Living Donor Testing
## Workgroup

<table>
<thead>
<tr>
<th>Name</th>
<th>Expertise</th>
<th>Program</th>
<th>E-Mail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Connie Davis¹</td>
<td>TN</td>
<td>U Washington</td>
<td><a href="mailto:cdavis@u.washington.edu">cdavis@u.washington.edu</a></td>
</tr>
<tr>
<td>Chris Freise²</td>
<td>TS</td>
<td>U California – San Fran</td>
<td><a href="mailto:chris.freise@ucsfmedctr.org">chris.freise@ucsfmedctr.org</a></td>
</tr>
<tr>
<td>Talia Baker</td>
<td>TS</td>
<td>Northwestern</td>
<td><a href="mailto:tabaker@nmh.org">tabaker@nmh.org</a></td>
</tr>
<tr>
<td>Stuart Flechner</td>
<td>TS</td>
<td>Cleveland Clinic</td>
<td><a href="mailto:flechns@ccf.org">flechns@ccf.org</a></td>
</tr>
<tr>
<td>David Mulligan</td>
<td>TS</td>
<td>Mayo Clinic – Arizona</td>
<td><a href="mailto:mulligan.david@mayo.edu">mulligan.david@mayo.edu</a></td>
</tr>
<tr>
<td>Kevin Korenblat</td>
<td>TH</td>
<td>Washington U</td>
<td><a href="mailto:kkorenblat@wustl.edu">kkorenblat@wustl.edu</a></td>
</tr>
<tr>
<td>John Friedewald</td>
<td>TN</td>
<td>Northwestern</td>
<td><a href="mailto:jfriedew@nmh.org">jfriedew@nmh.org</a></td>
</tr>
<tr>
<td>Carrie Comellas</td>
<td>CO</td>
<td>Stony Brook</td>
<td><a href="mailto:carrie.comellas@stonybrook.edu">carrie.comellas@stonybrook.edu</a></td>
</tr>
<tr>
<td>Dianne LaPointe-Rudow</td>
<td>CO</td>
<td>Mt. Sinai</td>
<td><a href="mailto:dianne.lapointerudow@mountsinai.org">dianne.lapointerudow@mountsinai.org</a></td>
</tr>
<tr>
<td>Doug Penrod</td>
<td>CO/PT</td>
<td>Northwestern</td>
<td><a href="mailto:dpenrod@nmh.org">dpenrod@nmh.org</a></td>
</tr>
<tr>
<td>Jamie Hanneman</td>
<td>SW</td>
<td>Northwestern</td>
<td><a href="mailto:jhannema@nmh.org">jhannema@nmh.org</a></td>
</tr>
</tbody>
</table>
Approach: in Subgroups

+ Review transmission events that have been identified
  + Understand errors that were made to attempt to avoid in the future

+ Review available guidelines for living donor screening
  + CDC and NY Department of Health Recommendations
  + OPTN Deceased Donor Policy & LD Evaluation Guidance Document
  + Global guidance documents on LD screening: Australia, UK, US

+ Review current guidelines by US PHS for screening healthy patients for HIV, HBV, and HCV
  + Review epidemiology as well

+ Survey the US transplant centers conducting living donation
  + Assess the current status of donor screening (assays, timing)
  + Assess challenges to live donor screening policy

+ Review available assays that could be used to screen donors
  + Serologic and NAT
  + Understand limitations and challenges with each assay

+ Understand the window period for each assay and its potential impact on live donor screening

+ Discuss process issues and impact on the privacy and psychology of the potential living donor
Living Donor Testing Overall Considerations

? Policy Goals

+ Is it no transmission ever?
+ Or minimization of transmission?
+ What about the risk of decreased number of transplants?
+ What about the impact on the donor’s psychological state?
+ What about donor autonomy?

