (n=93)  Intestine (n=4)

For an extended description of this chart, please see the description on page 231
For an extended description of this chart, please see the description on page 232.
55,497 Organs Transplanted from U.S. PHS
Increased Risk Organ Donors 2005-2018

For an extended description of this chart, please see the description on page 233
Organ Discard Rates from U.S. PHS Increased Risk Organ Donors

For an extended description of this chart, please see the description on page 234
611 GLDP PHS Increased Risk Organ Donors 2016 – 2018 by HCV Ab / HCV NAT Results

HCV Ab-, HCV NAT- (n=388, 64%)
HCV Ab-, HCV NAT+ (n=9, 1%)
HCV Ab+, HCV NAT- (n=78, 13%)
HCV Ab+, HCV NAT+ (n=136, 22%)
1109 GLDP Organ Donors NOT Identified as High Risk 2016 – 2018 by HCV Ab / HCV NAT Results

- **HCV Ab-, HCV NAT-** (n=1065, 96%)
- **HCV Ab-, HCV NAT+** (n=1, 0.1%)
- **HCV Ab+, HCV NAT-** (n=28, 3%)
- **HCV Ab+, HCV NAT+** (n=15, 1%)
Summary

• Significant increase in the number of PHS Increased Donors and organ utilization since 2014

• Medical Social History Questionnaire is increasingly complex

• Routine availability of NAT testing pre-recovery
ASTS PERSPECTIVE ON PROPOSED REVISION TO GUIDELINE RECOMMENDATIONS

DIXON KAUFMAN, MD
Chairman, Division of Transplantation
University of Wisconsin
AST COMMENT ON PROPOSED REVISION TO GUIDELINE RECOMMENDATIONS

NICOLE TURGEON, MD
Professor of Surgery, Division of Transplantation, Department of Surgery, Emory University School of Medicine
Director, Clinical Islet Transplant Program, Emory Transplant Center
Director of Pancreas Transplantation, Emory Transplant Center
Surgical Director, Living Donor Kidney and Living Donor Pancreas Transplant Programs, Emory Transplant Center
Director, Kidney Transplant Program, Children’s Healthcare of Atlanta
American Society of Transplantation
Comment on Increased Risk Donor Definitions

Dr. Nicole Turgeon
AST Councilor-at-Large
April 15-16, 2019
American Society of Transplantation

• Founded in 1982

• Largest transplant organization in North America, with over 4,000 members representing the comprehensive transplant team:
  – physicians and surgeons across all organ specialties, infectious disease experts, pharmacists, advanced practice providers, basic/clinical/translational researchers, psychosocial professionals, transplant administrators, etc.
Risk is Relative...

The comparative risk of transplant versus the small risk of HIV, HBV, and HCV transmission—particularly in the era of treatment—must be considered

• Long waits for organs for many
  – Risk tolerance feels different as illness progresses and a candidate remains on the wait list
  – Other risks besides infectious disease (e.g. donor age, organ quality, cold ischemic time)
### Put into Perspective - Comparative risks

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Per 10,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Being struck by lightning in your lifetime (80 yrs)</td>
<td>1</td>
</tr>
<tr>
<td>Dying in a plane crash in your lifetime</td>
<td>2</td>
</tr>
<tr>
<td>Dying in a car accident</td>
<td>125</td>
</tr>
<tr>
<td>Dying crossing the street</td>
<td>16</td>
</tr>
<tr>
<td>Missing HIV with NAT&lt;sup&gt;1,2&lt;/sup&gt;</td>
<td>0.04-5</td>
</tr>
<tr>
<td>Missing HCV with NAT&lt;sup&gt;1,2&lt;/sup&gt;</td>
<td>0.03-32</td>
</tr>
<tr>
<td>Dying if no liver transplant in next 3 months with MELD 20-29</td>
<td>2,000</td>
</tr>
<tr>
<td>Dying on kidney transplant waitlist in next year</td>
<td>900</td>
</tr>
<tr>
<td>Acquiring HCV per year of hemodialysis&lt;sup&gt;3,4&lt;/sup&gt;</td>
<td>37</td>
</tr>
</tbody>
</table>

 Courtesy of Peter Chin-Hong, MD, UCSF

## HCV Antiviral Revolution for Adults

<table>
<thead>
<tr>
<th>Year</th>
<th>Trade Name</th>
<th>Generic Name</th>
<th>Genotypes</th>
<th>Success (SVR rate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>Olysio</td>
<td>Simepravir</td>
<td>1</td>
<td>95-97%</td>
</tr>
<tr>
<td>2013</td>
<td>Sovaldi</td>
<td>Sofosbuvir (+Sim)</td>
<td>1,2,3,4</td>
<td>93-100%</td>
</tr>
<tr>
<td>2014</td>
<td>Harvoni</td>
<td>Ledispasvir / sofosbuvir</td>
<td>1,4,5,6</td>
<td>95-96%</td>
</tr>
<tr>
<td>2014</td>
<td>Viekira Pak</td>
<td>Dasabuvir/ombitsavir/paritaprevir/ R</td>
<td>1</td>
<td>96-100% (not ESLD)</td>
</tr>
<tr>
<td>2015</td>
<td>Technivie</td>
<td>Ombitsavir/paritaprevir/R</td>
<td>4</td>
<td>91-100%</td>
</tr>
<tr>
<td>2015</td>
<td>Daklinza</td>
<td>Daclatasvir</td>
<td>3</td>
<td>96-100% (inc HD/CKD)</td>
</tr>
<tr>
<td>2016</td>
<td>Zepatier</td>
<td>Elbasvir/Grazoprevir</td>
<td>1,4</td>
<td>92-100% (inc HD/CKD)</td>
</tr>
<tr>
<td>2016</td>
<td>Epclusa</td>
<td>Sofosbuvir / velpatasvir</td>
<td>1,2,3,4,5,6</td>
<td>95-100%</td>
</tr>
<tr>
<td>2017</td>
<td>Vosevi</td>
<td>Sofosbuvir / velpatasvir/ voxilaprevir</td>
<td>1,2,3,4,5,6</td>
<td>96-98% (in Rx failures)</td>
</tr>
<tr>
<td>2017</td>
<td>Mavyret (8w)</td>
<td>Glecaprevir / pibrentasvir</td>
<td>1,2,3,4,5,6</td>
<td>92-100% (inc HD/CKD)</td>
</tr>
</tbody>
</table>
Question 1: Is a new term needed to replace current term ‘PHS Increased Risk Donor’?

