Donation Testing and Donor Notification

Debra Kessler RN, MS
History

• Until 1980s testing focused on prevention of hemolytic transfusion reactions
  – ABO/Rh
  – Red cell antibody

• Two tests for potentially infectious units
  – Syphilis (<1950)
    ▪ Blood banks reported positive results to Departments of Health who notified donors
  – HBsAg (1970)
    ▪ Notifications done by Blood Center, initially driven by research interests
### Current Screening and Confirmatory Tests

**Screening Tests**
- HIV-1/HIV-2 antibody and NAT
- HTLV-I/II antibody
- Hepatitis B Surface Antigen and NAT
- Hepatitis B Core antibody
- HCV antibody and NAT
- Syphilis antibody
- West Nile Virus NAT
- *T. cruzi* antibodies (Chagas Disease)
- ABO/Rh
- *Babesia microti* (new)
- Cytomegalovirus (CMV)
- Sickle Cell (HgS)
- Red cell antibody Screen
- Extended red cell antigen typing

**Confirmatory Tests**
- HIV-1/HIV-2 Algorithm (only if antibody RR/NAT NR) - Western blot or IFA, HIV-2 antibody, HIV-2 Western blot
- HTLV-I/II Western Blot
- HCV-alternate antibody (only if antibody RR/NAT NR)
- HBsAg Neutralization (only if antibody RR/NAT NR)
- Syphilis (IgG-ABS)
- *T. cruzi* antibodies (Chagas Disease) ESA

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<table>
<thead>
<tr>
<th>Required tests</th>
<th>Inventory, special needs</th>
</tr>
</thead>
</table>

![New York Blood Center Logo]
Current Serological Rate Estimates

<table>
<thead>
<tr>
<th>Test</th>
<th>% RR</th>
<th>Of RR % Confirmed</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV 1/2</td>
<td>0.09</td>
<td>7.5</td>
</tr>
<tr>
<td>HCV</td>
<td>0.07</td>
<td>4.0</td>
</tr>
<tr>
<td>HBV</td>
<td>0.03</td>
<td>47.0</td>
</tr>
<tr>
<td>HTLV</td>
<td>0.03</td>
<td>27.1</td>
</tr>
<tr>
<td>Hep B core</td>
<td>0.55</td>
<td>N/A</td>
</tr>
<tr>
<td>Syphilis</td>
<td>0.13</td>
<td>34.0</td>
</tr>
<tr>
<td>WNV</td>
<td>0.00</td>
<td></td>
</tr>
<tr>
<td>Chagas</td>
<td>0.11</td>
<td>12.2</td>
</tr>
</tbody>
</table>

*Overall rate of units with a reactive screening result is 1%. This has decreased over time because the tests are more specific.*
## Risk of Transfusion Transmitted Infections

<table>
<thead>
<tr>
<th>Marker</th>
<th>TTD Risk per Unit</th>
<th>Donor Prevalence</th>
<th>Population Prevalence</th>
<th>Window Period (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-1/2</td>
<td>1:1,000,000</td>
<td>1:16,000</td>
<td>1:250</td>
<td>22 (6-38)</td>
</tr>
<tr>
<td>HIV NAT</td>
<td>1:2.3 million</td>
<td>same</td>
<td>same</td>
<td>11 (7-12)</td>
</tr>
<tr>
<td>HBsAg</td>
<td>1:200,000-1:500,000</td>
<td>1:3,700</td>
<td>1:33</td>
<td>51(36-72)</td>
</tr>
<tr>
<td>HTLV-I/II</td>
<td>1:500,000 - 1:3 million</td>
<td>1:7,000</td>
<td>N/A</td>
<td>82 (54-192)</td>
</tr>
<tr>
<td>HCV</td>
<td>1:105,000</td>
<td>1:3,100</td>
<td>1:75</td>
<td>59 (37-87)</td>
</tr>
<tr>
<td>HCV NAT</td>
<td>1:1.8 million</td>
<td>same</td>
<td>same</td>
<td>20 (11-22)</td>
</tr>
<tr>
<td>Syphilis</td>
<td>&lt;1:1 million</td>
<td>1:2,300</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Other</td>
<td>&lt;1:1 million</td>
<td>v. low</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