Differences LD vs DD

+ Time
+ Repetitive testing possible
+ Conversations about risks possible
+ Assigning responsibility possible
+ May not hear the truth
### Disease Transmission by Living Donors

OPTN data as of January 13, 2012

**Table 1.**
Living Donor Transplants Reported to the Improving Patient Safety Portal As a Potential Disease Transmission: 2006-2011

<table>
<thead>
<tr>
<th>Year</th>
<th>Total</th>
<th>Malignancy</th>
<th>Infections</th>
<th>Case Initiated From Disease in Recipient</th>
<th>Case Initiated From Disease in Donor</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>2007</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>2008</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>2009</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>2010</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2011</td>
<td>9</td>
<td>4</td>
<td>5</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>15</td>
<td>8</td>
<td>7</td>
<td>6</td>
<td>9</td>
</tr>
</tbody>
</table>
Survey of US Tx Administrators: Ison and work group

- RE-do with modifications of earlier survey
- Obtained the e-mail of all TAs from US TCs that conduct live donor procurement from OPTN/UNOS
- Sent to 407 email addresses, the same sample
- Responded 75
## Live Donor Risk Survey

<table>
<thead>
<tr>
<th>Question</th>
<th>1 Different Test Policy</th>
<th>2 Within 7 day HCV</th>
<th>3 Within 7 day HBV</th>
<th>4 Within 7 day HIV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>18.3%</td>
<td>57.7%</td>
<td>51.4%</td>
<td>57.7%</td>
</tr>
<tr>
<td>No</td>
<td>81.7%</td>
<td>42.3%</td>
<td>48.6%</td>
<td>42.3%</td>
</tr>
<tr>
<td>#Answered/ #Skipped</td>
<td>71/4</td>
<td>71/4</td>
<td>72/3</td>
<td>71/4</td>
</tr>
</tbody>
</table>
Who Follows Up on the Test Results

<table>
<thead>
<tr>
<th>Role</th>
<th>Response Percent</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coordinator</td>
<td>86.4%</td>
<td>38</td>
</tr>
<tr>
<td>Social Worker</td>
<td>0.0%</td>
<td>0</td>
</tr>
<tr>
<td>Infectious disease physician</td>
<td>0.0%</td>
<td>0</td>
</tr>
<tr>
<td>Transplant physician</td>
<td>6.8%</td>
<td>3</td>
</tr>
<tr>
<td>Transplant surgeon</td>
<td>6.8%</td>
<td>3</td>
</tr>
<tr>
<td>Other (please specify)</td>
<td></td>
<td>7</td>
</tr>
<tr>
<td>answered question</td>
<td></td>
<td>44</td>
</tr>
<tr>
<td>skipped question</td>
<td></td>
<td>31</td>
</tr>
</tbody>
</table>
### Other retesting times

6. Is your center retesting the living donor close to donation for HCV, HBV and HIV but greater than 7 days prior to transplant?

<table>
<thead>
<tr>
<th></th>
<th>Response Percent</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>27.4%</td>
<td>20</td>
</tr>
<tr>
<td>No</td>
<td>72.6%</td>
<td>53</td>
</tr>
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</table>

- answered question: 73
- skipped question: 2
Discuss with Donor that high risk behavior will be disclosed to Recipient?

8. Does your live donor advocate discuss with the potential donor that the recipient will be notified of the increased risk behavior and its potential consequences?

<table>
<thead>
<tr>
<th>Response</th>
<th>Response Percent</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>52.9%</td>
<td>36</td>
</tr>
<tr>
<td>No</td>
<td>47.1%</td>
<td>32</td>
</tr>
</tbody>
</table>

answered question 68
skipped question 7
Discussion of Opt Out for Donor

9. Does your live donor advocate discuss with the potential donor other options, including a medical opt out?

<table>
<thead>
<tr>
<th></th>
<th>Response Percent</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>97.1%</td>
<td>68</td>
</tr>
<tr>
<td>No</td>
<td>2.9%</td>
<td>2</td>
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</tbody>
</table>

answered question 70
skipped question 5
10. Does someone in your program discuss minimizing increased-risk behavior with the potential donor during the pre-donation phase between the last serology/NAT testing and the actual donation (window period)?