• Yes, this term can be confusing to transplant candidates!
  – Emphasizes the negative (though clearly more neutral than previous terminology!)
  – Can leave candidate with more questions than answers
    • Window periods
    • False positives
  – No specific term suggestion, but recommend working with psychosocial professionals to develop a new term
## HCV “Positive” Donor - definitions

<table>
<thead>
<tr>
<th>HCV Ab</th>
<th>HCV NAT</th>
<th>Means</th>
<th>Transmit</th>
</tr>
</thead>
<tbody>
<tr>
<td>+</td>
<td>+</td>
<td>Active infection</td>
<td>Yes</td>
</tr>
<tr>
<td>+</td>
<td>-</td>
<td>Cleared Treated False +</td>
<td>None documented</td>
</tr>
<tr>
<td>-</td>
<td>+</td>
<td>WP infection False +</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Exposure**

*Viremia*  
**ECLIPSE**  
Nucleic Acid Testing  
Serologic conversion  
Serologic Testing  
Window Period  

*Levitsky et al AJT 2017*
Risk of HIV, HCV window period infection by CDC risk factor: Serology (ELISA) vs NAT Testing

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>HIV ELISA</th>
<th>HIV NAT</th>
<th>HCV ELISA</th>
<th>HCV NAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men who have sex with men</td>
<td>10.2</td>
<td>4.2</td>
<td>32.5</td>
<td>3.5</td>
</tr>
<tr>
<td>IV Drug Users</td>
<td>12.1</td>
<td>4.9</td>
<td>300.6</td>
<td>32.4</td>
</tr>
<tr>
<td>Hemophiliacs</td>
<td>0.086</td>
<td>0.035</td>
<td>0.26</td>
<td>0.027</td>
</tr>
<tr>
<td>Commercial sex worker</td>
<td>6.6</td>
<td>2.7</td>
<td>114.9</td>
<td>12.3</td>
</tr>
<tr>
<td>Sex with a partner in above categories</td>
<td>0.7</td>
<td>0.3</td>
<td>114.9</td>
<td>12.3</td>
</tr>
<tr>
<td>Blood product exposure</td>
<td>1.5</td>
<td>0.6</td>
<td>4</td>
<td>0.4</td>
</tr>
<tr>
<td>Incarceration</td>
<td>2.3</td>
<td>0.9</td>
<td>7.2</td>
<td>0.8</td>
</tr>
</tbody>
</table>

American Journal of Transplantation 2011; 11: 1176–1187
False Negatives

- Window Phase by Donor Serologic and Nucleic Acid Testing (NAT)

<table>
<thead>
<tr>
<th>Virus</th>
<th>Serology</th>
<th>4th gen Ag/Ab</th>
<th>NAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV</td>
<td>17-22 days</td>
<td>~7-16 days</td>
<td>5-9 days</td>
</tr>
<tr>
<td>HBV</td>
<td>35-44 days</td>
<td></td>
<td>20-22 days</td>
</tr>
<tr>
<td>HCV</td>
<td>~66 days</td>
<td>40-50 days</td>
<td>3-7 days</td>
</tr>
</tbody>
</table>

Question 2: Should donors continue to be identified based on risk factors for HIV, HBV, HCV?

- High profile diseases with long-standing implications— inadvertent transmission could certainly affect trust in the system.

- Continued transparency and understanding anticipated risks based upon donor behavior must be communicated to recipients:
  - Enhanced communication about other infectious and non-infectious risks should not be sacrificed by these higher profile infections.
  - Education to communicate both anticipated and unanticipated transmission for donors need to be explained to candidates.
Question 2: Should donors continue to be identified based on risk factors for HIV, HBV, HCV?

• The AST supports continued identification based on HIV/HBV/HCV risk and suggests adding it in the context of all transmission potential as part of the routine education of candidates.
Question 3: Should time be shortened from 12 months?

- Data is not publicly available yet to make a determination here; however,
  - The AST’s Infectious Disease Community of Practice is supportive of a significant shortening of this time period based on the best evidence available to substantially mitigate risk
  - We also support the collection of information about timing of risk, if possible, so that this time period can be further honed to most accurate time period.
Question #4: Are there specific criteria which should be eliminated or revised?

• We’ve received minimal feedback from our membership on this due to the limits of the published data available.

• We believe that lower risk events could be safely eliminated:
  – Hemodialysis
  – Blood product exposure (i.e. hemodilution)
Thank you

The American Society of Transplantation appreciates this opportunity to provide input on this topic that is so important to our patients and our profession.
AOPO COMMENT ON PROPOSED REVISION TO GUIDELINE RECOMMENDATIONS

Diane Brockmeier, BSN, MA
President and CEO
Mid-America Transplant Services (MTS)
HHS Advisory Committee on Blood & Tissue Safety & Availability
Diane Brockmeier
AOPO President
Association of Organ Procurement Organizations – AOPO

• Incorporated in 1984

• AOPO is a non-profit organization acting as the unified voice for all of the 58 federally designated organ procurement organizations (OPOs) in the US

• OPOs are the primary organizations responsible for the identification of donors and the safe and timely recovery, preservation and transportation of organs for transplant
AOPO’s Mission and Vision

MISSION: To help member OPOs maximize the availability of organs and tissues for transplantation and enhance the quality, effectiveness and integrity of the donation process.

VISION: Those in need of a transplant receive donated organs or tissues in a timely manner in order to end deaths on the waiting list.
All Donors Recovered 2012-2018

From Deceased Donors

Based on OPTN data as of February 19, 2019

All Donors Recovered

Achieving more, together.