First time donors have marker rates 4-8x repeat donors
### Most common cause of death reported to FDA

<table>
<thead>
<tr>
<th>Complication</th>
<th>FY10 No.</th>
<th>FY10 %</th>
<th>FY11 No.</th>
<th>FY11 %</th>
<th>FY12 No.</th>
<th>FY12 %</th>
<th>FY13 No.</th>
<th>FY13 %</th>
<th>FY14 No.</th>
<th>FY14 %</th>
<th>Total No.</th>
<th>Total %</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRALI*</td>
<td>18</td>
<td>45%</td>
<td>10</td>
<td>33%</td>
<td>17</td>
<td>45%</td>
<td>14</td>
<td>37%</td>
<td>13</td>
<td>43%</td>
<td>72</td>
<td>41%</td>
</tr>
<tr>
<td>HTR (non-ABO)</td>
<td>5</td>
<td>13%</td>
<td>6</td>
<td>20%</td>
<td>5</td>
<td>13%</td>
<td>5</td>
<td>13%</td>
<td>4</td>
<td>13%</td>
<td>25</td>
<td>14%</td>
</tr>
<tr>
<td>HTR (ABO)</td>
<td>2</td>
<td>5%</td>
<td>3</td>
<td>10%</td>
<td>3</td>
<td>8%</td>
<td>1</td>
<td>3%</td>
<td>4</td>
<td>13%</td>
<td>13</td>
<td>7%</td>
</tr>
<tr>
<td>Microbial Infection</td>
<td>2</td>
<td>5%</td>
<td>4</td>
<td>13%</td>
<td>3</td>
<td>8%</td>
<td>5</td>
<td>13%</td>
<td>1</td>
<td>3%</td>
<td>15</td>
<td>8%</td>
</tr>
<tr>
<td>TACO</td>
<td>8</td>
<td>20%</td>
<td>4</td>
<td>13%</td>
<td>8</td>
<td>21%</td>
<td>13</td>
<td>34%</td>
<td>5</td>
<td>17%</td>
<td>38</td>
<td>22%</td>
</tr>
<tr>
<td>Anaphylaxis</td>
<td>4</td>
<td>10%</td>
<td>2</td>
<td>7%</td>
<td>2</td>
<td>5%</td>
<td>0</td>
<td>0%</td>
<td>2</td>
<td>7%</td>
<td>10</td>
<td>6%</td>
</tr>
<tr>
<td>Other**</td>
<td>1**</td>
<td>3%</td>
<td>1**</td>
<td>3%</td>
<td>0</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
<td>1**</td>
<td>3%</td>
<td>3</td>
<td>2%</td>
</tr>
<tr>
<td>Totals</td>
<td>40</td>
<td>100%</td>
<td>30</td>
<td>100%</td>
<td>38</td>
<td>100%</td>
<td>38</td>
<td>100%</td>
<td>30</td>
<td>100%</td>
<td>176</td>
<td>100%</td>
</tr>
</tbody>
</table>

*TThese numbers include both “TRALI” and “possible TRALI” cases\(^{16,17}\)

**Other:
- FY2010: Graft vs. Host Disease (GVHD)
- FY2011: GVHD
- FY2014: Hypotensive Reaction\(^{18}\)
Detection of Bacterial Contamination in Platelets
Bacterial Detection in Single Donor Platelets

- Major cause of transfusion related fatalities; typically gram negative organisms
  - Clusters of infection/deaths occurred in 2002/2003
  - WB plt Contamination = 1:2-4,000
  - SDP Contamination = 1:15,000
  - Culture positive results – 1:1,500
  - Fatalities = ~ 1:40,000 (under reported)
- AABB standard - All platelets must be tested for bacterial contamination (2004)
- FDA Guidance requiring hospitals to report fatalities related to contamination
Fatalities from bacteria in transfusion
Sources and Remediation of Bacterial Contamination of Platelets

• Sources
  – Donor skin flora (50-60%)
  – Donor bacteremia (40-50%)
  – Blood bag or container manufacture damage or defect (rare)
  – Blood processing contamination

• Current practices
  – Skin disinfection
  – Diversion pouches
  – SDPs instead of RDPs (Septic reactions decreased from 1:4818 to 1:15,098 (Ness et al, Transfusion 1999;39:89))
  – Donor history questions f
Detection of Bacterial Contamination in Platelets

• Use of approved devices for SDP – Culture methods
  – Culture media (BacT/Alert, CO₂ production)
  – Growth in situ (Pall BDS; O₂ consumption)

• Other methods - Dip-stick, glucose meters, pH, culture plates are no longer allowed.