<table>
<thead>
<tr>
<th>Response</th>
<th>Response Percent</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>72.5%</td>
<td>50</td>
</tr>
<tr>
<td>No</td>
<td>27.5%</td>
<td>19</td>
</tr>
</tbody>
</table>

answered question 69
skipped question 6
11. When do you inform donors about limiting increased risk behavior?

<table>
<thead>
<tr>
<th>Timing of discussion</th>
<th>Response Percent</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>At the first visit</td>
<td>67.3%</td>
<td>33</td>
</tr>
<tr>
<td>When they have cleared donor testing</td>
<td>16.3%</td>
<td>8</td>
</tr>
<tr>
<td>When they are scheduled for surgery</td>
<td>8.2%</td>
<td>4</td>
</tr>
<tr>
<td>At the last time NAT or other final viral testing is done</td>
<td>8.2%</td>
<td>4</td>
</tr>
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</table>

answered question 49
skipped question 26
Who discusses high risk behavior modification with potential donor?

**12. Who talks to the increased-risk donor about modifying behavior to low risk during this pre-donation phase?**

<table>
<thead>
<tr>
<th>Role</th>
<th>Response Percent</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coordinator</td>
<td>68.2%</td>
<td>30</td>
</tr>
<tr>
<td>Social Worker</td>
<td>9.1%</td>
<td>4</td>
</tr>
<tr>
<td>Infectious disease physician</td>
<td>2.3%</td>
<td>1</td>
</tr>
<tr>
<td>Transplant physician</td>
<td>11.4%</td>
<td>5</td>
</tr>
<tr>
<td>Transplant surgeon</td>
<td>9.1%</td>
<td>4</td>
</tr>
<tr>
<td>Other (please specify)</td>
<td></td>
<td>12</td>
</tr>
</tbody>
</table>

- answered question 44
- skipped question 31
14. Do you have the donors sign any type of document stating that they agree not to participate in increased-risk behavior in the window period (i.e. from point of last serology/NAT testing until time of donation)?

<table>
<thead>
<tr>
<th>Response</th>
<th>Percentage</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>4.4%</td>
<td>3</td>
</tr>
<tr>
<td>No</td>
<td>95.6%</td>
<td>65</td>
</tr>
</tbody>
</table>

- Answered question: 68
- Skipped question: 7
15. If a potential donor meets criteria for increased risk behavior, does someone in your program discuss the increased disease transmission risk with the recipient?

<table>
<thead>
<tr>
<th>Response</th>
<th>Response Percent</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>75.8%</td>
<td>50</td>
</tr>
<tr>
<td>No</td>
<td>24.2%</td>
<td>16</td>
</tr>
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</table>

- answered question: 66
- skipped question: 9
Does Recipient sign consent?

| 13. Do you have the recipient sign a consent form acknowledging the increased risk potential? |
|---------------------------------------------------------------|-----------------|-----------------|
|                                                            | Response Percent | Response Count  |
| Yes                                                         | 51.1%            | 24              |
| No                                                          | 48.9%            | 23              |

answered question 47
skipped question 28
HCV product

+ **Statement of problem**
  + Prevalence of HCV in the US: 1.6% (4.1 million)¹
  + To date, small but finite risk of donor transmitted HCV infection
    + Deceased donors: conditions of transmission varied (misread NAT testing, transmission from inadvertent use of donor vessels, antibody testing negative/NAT testing not performed
    + Living donors: One case of live donor transmission reported in media as administrative error

+ **Statement of goal**
  + *Eliminate* the risk of live donor transmitted HCV infection
  + Standardize hepatitis C testing in living donors

+ **Tests appropriate for detection**
  + Serologic testing
    + Five antibody-based FDA approved tests
      + Excellent specificity and sensitivity
      + “Window period” up to 70 days
    + Recombinant Immunoblot
      + Superseded by nucleic acid testing