For an extended description of this chart, please see the description on page 235
All Organs Recovered 2012-2018

From Deceased Donors

Based on OPTN data as of February 19, 2019

All Organs Recovered

2012 2013 2014 2015 2016 2017 2018

28,602 29,405 30,158 31,917 35,361 36,424 37,850

For an extended description of this chart, please see the description on page 236
All Organs Transplanted 2012-2018

From Deceased Donors

Based on OPTN data as of February 19, 2019

All Organs Transplanted

Achieving more, together.

For an extended description of this chart, please see the description on page 237
Number of Deceased Donors Recovered by Year and PHS Increased Risk Status

For an extended description of this chart, please see the description on page 238
% PHS High Risk Donors by DSA  1/1/2017 – 12/31/2018

N=5,608
Mean=27%

Achieving more, together.

For an extended description of this map, please see the description on page 228
AOPO Conclusions

- Appreciative of effort to consider changes to PHS IRD
- IR donors identified through extensive interviews/serological testing
- Medical-Social Questionnaire “accuracy” limited by the reliability of the historian
- Transmission of information to transplant centers
  - Documentation includes Donor Net
  - Pre-recovery time-out and disclosure signed by recovery surgeon

Achieving more, together.
AOPO Conclusions (cont’d)

- Does the available information support a reduction of the current 12 month risk behaviors time frame?
  - Would defer to our medical colleagues as this is a medical decision
  - For consideration, NAT testing in routinely available in real-time for all OPOs

- Is there a more appropriate term than “increased risk donor” to designate donors with risk factors for undetected HIV, HBV, or HCV infection?
  - Yes: Suggest changing the name to a more neutral term
  - High risk verbiage negatively perceived by donor families

- Should some criteria for increased donors be modified?
Achieving more, together.
PHS GUIDELINES FOR REDUCING HIV, HCV, AND HBV THROUGH ORGAN TRANSPLANTATION

• Does the available information support a reduction of the current 12-month risk behaviors time frame for determining Increased Risk Donor designation?

• Is there a more appropriate term than “Increased Risk Donor” to designate donors with risk factors for undetected HIV, HBV, or HCV infection?

• Should some criteria for Increased Risk Donors be modified (e.g., hemodilution of specimen used for HIV, HBV, or HCV testing, history of STD, or outpatient hemodialysis)?
RECAP DAY ONE
ADJOURNMENT
DAY ONE
Extended Descriptions

Organ Vigilance through DTAC
The chart shows the flow of communication within an organ vigilance system through DTAC that involves transplant centers, OPOs, OPTN/UNOS, and government agencies (CDC, HRSA, and FDA). On the left side of the chart are Transplant Centers and OPOs. On the right side of the chart are CDC, HRSA, and FDA. On the top of the chart (above DTAC) is Patient Safety/Member Quality. There is a two-way arrow between Transplant Centers and OPOs. There are two one-way arrows pointing from Transplant Centers and OPOs to DTAC. There are three one-way arrows pointing from DTAC to CDC, HRSA, and FDA. There is a two-way arrow between CDC and FDA. There is one curved arrow pointing from DTAC to Transplant Centers, and a one-way arrow pointing from DTAC to Patient Safety/Member Quality. There is a one-way arrow pointing from CDC to Patient Safety/Member Quality, and another one-way arrow pointing from Patient Safety/Member Quality to Transplant Centers. Go back to page 5

DTAC case evaluation
The left-to-right flow chart shows DTAC’s case evaluation and adjudication process. On the left side of the chart are Case adjudication and Not a Case. In the middle of the chart are categories of the cases determined by DTAC, including Proven, Probable, Possible, Prevented, Unlikely, or Excluded. On the right of the chart are severity indexes associated with different cases. Cases that are proven, probable, or possible may have an severity index of death, severe, non-severe, non-evaluable, or potential for late morbidity. Cases that are classified as prevented may have an severity index of potential for late morbidity; non-severe, not sure if Rx needed; non-severe but treatment needed; or severe. Cases that are considered unlikely or excluded have an severity index of no severity indication.

There is a line between Case adjudication and Not a Case, and a line between Case adjudication and each of the case categories. There are also arrows and lines pointing from the case categories to the severity indexes. There is a star on the top-right corner of Not a Case. Go back to page 7
Chagas Disease / West Nile Virus: Emerging problems?