• Point of issue test (Verax and BacTx) available as addition to culture methods
Detection of Bacterial Contamination in Platelets - Procedure

- Sample platelets into vials containing bacterial culture medium after a 24 h pre-incubation at 22 °C
- Incubated in the BacT/Alert and check on growth continuously.
- Initial testing in aerobic culture only
- If negative at 16 hrs of incubation release platelets inventory; continue to monitor until expiration.
- If positive, interdict product and send samples for confirmation and species identification.
And NOW Pathogen Reduction Technology (PRT)

- Pathogen Reduction/Inactivation: Exposure of blood components to a system designed to reduce the risk of transfusion transmitted infections.
- So far there is technology for PRT:
  - Single donor platelets
  - Plasma
- NEW! PRT can be used as an alternative to doing bacteria detection tests.
AND 7 Day Platelets!!!

• Which ever method of reducing risk for bacterial contamination is used a single donor platelet may be used on day 6 or 7 if subsequently:

• Secondary testing of platelets for the purpose of extending the dating period of platelet components past 5 days must be conducted only with a test labeled as a “safety measure”.

• These may be either a culture-based bacterial detection device (none currently approved), or a rapid bacterial detection device (two approved), based on the needs of the blood establishment.

• Perform rapid testing, within 24 hours prior to transfusion

• Additionally, platelets must be stored in FDA-cleared or approved 7-day platelet storage containers
TRALI

Transfusion Related Acute Lung Injury
TRALI – Clinical Aspects and Causes

• Pulmonary injury (difficulty breathing, fluid in the lungs, fever)
• Associated in time with blood transfusion (onset within 6 hours after transfusion)
• Causes are not clear but TRALI seems to be associated with the presence of antibodies to white blood cells (anti-HLA or anti-leukocyte) in the donated blood that react with the recipient’s white cells
TRALI fatality reports by year
Rate of HLA Alloimmunization in LAPS Donors

- Non tx'd males n=1138
- Never preg n=1816
- Tx'd males n=895
- Prev Preg n=3992

% positive
Effect of Pregnancy on the Rate of HLA Alloimmunization

- No Preg (n = 1816)
- 1 preg (n=634)
- 2 preg (n=1307)
- 3 preg (n=1058)
- 4+ preg (n=993)

% Positive for any HLA antibody
TRALI – What to Do About It

• AABB Standard 5.4.1.2 to reduce the risk of TRALI (2016)

Plasma, Apheresis Platelets and whole blood for allogeneic transfusion shall be from males, females who have not been pregnant, or females who have been tested since their most recent pregnancy and results interpreted as negative for HLA antibodies.
Platelets - Risk Reduction Measures

• At NYBC 50% of SDP donors are women
  • We can not afford to lose these donors and still supply the needs of the community

• Testing all female platelet donors who have had one or more pregnancies for the presence of HLA antibodies

• Defer women with HLA antibodies from future platelet donations. These donors would be permitted to donate DRBCs or whole blood.

• Repeat screening of female donors with a history of an additional pregnancy after their last negative screening test.

• Outcome 13.6% of previously pregnant female platelet donors are positive for HLA antibodies.
Donor Notification and Counseling
The Impact of HIV Testing

HIV testing brought major shift in notification for donors who confirmed as positive:

- Extensive counseling
- Confidentiality
- Social stigma
- Donor's right to information
Current Scene

• Tests now performed include HIV (antibody and NAT), HTLV, HCV (antibody and NAT), HBV (NAT and/or surface antigen and core antibody), Syphilis, WNV NAT, *T. Cruzi* and now *Babesia microti*.