HCV product

- Tests appropriate for detection
  - Nucleic acid testing
    - “Window period” 7 days
  - Two FDA-approved testing using RT-PCR technology with LLD 50 IU/mL
  - Two FDA-approved assays for HIV&HCV using TMA/HPA
  - Serology and NAT (pooled or individual) testing current standard for blood donation in US

- Testing strategies – background
  - Estimates of window period infection by incidence-window period model
    - Incidence of infection x length of window period
  - Estimated risk of HCV infection during window period of serologic testing for first time blood donors: 1:270,000
  - Estimate of HCV infection during window period of serologic testing in tissue donors: 1:42,000
  - Estimate of risk of HCV infection among organ donors from 17 OPOs
    - Overall adjusted anti-HCV positivity in organ donors 5.58% (3.45% low risk; 18.20% high risk)
  - Estimated incidence of undetected HCV infection during window period for serologic testing 19.91 per 100,000 person-years
  - Estimated incidence of undetected HCV infection during window period for NAT testing 1.99 per 100,000 person-years
  - For high-risk donors, estimated incidences of HCV infection are 104.94 (serologic testing) and 10.49 (NAT testing) per 100,000 person-years

HCV product

**Testing strategies – recommendations**
- Avoid risk stratification of donors – 63% of anti-HCV positive organ donors deemed “normal” risk
- Combined antibody and NAT testing (as currently done for all blood donations) provides a superior risk reduction in preventing window period infection
- Assuming 6,200 live donor transplants annually
  - ~1 infection per year for 16 years vs. 1 infection every 10 years...actual rate of infection based on published reports appear to be much less

**Timing thought best for detection**
- Antibody testing for initial screening of the live donor
- NY DOH recommends serology and NAT testing no longer than 14 days before live donor organ transplant. This seems like a reasonable balance to limit the risk of window period infection but enough time for transplant programs to review and confirm results.

**Psychosocial**
- All donors should be counseled about avoiding high-risk practices
- Reactive antibody and positive NAT testing should be disclosed to the donor and referral provided to permit follow up with appropriate medical personal to further evaluate the findings

**Gaps in needs and knowledge**
- Assessment of cost of implementation
- Feasibility of using non-FDA approved NAT testing
  - Recommend FDA approved assays but not make it mandatory
Available HCV NAT Assays

+ Detects the presence of HCV RNA
+ Window Period: 7 – 10 days
+ Approved for donor screening
  + COBAS AmpliScreen HCV Test (v 2.0) – LOD: 10 – 100 c/mL
  + COBAS TaqScreen MPX Test – LOD: 10 c/mL
  + Procleix HIV-1/HCV – LOD: 100 c/mL
  + Procleix Ultrio – LOD: 100 c/mL
+ Approved for viral load assessment
  + Amplicor HCV Monitor – LOD: 600-500,000 IU/mL.
  + Cobas Amplicor HCV Monitor V2.0 – LOD: 600-500,000 IU/mL.
  + Versant HCV RNA 3.0 Assay (bDNA) – LOD: 615-7,700,000 IU/mL.
  + LCx HCV RNA-Quantitative Assay – LOD: 25-2,630,000 IU/mL.
  + SuperQuant – LOD: 30-1,470,000.
  + Cobas Taqman HCV Test – LOD: 49-69,000,000 IU/mL.
  + Abbott RealTime – LOD: 12-100,000,000 IU/mL
  + Cobas Amplicor Hepatitis C Virus Test, version 2.0 – LOD: 50 IU/mL
  + Versant HCV RNA Qualitative Assay – LOD: 10 IU/mL
HEPATITIS B VIRUS
HBV Testing of Living Donors