2011 Incidence in US

<table>
<thead>
<tr>
<th>Incidence per 10,000</th>
<th>States</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.00</td>
<td>Washington, Oregon, South Dakota, New Hampshire, Maine</td>
</tr>
<tr>
<td>0.01 - 0.99</td>
<td>California, Nevada, Arizona, New Mexico, Colorado, Kansas, Texas,</td>
</tr>
<tr>
<td></td>
<td>Minnesota, Missouri, Louisiana, Mississippi, Georgia, Florida, South</td>
</tr>
<tr>
<td></td>
<td>Carolina, North Carolina, Tennessee, Kentucky, Illinois, Indiana, Ohio,</td>
</tr>
<tr>
<td></td>
<td>Michigan, Maryland, Delaware, New Jersey, Pennsylvania, New York,</td>
</tr>
<tr>
<td></td>
<td>Connecticut, Rhode Island, Massachusetts</td>
</tr>
<tr>
<td>1.00 - 2.49</td>
<td>California, Utah, Arizona, New Mexico, Texas, Nebraska, Iowa,</td>
</tr>
<tr>
<td></td>
<td>Arkansas, Louisiana, Mississippi, Florida, Tennessee, Kansas, Virginia,</td>
</tr>
<tr>
<td></td>
<td>West Virginia, New York</td>
</tr>
<tr>
<td>2.50 - 9.99</td>
<td>California, Nevada, Wyoming, Colorado, North Dakota, Nebraska, Iowa,</td>
</tr>
<tr>
<td></td>
<td>Missouri, Oklahoma, Mississippi, Georgia, Tennessee, Illinois, Indiana,</td>
</tr>
<tr>
<td></td>
<td>Michigan, Vermont</td>
</tr>
<tr>
<td>&gt;= 10.00</td>
<td>Idaho, Montana, Kansas, Missouri, Mississippi</td>
</tr>
<tr>
<td>Incidence per 10,000</td>
<td>States</td>
</tr>
<tr>
<td>----------------------</td>
<td>--------</td>
</tr>
<tr>
<td>0.00</td>
<td>Oregon</td>
</tr>
<tr>
<td>0.01 - 0.99</td>
<td>Washington, Idaho, California, Nevada, Utah, Arizona, New Mexico, Colorado, Nebraska, Kansas, Oklahoma, Texas, Minnesota, Michigan, Missouri, Arkansas, Louisiana, Mississippi, Georgia, Florida, South Carolina, North Carolina, Tennessee, Kentucky, Illinois, Indiana, Ohio, West Virginia, Maryland, Delaware, New Jersey, Pennsylvania, New York, Connecticut, Rhode Island, Massachusetts, Vermont, New Hampshire, Maine</td>
</tr>
<tr>
<td>1.00 - 2.49</td>
<td>California, Utah, Arizona, New Mexico, Texas, Nebraska, Iowa, Arkansas, Louisiana, Mississippi, Florida, Tennessee, Kansas, Virginia, West Virginia, New York</td>
</tr>
<tr>
<td>2.50 - 9.99</td>
<td>California, South Dakota, Nevada, Wyoming, Colorado, North Dakota, Nebraska, Iowa, Missouri, Oklahoma, Mississippi, Georgia, Tennessee, Illinois, Indiana, Michigan, Vermont</td>
</tr>
<tr>
<td>&gt; = 10.00</td>
<td>Idaho, Montana, North Dakota, South Dakota, Colorado, Nebraska, Kansas, Oklahoma, Texas, Mississippi, Louisiana, Alabama, Georgia, Minnesota, Iowa, Missouri, Arkansas, Illinois, Indiana, West Virgina</td>
</tr>
</tbody>
</table>
The U.S. map shows the percentage of HCV-positive donors (per 100 deceased donors recovered for TX) varies across the country. In 2017, up to 25% of deceased donors were HCV positive, with the highest percentages (15-20, and 20-25%) reported in the northeastern parts of the country, and lower percentages in the middle and west parts of the country.

<table>
<thead>
<tr>
<th>Donors</th>
<th>States</th>
</tr>
</thead>
<tbody>
<tr>
<td>[0, 5]</td>
<td>Hawaii, Oregon, California, Idaho, Nevada, Utah, Colorado, North Dakota, South Dakota, Minnesota, Nebraska, Kansas, Oklahoma, Texas, Missouri, Arkansas, Illinois, Georgia, North Carolina, Florida</td>
</tr>
<tr>
<td>(10,15)</td>
<td>Florida, Missouri, Arkansas, Tennessee, Kentucky, Indiana, Ohio, Pennsylvania, West Virginia, Maryland, North Carolina, New York</td>
</tr>
<tr>
<td>(15, 20)</td>
<td>Pennsylvania, Delaware, Connecticut, Massachusetts, Vermont, New Hampshire, Maine</td>
</tr>
<tr>
<td>(20, 25)</td>
<td>Ohio, New York</td>
</tr>
</tbody>
</table>

Go back to page 15
Increased Risk Donor issues vs Graft Issues:

Two graphs demonstrating the risk of liver graft failure (left graph) is much lower than the risk of HIV/HCV transmission (right graph) from increased risk donors. On the bottom of the graphs is a notation for dark blue, which indicates the range of risk of graft failure or disease transmission depending on donor factors.
## Results: Indication for PHS IR Designation

The Bar graph shows IVDA (16%) and incarceration (15%) as main indications for PHS IR designation (N=288)

<table>
<thead>
<tr>
<th>Indication</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVDA</td>
<td>46 (16)</td>
</tr>
<tr>
<td>Incarceration</td>
<td>43 (15)</td>
</tr>
<tr>
<td>Sex with Individual with IVDU</td>
<td>22 (8)</td>
</tr>
<tr>
<td>Poor Historian</td>
<td>22 (8)</td>
</tr>
<tr>
<td>Hemodilution</td>
<td>21 (7)</td>
</tr>
<tr>
<td>Hemodialysis</td>
<td>11 (4)</td>
</tr>
<tr>
<td>Sex with Indiv. Who Had Sex for Money/Drugs</td>
<td>5 (2)</td>
</tr>
<tr>
<td>Sex for Money or Drugs</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Dx/Rx for STI</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Sex with Indiv. Known/Susp. With HIV/HBV/HCV</td>
<td>1 (0)</td>
</tr>
<tr>
<td>MSM</td>
<td>1 (0)</td>
</tr>
<tr>
<td>Female Who Had Sex with MSM</td>
<td>1 (0)</td>
</tr>
<tr>
<td>Child: Born to MO with or IR for HIV/HCV/HBV</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Child: Breastfed by MO with or IR for HIV</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>
Results: N=179 donors with 1 Criterion only for PHS IRD

Bar chart highlighting among donors who met only one criterion for PHS IRD, incarceration is the most common reason (N=179)

<table>
<thead>
<tr>
<th>Indication</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incarceration</td>
<td>46 (26)</td>
</tr>
<tr>
<td>IVDA</td>
<td>43 (24)</td>
</tr>
<tr>
<td>Poor Historian</td>
<td>22 (12)</td>
</tr>
<tr>
<td>Hemodialysis</td>
<td>22 (12)</td>
</tr>
<tr>
<td>Hemodilution</td>
<td>21 (12)</td>
</tr>
<tr>
<td>Dx/Rx for STI</td>
<td>11 (6)</td>
</tr>
<tr>
<td>MSM</td>
<td>5 (3)</td>
</tr>
<tr>
<td>Sex with Individual with IVDU</td>
<td>3 (2)</td>
</tr>
<tr>
<td>Sex with Indiv. Known/Susp. With HIV/HBV/HCV</td>
<td>3 (2)</td>
</tr>
<tr>
<td>Sex with Indiv. Who Had Sex for Money/Drugs</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Sex for Money or Drugs</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Child: Born to MO with or IR for HIV/HCV/HBV</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Female Who Had Sex with MSM</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Child: Breastfed by MO with or IR for HIV</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>
HIV epidemiology (extended description)

**Left:** The bar graph shows estimated HIV incidences among persons aged at least 13 years remained stable (around 40,000) in the U.S. between 2010 and 2016. Note: The estimates were derived from a CD4 depletion model using HIV surveillance data. Bars indicate the range of the lower and upper bounds of the confidence intervals for the point estimate.