• Due to high false reactive rate in many of these screening tests, most of these donors are not infected or infectious.
Objectives of Donor Notification and Counseling

• To fulfill ethical and regulatory requirements of disclosure (FDA Rule - 6/11/2001)

• To protect the health of the donor

• Possibly to protect the health of contacts (sexual partners, pregnancy, needle sharing)

• To maintain the safety of the blood supply (communicate that the donor must not donate in the future)

• To monitor the effectiveness of donor selection procedures
Significance of Deferral from Donating Blood

- Donors who are deferred because of positive test results can be anxious, upset or angry.

- They attempted to join their peers and help patients and now feel rejected.

- Generally, they believed that they were healthy, or they would not have donated.
Complexity of Donor Notification

• Donor notification of test results continues to increase in complexity
  – multiple results
  – non-specific results
Counseling Donors About Indeterminate and False Positive Results

• Time for seroconversion - retest

• Risk review

• Offer re-entry:
  – not always successful
  – may be unavailable (eg. T. Cruzi, babesia)
Other Legal/Ethical Considerations

- Laws regarding the test (HIV)
- Laws regarding donors and information generated about them
- Insurance issues
- Confidentiality
Notification Process Difficulties

• No notification process satisfies the needs of all donors
  – expectations of blood center
  – understanding of technical material
  – response to information about health
Notification Background

• Blood donors are, or should be, aware of the standard tests being performed on their blood
• By proceeding with the donation, the donor has given up the right not to be tested and be notified of unacceptable test results
• Blood Centers need to have processes in place to ensure confidentiality of donor test results
• Notification should be timely
• The quality of the information given to the donor must be current, reliable and understandable
• Notification and counseling must be performed by knowledgeable personnel who are appropriate to the task
Approaches to Notification

• **Letter and fact sheets**
  – method of the majority of notifications

• **Phone Call**
  – almost never used
  – may violate confidentiality

• **In person**
  – HIV and HTLV positive results
Structure of Notification Letters

- Donor notification letters are composed of discreet segments, each containing an element of the notification message
  - standard introduction
  - description and meaning of each test result
  - recommended medical follow-up
  - future donation eligibility
  - degree of follow-up by Blood Center
  - phone number to call with questions
  - standard closing
Contacting HIV+ Donors

May be NAT+ and/or antibody +
(NAT-/Confirmed Ab Positive - donor most likely on HAART)

• Non-specific letter - finding of significance to donor's health

• Stronger worded letter - still non-specific

• Telephone call to donor - no specific information given

• Test results given by certified mail; addressee only. Counseling still offered
HIV Positive Counseling

- **Crisis Intervention**
  - Allow for expression of feelings
- **Risk assessment**
- **Education**
  - Explanation of test
  - Meaning to health
  - Risk reduction
- **Assess understanding**
- **Referral for follow-up**
- **Written information**
- **Retest and second appointment**
HIV ELISA RR/IFA Confirmation Non-Specific Test Results

• NAT +/- Confirmation Ab Negative or Indeterminate - Possible recent infection.

• NAT-/- Confirmation Ab Negative or Indeterminate - In the absence of recent risk, no infection, no follow-up.
• Reentry possible.
HIV-1/2 Re-entry Algorithm (Issued May 2010)

**Group I**
- NAT Reactive¹
- Anti-HIV-1/2 Test Negative
- HIV-1 p24 EIA² Negative

**Group II**
- NAT Non- Reactive or Not Done
- Anti-HIV-1/2 Test RR
- HIV-1 WB or IFA
  - Indeterminate, Unreadable,
    - Negative, or Not Done
- HIV-1 p24 EIA² Negative
- Second, different HIV-2 Test
  - Negative or, if RR,
    - Investigational³ HIV-2
- Supplemental test (if performed) was not Positive

**Group III**
- NAT Non- Reactive or Not Done
- Anti-HIV-1/2 Test RR
- HIV-1 p24 EIA² Neutralization Test(s)
  - Positive or Indeterminate
    - (Non-Neutralized or Invalid)

**After 8 weeks⁴,**
*Test follow-up sample using HIV-1 ID-NAT⁵,⁶ and Anti-HIV-1/2 test⁷*

**Group I**
- ID-NAT Reactive / Anti-HIV-1/2 Test RR
  - DEFER DONOR PERMANENTLY

**Group II**
- ID-NAT Reactive / Anti-HIV-1/2 Test Negative
  - DEFER DONOR PERMANENTLY

**Group III**
- ID-NAT Non-Reactive / Anti-HIV-1/2 Test RR
  - DEFER DONOR AND CONTINUE FOLLOW-UP⁸

- ID-NAT Non-Reactive / Anti-HIV-1/2 Test Negative
  - REENTER DONOR
    - (Donor Eligible for Future Donation, Provided Donor Meets Eligibility Criteria)
Footnotes