+ Potential for Transmission of HBV exists in living donor organ transplant
+ Determine best strategy to test donor and potentially prophylax recipient to prevent transmission or development of HBV related hepatitis
+ Tests appropriate for detection
  + FDA approved Serologic Tests (window period 35-44 days)
    + Abbott PRISM HBsAg Assay
    + Ortho Antibody to HBsAg ELISA Test System
  + NAT testing (window period 20-22 days)
    + COBAS AmpliScreen HBV Test – LOD: 10 – 100 c/mL
    + COBAS TaqScreen MPX Test – LOD: 10 c/mL
    + Procleix Ultrio – LOD: 100 c/mL
+ Screening at initial evaluation
  + Serologic testing HBsAg HBeAb (IgG), (IgM if positive)
+ Screening prior to transplant NAT testing at 7-14 days prior to transplant
HBV : Other Considerations

- Immunize Potential Donor if Hep B sAb negative
  - Since HBV is a potential blood-borne pathogen and donors may require blood products, the donors should be offered HBV vaccine if they are not previously immune
  - HBV vaccination series should be initiated pre-donation and completed post-donation for HBsAb negative donors

- Immunize Potential Recipient if Donor Hep B cAb positive
  - Consider HBIG for up to one year (probably more important in situation of liver donor) if no response to vaccination
Available HBV NAT Assays

- Detects the presence of HBV DNA
- Window Period: 20 – 22 days
- Approved for donor screening
  - COBAS AmpliScreen HBV Test – LOD: 10 – 100 c/mL
  - COBAS TaqScreen MPX Test – LOD: 10 c/mL
  - Procleix Ultrio – LOD: 100 c/mL
- Approved for viral load assessment
  - HBV Digene Hybrid Capture I – LOD: \(\sim 10^6\) c/mL
  - HBV Digene Hybrid Capture II – LOD: \(\sim 10^5\) c/mL
  - Ultra-sensitive Digene Hybrid Capture II – LOD: \(\sim 10^{3.5}\) c/mL
  - Amplicor HBV Monitor – LOD: \(\sim 10^3\) c/mL
  - Cobas Amplicor HBV Monitor – LOD: \(\sim 10^2\) c/mL
  - Cobas Taqman 48 HBV – LOD: \(\sim 10\) c/mL
  - Versant HBV DNA 1.0 – LOD: \(\sim 10^{5.5}\) c/mL
  - Versant HBV DNA 3.0 – LOD: \(\sim 10^5\) c/mL
HIV
HIV product

+ **Statement of problem**
  + The prevalence is about 1.8 million people in USA
  + Yearly approximately 50,000 contract HIV

+ **Statement of goal**
  + *Eliminate* the risk of live donor transmitted HIV infection
  + Standardize HIV testing in living donors

1 Armstrong, et al Ann Int Med 2006:144;705
HIV product

Tests appropriate for detection
- Serology and NAT (pooled or individual) testing current standard for blood donation in US
- Genetic Systems HIV 1 and 2 plus O EIA
- Abbott Prism HIV O Plus
- HIVAB HIV-1/HIV-2 (rDNA)EIA

Testing strategies – background
- 0.03 to 0.05% false positive for serologic testing
- 0.1 to 0.85% false positive for NAT testing

Available HIV NAT Assays for detection

+ Detects the presence of HIV-1 RNA only (not HIV-2)
+ Window Period: 7 – 10 days
+ Approved for donor screening
  + COBAS AmpliScreen HIV-1 Test (v 1.5) – LOD: 10 – 100 c/mL
  + COBAS TaqScreen MPX Test – LOD: 10 c/mL
  + Procleix HIV-1/HCV – LOD: 100 c/mL
  + Procleix Ultrio – LOD: 100 c/mL

+ Approved for viral load assessment (PCR load)
  + AMPLICOR HIV Monitor Test – LOD: 400 or 50 c/mL
  + Versant HIV-1 RNA 3.0 assay – LOD: 75 c/mL
  + NucliSens HIV RNA QT – LOD: 176 c/mL
  + COBAS AmpliPrep/COBAS TaqMan HIV-1 Test – LOD: 48 c/mL
  + RealTime HIV-1 – LOD: 40 to 10,000,000 c/mL
HIV product

- **Testing strategies – recommendations**
  - Serology and NAT
- **Timing thought best for detection**
  - CDC within 7 days
  - NYDH 7-14 days
  - Our recommendation within 14 days
Psychosocial Aspect of Testing
Psychosocial Aspect

- The psychological stressors of being screened for high risk behavior must be balanced with the medical testing and questioning needed to ensure that there is no transmission of infectious disease to the recipient.