**Right:** The multiple-line graph demonstrates the trends in estimated HIV incidences in different age groups in the U.S. between 2010 and 2016. The incidence slightly reduced in the 13-24-year group, increased in 25-34-year group, and remained relatively stable for other age groups (35-44, 45-54, and 55 years and older). In 2010, the incidence was highest in the 13-24-year group, followed by 25-34, 35-44, 45-54, and 55 and above groups. From 2011 to 2016, the incidence was highest in the 25-34-year group, followed by 13-24, 35-44, 45-54, and 55 and above groups.

Go back to [page 56]
## Evolution of HIV treatment

(extended description)

<table>
<thead>
<tr>
<th>Year</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1987</td>
<td>Zidovudine (NRTI)</td>
</tr>
<tr>
<td>1991</td>
<td>Didanosine (NRTI)</td>
</tr>
<tr>
<td>1992</td>
<td>Zalcitabine (NRTI)</td>
</tr>
<tr>
<td>1994</td>
<td>Stavudine (NRTI)</td>
</tr>
<tr>
<td>1995</td>
<td>Lamivudine (NRTI), Saquinavir (PI)</td>
</tr>
<tr>
<td>1996</td>
<td>Indinavir (PI)*, Nevirapine (NNRTI), Ritonavir (PI)</td>
</tr>
<tr>
<td>1997</td>
<td>Combivir (FDC), Delavirdine (NNRTI)<em>, Nelfinavir (PI)</em></td>
</tr>
<tr>
<td>1998</td>
<td>Abacavir (NRTI), Efavirenz (NNRTI)</td>
</tr>
<tr>
<td>1999</td>
<td>Amprenavir (PI)*</td>
</tr>
<tr>
<td>2000</td>
<td>Didanosine EC (NRTI), Kaletra (FDC), Trizivir (FDC)</td>
</tr>
<tr>
<td>2001</td>
<td>Tenofovir DF (NRTI)</td>
</tr>
<tr>
<td>2003</td>
<td>Atazanavir (PI) Emtricitabine (NRTI) Enfuvirtide (FI) Fosamprenavir (PI)</td>
</tr>
<tr>
<td>2004</td>
<td>Epzicom (FDC), Truvada (FDC)</td>
</tr>
<tr>
<td>2005</td>
<td>Tipranavir (PI)</td>
</tr>
<tr>
<td>2006</td>
<td>Atripla (FDC), Darunavir (PI)</td>
</tr>
<tr>
<td>2007</td>
<td>Maraviroc (CA,) Raltegravir (INSTI)</td>
</tr>
<tr>
<td>2008</td>
<td>Etravirine (NNRTI)</td>
</tr>
<tr>
<td>2011</td>
<td>Complera (FDC), Nevirapine XR (NNRTI), Rilpivirine (NNRTI)</td>
</tr>
<tr>
<td>2012</td>
<td>Stribild (FDC)</td>
</tr>
<tr>
<td>2013</td>
<td>Dolutegravir (INSTI)</td>
</tr>
<tr>
<td>2014</td>
<td>Cobicistat (PE), Elvitegravir (INSTI), Triumeq (FDC)</td>
</tr>
<tr>
<td>2015</td>
<td>Evotaz (FDC), Genvoya (FDC), Prezcobix (FDC)</td>
</tr>
<tr>
<td>2016</td>
<td>Descovy (FDC), Odefsey (FDC)</td>
</tr>
<tr>
<td>2017</td>
<td>Juluca (FDC)</td>
</tr>
<tr>
<td>2018</td>
<td>Biktarvy (FDC), Cimduo (FDC), Delstrigo (FDC), Doravirine (NNRTI), Ibalizumab (PAI), Symfi (FDC), Symfi Lo (FDC), Symtuza (FDC)</td>
</tr>
</tbody>
</table>

* No longer available

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A Survival

The statistical curves compare the patient survival of HIV-infected kidney transplant patients with the U.S. Scientific Registry of Transplant Recipients (SRTR) data for all kidney-transplant recipients and SRTR data for kidney-transplant recipients 65 years of age or older. Patient survival rates at 1 year and 3 years were about 95% and 91%, respectively. Patient survival rates were generally between those reported in the SRTR database for kidney-transplant recipients 65 years of age or older and for all kidney-transplant recipients.

B Graft survival

The statistical curves compare the graft survival of HIV-infected kidney transplant patients with the U.S. Scientific Registry of Transplant Recipients (SRTR) data for all kidney-transplant recipients and SRTR data for kidney-transplant recipients 65 years of age or older. Graft survival rates at 1 year and 3 years were about 90% and 74%, respectively. Graft survival rates were generally between those reported in the SRTR database for kidney-transplant recipients 65 years of age or older and for all kidney-transplant recipients.
Patient survival:
The statistical curves show that the 1-year, 2-year, and 3-year patient survival rates (95% CI) were 76%, 72%, and 60% in HCV/HIV-coinfected patients; and 92%, 81%, and 79% in HCV mono-infected patients.