1. Reactive on a Discriminatory NAT for HIV-1 or on a Single Virus NAT for HIV-1.
2. May not have been performed, depending upon the conditions of the specific NAT approval.
3. Performance of an investigational HIV-2 supplemental test (if available) is optional. If a supplemental test is licensed in the future it should be performed and it must not have been positive for the donor to be eligible for reentry.
4. HIV-1 ID-NAT and/or an anti-HIV-1/2 test, if performed during the 8 week waiting period, must be negative for the donor to be eligible for reentry.
5. If the original donor sample was reactive on both of the Discriminatory NAT tests for HIV-1 and HCV, we recommend that you test a follow-up sample using HCV ID-NAT and an anti-HCV test also, as in the HCV Reentry Algorithm (see Figure 6).
6. If the original donor sample was reactive on the NAT for HIV-1 (Group I donors), we recommend that you use the same ID-NAT (i.e., the Discriminatory NAT for HIV-1 or the Single Virus NAT for HIV-1) that was run on the original donor sample. If the original NAT is no longer available (e.g., an investigational NAT), we recommend that you use a NAT that has the same sensitivity claims as the original NAT or greater sensitivity claims (e.g., a NAT labeled in the Intended Use as sensitive for HIV-1 including Group O, if available).
7. If the original donor sample was RR on the anti-HIV-1/2 test (Group II donors) we recommend that you use that same test to test this follow-up sample. If the original donor sample was negative on the anti-HIV-1/2 test (Group I donors or Group III donors) or if the original test is no longer available, we recommend that you use an anti-HIV-1/2 test that is labeled in the Intended Use as sensitive for HIV-1 including Group O.
8. At your option you may further test the donor’s sample using HIV-1 WB or IFA. If WB or IFA is negative, unreadable, or indeterminate, you may reconsider the donor for reentry by conducting follow-up testing after one or more additional waiting period of 8 weeks. If WB or IFA is positive, we recommend that you defer the donor permanently. 34
HTLV I/II Positive Counseling

- Not HIV, not related to AIDS
- Minimal chance of developing disease
- Risk assessment
- Significance to health
- Transmission routes - risk reduction
- Physician follow-up
- Written information
- Retest and second appointment
HTLV RR

- **Confirmation Negative** - Donor deferred after second occasion only. No supplemental testing done. No follow-up.

- **Confirmation Positive** – by HBV NAT or HBsAg neutralization. Donor deferred. Counseling as necessary.
Donors with Positive Results for Hepatitis

- **HBsAg**
  - Confirmation negative and Core NR, probable false reactive screening result; no follow-up. Donor deferred for 8 weeks.
  - **Next donation** - If HBsAg and Core are negative on next donation, donor is re-entered, unit may be used. If Core is reactive on any subsequent donation donor is permanently deferred. If HBsAg is RR/NN, donor is deferred for another 8 weeks.

- Confirmation positive, donor is HBV carrier
  - Potential transmission to contacts
  - Potential for liver disease
  - See physician
Donors with Positive Results for Hepatitis

- HBV NAT is a DNA test (HIV and HCV are RNA).
- Done in Triplex format
- If reactive for HBV NAT only (HBsAg and anti HBc are non-reactive) donor may be tested for reentry after 8 weeks.
- Reentry testing must include ID HBV NAT, HBsAg and anti-HBc tests and all must be non-reactive.
Donors with Positive Results for Hepatitis

- HBcAb only
  - Donor deferred and notified after second occurrence only
  - Donor may have been exposed to HBV
  - No follow-up indicated
  - Reentry possible
Anti-HBc 2 Hit Re-entry Algorithm

APPENDIX

REQUALIFICATION PROCESS FOR DONORS DEFERRED BECAUSE OF REPEATEDLY REACTIVE TEST RESULTS FOR ANTI-HBc

Donors previously deferred solely because of repeatedly reactive (RR) anti-HBc test on more than one occasion

After a minimum of 8 weeks following the last repeatedly reactive anti-HBc test result, test a follow-up sample using FDA-licensed HBsAg and anti-HBc tests, and HBV NAT.