- It is proposed that ALL live organ donors are treated universally as high risk from a medical testing standpoint (just prior to donation) and are educated throughout the process to prevent transmission.

- By treating everyone the same, one can ensure that all omissions, intentional or not, will not result in preventable transmission.
What is high risk behavior for each of the infection transmission possibility?

+ High Risk Behavior definitions are the same for the live donor as for any donors
+ Development of an educational booklet could be created for donors summarizing existing data “How to stay infection free prior to live donation”
+ It is critical is that a donor is screened for infectious diseases and high risk behaviors that make them at risk for infectious disease, tested for viruses and educated about prevention of infection prior to donation.
What is high risk behavior for each of the infection transmission possibility?

+ Propose that all donors are screened as “high risk” (NAT testing close to the surgery). Though most donors are honest, love the person they are donating to and don’t want to transmit infection, with Paired Kidney Donation and non-directed donation and the solicitation of donors one may not get the full truth from all donors. Process would be similar to “Universal Precautions”

+ An alternative to universal NAT testing could be universal rescreening prior to surgery and testing based on a risk stratification which based on the donor’s answers to the questionnaire? HOWEVER: NAT is optimal since goal is “zero transmission”. Therefore we should use tests that narrows window as much as possible on every case
What is the optimal information to discuss with the potential donor?

- Educate about what are considered High Risk behaviors
- Educate about why being honest about previous high risk behaviors is so critical
- Educate about what testing is done and in what time frame. Additionally discuss implications of a positive result (reportable to state agencies)
- The process of disclosing information about the donor to the recipient should first and foremost protect the donor’s confidentiality. Inform the donor that the information they provide is confidential and will only be disclosed with their permission to the recipient, and only if requested by the recipient
  - They have the choice of opting out of donation if they do not want to disclose something the team feels needs to be disclosed.
  - Failure to disclose to the transplant team may result in cancelation of surgery
What is the optimal information to discuss with the potential donor?

- A HCV positive result or a HIV positive result may make the donor medically unsuitable if confirmed as a true positive. (Note: patients with false positive Elisa HCV Ab tests that can be confirmed negative by RIBA and PCR and be approved for donation.)

- Donor needs to agree to abstain from high risk behavior-- this includes no IV drug use (would likely be ruled out on that alone) and agree to use barrier protection and abstain from HR sexual practice in the period of time from last pre-donation infectious disease testing and actual donation (ie. 7-14 days)
What is the optimal information to discuss with the potential recipient

- Recipient needs to know what types of infectious disease screening is performed and when and what the window period would be.

- Recipients need to know that no test is 100% guarantee that donor is disease free (live and deceased donor)

- Recipient must be informed that the donor may have increased risk of transmission that has not been disclosed or is not known.

- A question of debate:
  - If the donor has high risk behaviors is the transplant program obligated to inform the recipient of an increased risk regardless of the lab test result?
  - In reality the high risk behavior, really wouldn’t need to be disclosed in detail (donors confidentiality is important) but the program must do appropriate testing to ensure that proper testing prior to surgery is done.
What is the optimal time to discuss with the potential donor

- At initial screening visit and final crossmatch/clearance visit
  - Assessment of previous or ongoing risk of infection
  - What testing will be done
  - The implications of a positive result – will a public health agency be notified?

- Programs need policies in place for education requirements

- Training for those performing the education

- Policies on how to counsel and refer for positive results
If an initial negative test result retests as positive a week prior to transplant, how is recipient told of this?

- Recipient is told donor is **Medically** not suitable, potentially some testing will be repeated.

- Same would be true if during the “window period” the donor disclosed behavior to the transplant center that was high risk and did not want this information shared with recipient.