Graft survival:
The statistical curves show that the 1-year, 2-year, and 3-year graft survival rates (95% CI) were 72%, 65%, and 53% in HCV-HIV-coinfected patients; and 88%, 77%, and 74% in HCV mono-infected patients.
The top-to-bottom flow chart shows the donor and recipient selection process in the HOPE IN ACTION study. On the top of the chart is “eligible HIV positive kidney or liver candidates.” In the middle of the chart is “UNOS organ offers per availability ‘Natural randomization’.” On the bottom of the chart are “HIV negative donor/positive recipient” and “HIV positive donor/positive recipient.”
HCV epidemiology (extended description)

Figure 4.1

Reported number of acute hepatitis C cases – United States, 2001-2016
The line graph shows that the number of acute hepatitis C cases reported to CDC dropped between 2001 (around 1,600 cases) and 2004 (around 700 cases), remained relatively stable between 2004 and 2010, but drastically increased between 2010 and 2016 (more than 3,000 cases).
Source: CDC, National Notifiable Diseases Surveillance System (NNDSS). CDC logo, DEPARTMENT OF HEALTH AND HUMAN SERVICES. USA

Figure 4.2

Incidence of acute hepatitis C, by age group – United States, 2001-2016
The multiple-line graph shows the changes in the number of acute hepatitis C cases (per 100,000 population) reported to CDC in different age groups between 2001 and 2016.

Between 2001 and 2004, the numbers of reported cases dropped in the 40-49, 30-39, and 50-59 years groups; the numbers remained relatively stable in the other age groups. During this period, the number of reported cases was highest in the 40-49 years group, followed by 30-39, 20-29, 50-59, 60 and older, and 0-19 years groups.

Between 2004 and 2010, the numbers remained relatively stable in all age groups.

Between 2010 and 2016, the numbers increased drastically in the 20-29 and 30-39 years groups. During the same period, the reported cases moderately increased in the 40-49 and 50-59 years groups, and remained relatively stable in the 60 years and older as well as 0-19 years groups. Overall, the number of reported cases was highest in the 20-29 years group, followed by 30-39, 40-49, 50-59, 60 and older, and 0-19 years groups.

Source: CDC, National Notifiable Diseases Surveillance System (NNDSS). CDC logo, DEPARTMENT OF HEALTH AND HUMAN SERVICES. USA

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The bar chart shows that advancements in HCV treatment (1989 to 2014) has drastically increased patient survival rates (SVR; %). Between 1989 and 1998, IFN-alpha was the only treatment option, and the survival rate was around 20%. Between 1998 and 2001, treatment options included IFN-alpha and RBV, and the survival rate was around 40%. Between 2001 and 2011, treatment options included PEG-IFN-alpha and RBV, and the survival rate was close to 50%. Between 2011 and 2014, treatment options included 1st generation PI-based triple, and the survival rate was around 75%. Since 2014, new DAA combinations became available, and the survival rate has increased to close to 100%.
Increasing number and quality of HCV+ donor organs over time (extended description)

The multiple-line graph shows the prevalence (percent) of HCV positive donors (identified based on antibody) between 2000 and 2016. The percentage of deceased donors who died of opioid overdose and were HCV positive remained relatively stable between 2000 and 2010 (around 10%); however, the percentage drastically increased from 2010 to 2016 (near 30%). In contrast, the percentage (less than 5%) of deceased donors who died of trauma or other medical conditions remained relatively stable from 2000 to 2016.
The figure contains four multiple-line graphs (A, B, C, and D), showing predicted survival outcomes for different recipients after accepting or declining an IRD kidney. The graphs show that the percentage of patients alive after transplant decreases as time goes on, and that overall accepting an IRD kidney appears to be associated with increased survival benefit. The following table shows the percent of patients alive 60 months after transplant.

<table>
<thead>
<tr>
<th>Figure</th>
<th>Accepted IRD (base-case)</th>
<th>Accepted IRD (worst-case)</th>
<th>Declined IRD</th>
</tr>
</thead>
<tbody>
<tr>
<td>A: 40 F, 3 months until non-IRD transplant</td>
<td>93</td>
<td>90</td>
<td>92</td>
</tr>
<tr>
<td>B: 65F, diabetic, 60 months to non-IRD transplant</td>
<td>69</td>
<td>67</td>
<td>33</td>
</tr>
<tr>
<td>C: 50 M, non-diabetic, 24 months to non-IRD transplant</td>
<td>87</td>
<td>85</td>
<td>81</td>
</tr>
<tr>
<td>D: 75 F, ABO, AB, PRA 100, diabetic, 24 months to non-IRD transplant</td>
<td>51</td>
<td>49</td>
<td>44</td>
</tr>
</tbody>
</table>

If not specified, the patient is Caucasian, non-diabetic, with a BMI of 25, PRA of 0, no previous transplants, and O blood type. M, male; F, female.
### % PHS High Risk Donors by DSA 1/1/2015 – 12/31/2016 (extended description)

<table>
<thead>
<tr>
<th>Percentages</th>
<th>States</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-40%</td>
<td>New Mexico, Kentucky, Ohio, Pennsylvania, New York, Delaware, New Jersey, Connecticut, Rhode Island, Massachusetts, Vermont, New Hampshire, Maine</td>
</tr>
<tr>
<td>25-29%</td>
<td>Arizona, Texas, Louisiana, Alabama, Florida, Missouri, Illinois, Indiana, Michigan, Wisconsin, Virginia, Maryland, Connecticut, Massachusetts</td>
</tr>
<tr>
<td>15-19%</td>
<td>California, Nevada, North Dakota, South Dakota, Nebraska, Wisconsin, Kansas, Oklahoma, Texas, Missouri, Mississippi, Georgia, South Carolina, Florida</td>
</tr>
<tr>
<td>&lt;15%</td>
<td>Iowa, South Carolina</td>
</tr>
</tbody>
</table>
% PHS High Risk Donors by DSA 1/1/2017 – 12/31/2018 (extended description)

<table>
<thead>
<tr>
<th>Percentage</th>
<th>States</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-42%</td>
<td>Michigan, Wisconsin, Indiana, Ohio, Kentucky, Louisiana, Florida, North Carolina, West Virginia, Maryland, Delaware, Pennsylvania, New Jersey, Connecticut, Rhode Island, Massachusetts, New York, Vermont, New Hampshire, Maine</td>
</tr>
<tr>
<td>20-24%</td>
<td>California, Nevada, Idaho, Utah, Wyoming, Arizona, New Mexico, Texas, Iowa, Illinois, Arkansas, Mississippi, Florida, Virginia, Washington DC, Maryland</td>
</tr>
<tr>
<td>15-19%</td>
<td>California, North Dakota, South Dakota, Nebraska, Kansas, Oklahoma, Minnesota, Wisconsin, Missouri, Georgia</td>
</tr>
<tr>
<td>&lt;15%</td>
<td>-</td>
</tr>
</tbody>
</table>
## % HCV Seropositive Donors by DSA
### 1/1/2015 – 12/31/2016
*(extended description)*

<table>
<thead>
<tr>
<th>Percentages</th>
<th>States</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-16%</td>
<td>Ohio, Maryland, Delaware, New Jersey, Pennsylvania, Connecticut, Rhode Island, Massachusetts, Vermont, New Hampshire, Maine</td>
</tr>
<tr>
<td>7-11%</td>
<td>Arizona, New Mexico, Missouri, Arkansas, Louisiana, Florida, Tennessee, Kentucky, Illinois, Ohio, West Virginia, Virginia, Pennsylvania, New York</td>
</tr>
<tr>
<td>2-3%</td>
<td>Oregon, Idaho, California, Nevada, Utah, Wyoming, Texas, Kansas, Missouri, Illinois, Wisconsin, Georgia</td>
</tr>
<tr>
<td>&lt;2%</td>
<td>North Dakota, South Dakota, Minnesota, Iowa, Nebraska, Arkansas, Tennessee, Mississippi, South Carolina</td>
</tr>
</tbody>
</table>
% HCV Seropositive Donors by DSA
1/1/2017 12/31/2018 (extended description)

<table>
<thead>
<tr>
<th>Percentages</th>
<th>States</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-16%</td>
<td>Kentucky, Ohio, Maryland, Delaware, New Jersey, Pennsylvania, New York, Connecticut, Rhode Island, Massachusetts, Vermont, New Hampshire, Maine</td>
</tr>
<tr>
<td>2-3%</td>
<td>California, Nevada, Utah, Idaho, Wyoming, Texas, Kansas, Missouri, Arkansas, Georgia</td>
</tr>
<tr>
<td>&lt;2%</td>
<td>North Dakota, South Dakota, Minnesota, Nebraska</td>
</tr>
</tbody>
</table>
The stacked bar graph shows an overall increase in the number of organs transplanted from GLDP PHS increased risk organ donors each year from 2005 to 2018.

<table>
<thead>
<tr>
<th>Recovery Year</th>
<th>Kidney (1869)</th>
<th>Liver (932)</th>
<th>Heart (367)</th>
<th>Lung (419)</th>
<th>Pancreas (93)</th>
<th>Intestine (4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>67</td>
<td>27</td>
<td>9</td>
<td>13</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>2006</td>
<td>99</td>
<td>37</td>
<td>16</td>
<td>13</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>2007</td>
<td>68</td>
<td>29</td>
<td>7</td>
<td>6</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>2008</td>
<td>52</td>
<td>25</td>
<td>7</td>
<td>6</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>2009</td>
<td>48</td>
<td>33</td>
<td>9</td>
<td>9</td>
<td>2</td>
<td>0</td>
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<tr>
<td>2010</td>
<td>65</td>
<td>26</td>
<td>8</td>
<td>8</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>2011</td>
<td>91</td>
<td>41</td>
<td>15</td>
<td>17</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>2012</td>
<td>79</td>
<td>41</td>
<td>17</td>
<td>20</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>2013</td>
<td>105</td>
<td>51</td>
<td>25</td>
<td>21</td>
<td>4</td>
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<tr>
<td>2014</td>
<td>174</td>
<td>94</td>
<td>28</td>
<td>41</td>
<td>7</td>
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</tr>
<tr>
<td>2015</td>
<td>183</td>
<td>98</td>
<td>46</td>
<td>49</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>2016</td>
<td>249</td>
<td>146</td>
<td>47</td>
<td>59</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>2017</td>
<td>277</td>
<td>149</td>
<td>65</td>
<td>76</td>
<td>22</td>
<td>2</td>
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</tbody>
</table>
Organ Discard Rates from GLDP PHS
Increased Risk Organ Donors
(extended description)

<table>
<thead>
<tr>
<th>Recovery Year</th>
<th>Organ Discard Rate</th>
<th>Non-increased Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Increased Risk</td>
<td></td>
</tr>
<tr>
<td>2005</td>
<td>14%</td>
<td>14%</td>
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<td>2006</td>
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<td>2007</td>
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<tr>
<td>2008</td>
<td>25%</td>
<td>23%</td>
</tr>
<tr>
<td>2009</td>
<td>22%</td>
<td>25%</td>
</tr>
<tr>
<td>2010</td>
<td>16%</td>
<td>22%</td>
</tr>
<tr>
<td>2011</td>
<td>22%</td>
<td>26%</td>
</tr>
<tr>
<td>2012</td>
<td>24%</td>
<td>31%</td>
</tr>
<tr>
<td>2013</td>
<td>24%</td>
<td>27%</td>
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</tr>
<tr>
<td>2015</td>
<td>22%</td>
<td>27%</td>
</tr>
<tr>
<td>2016</td>
<td>20%</td>
<td>28%</td>
</tr>
<tr>
<td>2017</td>
<td>20%</td>
<td>24%</td>
</tr>
<tr>
<td>2018</td>
<td>19%</td>
<td>27%</td>
</tr>
</tbody>
</table>
55,497 Organs Transplanted from U.S. PHS
Increased Risk Organ Donors 2005-2018
(extended description)