- If donor consents to this information being disclosed to recipient, the recipient and transplant team may decide to proceed with donation without further testing, with the recipient’s informed consent.
How, who, why to manage this?

- All donors should be educated and screened by donor team at initial evaluation
  - Live donor coordinator and physician should educate and assess risk
  - Health care providers with skill set to handle psychosocial aspects of donor, as well as understanding of high risk behavior should conduct screening (physician, live donor coordinator, ILDA)
  - Serology testing performed as outlined previously

- All donors should be educated and screened at final clearance/crossmatch (1-2 weeks before surgery)
  - Live donor coordinator should educate and screen
  - NAT testing performed (which will be disease specific)
How, who, why to manage this?

Positive tests will be discussed with the donor by the physician and determined if:
- Declined as a donor,
- Retesting is needed
- If safe to move forward with donation, donor consent needed to disclose results to recipient
- If donor ruled out, appropriate referrals/work-up for newly diagnosed condition should be initiated by transplant center

Usually donor would be declined if results are true positive and then no need to discuss with Recipient or their team. However if donor is not ruled out and transplant team feels it is safe to proceed:
- Discussion with recipient team and risk of infectious transmission can happen only after consent from donor
- Discussion and informed consent with the intended recipient

ILDA should be aware of above and make sure it is something he/she discusses during her interactions with the patient.
Timing of the testing

- Baseline
- 7-14 days prior to surgery.
- Hard to dictate more specific due to barriers
  - Donors need to retain work and minimize days off prior to surgery
  - Crossmatch typically done within two weeks of surgery
  - Donors may live a far from transplant center
  - Turn around time varies for NAT testing
  - Need to minimize number of canceled surgeries for logistics
## Cost Factors

<table>
<thead>
<tr>
<th>ASSAY</th>
<th>MEDIAN ALLOWABLE COST</th>
<th>FACILITY FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Serology</td>
<td>$78.75</td>
<td>$12.50</td>
</tr>
<tr>
<td>HIV NAT</td>
<td>$302.94</td>
<td>$119.75</td>
</tr>
<tr>
<td>HBsAb</td>
<td>$73.01</td>
<td>$15.12</td>
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<tr>
<td>HBsAg</td>
<td>$71.95</td>
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<td>HBeAb</td>
<td>$73.01</td>
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<td>HBV NAT</td>
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<tr>
<td>HCV Serology</td>
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<td>HCV NAT</td>
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<tr>
<td>Serology</td>
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<td>Serology + NAT*</td>
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<tr>
<td>Serology = NAT**</td>
<td>$1,208.06</td>
<td>$320.09</td>
</tr>
</tbody>
</table>

*HIV,HCV only  **HIV,HBV,HCV
WG Live Donor Screening Recs
Consensus conference

- All live donors
  - HIV: HIV Serology
  - HBV: HBsAg, HBsAb, HBcAb
  - HCV: HCV Serology
  - Timing Pre-Transplant: Minimum but no definite time
  - Consensus HBV NAT not performed on all or with identified risk factors

- Donors with identified risk factors
  - No consensus on additional testing
Conclusions

- Educate all donors and recipients
- Discuss the importance of decreasing risky behavior
- Test all donors the same way
- Consent recipients there may be infection risk that is unknown
- Serologic and NAT for all donors, but time frame 7-14 days
- Donors with positive tests need to be referred to appropriate counseling and care
- Pilot data is needed
Knowledge needs

Gaps in needs and knowledge

- *Pilot Study*: all potential donors for one year from all or some centers; how many are positive by antibody and/or NAT testing, pick different time periods of testing and....
- Assessment of cost of implementation of testing all donors
- Study potential factors related to false positive results
- Study the number and impact of false positive tests on number of transplants, recipient transmissions, wait listing time and on potential donor psychological, medical and financial outcome.
- Consider the feasibility of using non-FDA approved NAT testing
  - Recommend FDA approved assays but not make it mandatory
Process

- Continually review testing results, refine, redesign, report
Group Vote