<table>
<thead>
<tr>
<th>Recovery Year</th>
<th>Kidney (26250)</th>
<th>Liver (14539)</th>
<th>Heart (5894)</th>
<th>Lungs (6692)</th>
<th>Pancreas (1964)</th>
<th>Intestine (158)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>776</td>
<td>474</td>
<td>171</td>
<td>179</td>
<td>113</td>
<td>2</td>
</tr>
<tr>
<td>2006</td>
<td>944</td>
<td>532</td>
<td>188</td>
<td>172</td>
<td>113</td>
<td>6</td>
</tr>
<tr>
<td>2007</td>
<td>844</td>
<td>470</td>
<td>146</td>
<td>146</td>
<td>81</td>
<td>6</td>
</tr>
<tr>
<td>2008</td>
<td>880</td>
<td>479</td>
<td>164</td>
<td>147</td>
<td>96</td>
<td>9</td>
</tr>
<tr>
<td>2009</td>
<td>877</td>
<td>504</td>
<td>176</td>
<td>207</td>
<td>74</td>
<td>8</td>
</tr>
<tr>
<td>2010</td>
<td>1083</td>
<td>555</td>
<td>209</td>
<td>223</td>
<td>97</td>
<td>14</td>
</tr>
<tr>
<td>2011</td>
<td>1261</td>
<td>645</td>
<td>250</td>
<td>280</td>
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<tr>
<td>2012</td>
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<td>740</td>
<td>268</td>
<td>295</td>
<td>120</td>
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<tr>
<td>2013</td>
<td>1641</td>
<td>847</td>
<td>337</td>
<td>380</td>
<td>125</td>
<td>11</td>
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<td>2014</td>
<td>2358</td>
<td>1395</td>
<td>553</td>
<td>647</td>
<td>183</td>
<td>20</td>
</tr>
<tr>
<td>2015</td>
<td>2771</td>
<td>1592</td>
<td>646</td>
<td>742</td>
<td>165</td>
<td>14</td>
</tr>
<tr>
<td>2016</td>
<td>3418</td>
<td>1952</td>
<td>806</td>
<td>911</td>
<td>205</td>
<td>14</td>
</tr>
<tr>
<td>2017</td>
<td>3799</td>
<td>2127</td>
<td>913</td>
<td>1094</td>
<td>234</td>
<td>21</td>
</tr>
<tr>
<td>2018</td>
<td>4194</td>
<td>2227</td>
<td>1067</td>
<td>1269</td>
<td>265</td>
<td>18</td>
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</table>
Organ Discard Rates from U.S. PHS Increased Risk Organ Donors (extended description)

<table>
<thead>
<tr>
<th>Recovery Year</th>
<th>Organ Discard Rate</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Increased Risk</td>
<td>Non-increased Risk</td>
</tr>
<tr>
<td>2005</td>
<td>15%</td>
<td>13%</td>
</tr>
<tr>
<td>2006</td>
<td>14%</td>
<td>13%</td>
</tr>
<tr>
<td>2007</td>
<td>15%</td>
<td>14%</td>
</tr>
<tr>
<td>2008</td>
<td>12%</td>
<td>14%</td>
</tr>
<tr>
<td>2009</td>
<td>13%</td>
<td>14%</td>
</tr>
<tr>
<td>2010</td>
<td>11%</td>
<td>14%</td>
</tr>
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<td>2011</td>
<td>12%</td>
<td>13%</td>
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<tr>
<td>2016</td>
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<tr>
<td>2017</td>
<td>12%</td>
<td>14%</td>
</tr>
<tr>
<td>2018</td>
<td>12%</td>
<td>14%</td>
</tr>
</tbody>
</table>
All Donors Recovered 2012-2018 From Deceased Donors

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of donors recovered</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>8,143</td>
</tr>
<tr>
<td>2013</td>
<td>8,268</td>
</tr>
<tr>
<td>2014</td>
<td>8,596</td>
</tr>
<tr>
<td>2015</td>
<td>9,079</td>
</tr>
<tr>
<td>2016</td>
<td>9,971</td>
</tr>
<tr>
<td>2017</td>
<td>10,286</td>
</tr>
<tr>
<td>2018</td>
<td>10,721</td>
</tr>
</tbody>
</table>

Go back to page 200
<table>
<thead>
<tr>
<th>Year</th>
<th>Number of donors recovered</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>28,602</td>
</tr>
<tr>
<td>2013</td>
<td>29,405</td>
</tr>
<tr>
<td>2014</td>
<td>30,158</td>
</tr>
<tr>
<td>2015</td>
<td>31,917</td>
</tr>
<tr>
<td>2016</td>
<td>35,361</td>
</tr>
<tr>
<td>2017</td>
<td>36,424</td>
</tr>
<tr>
<td>2018</td>
<td>37,850</td>
</tr>
</tbody>
</table>

Based on OPTN data as of February 19, 2019
## All Organs Transplanted 2012-2018 From Deceased Donors

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of donors recovered</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>24,625</td>
</tr>
<tr>
<td>2013</td>
<td>25,513</td>
</tr>
<tr>
<td>2014</td>
<td>26,110</td>
</tr>
<tr>
<td>2015</td>
<td>27,540</td>
</tr>
<tr>
<td>2016</td>
<td>30,497</td>
</tr>
<tr>
<td>2017</td>
<td>31,608</td>
</tr>
<tr>
<td>2018</td>
<td>32,857</td>
</tr>
</tbody>
</table>

Go back to page 202
# Number of Deceased Donors Recovered by Year and PHS Increased Risk Status

<table>
<thead>
<tr>
<th>Year of Donor Recovery</th>
<th>Number of Deceased Donors Recovered</th>
<th>Percent of Increased Risk Donors (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>Between 7,500 and 10,000</td>
<td>8.1</td>
</tr>
<tr>
<td>2009</td>
<td>Between 7,500 and 10,000</td>
<td>8.4</td>
</tr>
<tr>
<td>2010</td>
<td>Between 7,500 and 10,000</td>
<td>9.0</td>
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<tr>
<td>2011</td>
<td>Between 7,500 and 10,000</td>
<td>10.4</td>
</tr>
<tr>
<td>2012</td>
<td>Between 7,500 and 10,000</td>
<td>11.9</td>
</tr>
<tr>
<td>2013</td>
<td>Between 7,500 and 10,000</td>
<td>13.4</td>
</tr>
<tr>
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