- HBsAg RR or Anti-HBc RR or HBV NAT Reactive
  - Defer donor indefinitely
- All tests negative
  - Reenter donor (Donor eligible for future donations, provided donor meets eligibility criteria)

1 If, for donor notification purposes or for medical reasons, you wish to perform follow-up testing on a donor who is deferred because of repeatedly reactive anti-HBc test results before the end of the 8-week waiting period and the blood sample tests HBsAg RR or anti-HBc RR or HBV NAT reactive, the donor should be indefinitely deferred. If, however, the sample tests negative on all three of these tests, the donor should be retested after a minimum of 8 weeks following the last repeatedly reactive anti-HBc test result using licensed HBsAg and anti-HBc tests, and HBV NAT. If, at that time, the sample tests negative on all three of these tests (HBsAg, anti-HBc, and HBV NAT), the donor may be eligible to donate.

2 The sensitivity of the HBV NAT used should be $\leq 2$ IU/mL, at 95% detection rate.

3 Regardless of the neutralization test result.
Donors with Positive Results for Hepatitis

- HCV NAT+/antibody NR - Possible window period infection, follow-up

- HCV antibody RR - three possibilities
  1. NAT Reactive /ELISA RR - infected, see MD
  2. NAT Non-reactive/Alternate ELISA RR - Resolved infection. No follow-up
  3. NAT Non-reactive/Alternate ELISA NR - false reactive antibody. No follow-up.
HCV Re-entry Algorithm (Issued May 2010)

Group A
- NAT Reactive
- Anti-HCV Test Negative

Group B
- NAT Non-Reactive or Not Done
- Anti-HCV Test RR
- RIBA Indeterminate, Negative, or Not Done

AFTER 6 MONTHS, TEST FOLLOW-UP SAMPLE USING HCV ID-NAT AND ANTI-HCV Test

- ID-NAT Reactive / Anti-HCV Test RR: DEFER DONOR PERMANENTLY
- ID-NAT Reactive / Anti-HCV Test Negative: DEFER DONOR PERMANENTLY
- ID-NAT Non-Reactive / Anti-HCV Test RR: DEFER DONOR AND CONTINUE FOLLOW-UP
- ID-NAT Non-Reactive / Anti-HCV Test Negative: REENTER DONOR (Donor Eligible for Future Donation, Provided Donor Meets Eligibility Criteria)
Footnotes

1 Reactive on a Discriminatory NAT for HCV or on a Single Virus NAT for HCV.

2 HCV ID-NAT and/or an anti-HCV test, if performed prior to 6 months, must be negative for the donor to be eligible for reentry.

3 If the original donor sample was reactive on both of the Discriminatory NAT tests for HIV-1 and HCV, test a follow-up sample using HIV-1 ID-NAT and an anti-HIV-1/2 test also, as in the HIV-1 Reentry Algorithm (see Figure 5).

4 If the original donor sample was reactive on the NAT for HCV (Group A donors), we recommend that you use the same ID-NAT (i.e., the Discriminatory NAT for HCV or the Single Virus NAT for HCV) that was run on the original donor sample. If the original NAT is no longer available (e.g., an investigational NAT) we recommend you use a NAT that has the same sensitivity claims as the original NAT or greater sensitivity claims.

5 If the original donor sample was RR on the anti-HCV test (Group B donors) we recommend that you use the same test or a later, more sensitive version (i.e., HCV antibody version 3.0 or later) to test this follow-up sample.

6 At your option you may further test the donor’s sample using HCV RIBA. If RIBA is negative or indeterminate, you may reconsider the donor for reentry by conducting follow-up testing after one or more additional waiting period of 6 months. If RIBA is positive, we recommend that you defer the donor permanently.
Donors with Reactive Results for Syphilis

• Olympus PK-TP treponemal test positive (~MHA-TP, Ab persists after infection)
• Confirmation (FTA or Syph G; RPR for counseling purposes).

  – Conf. negative (20%), no infection, no deferral
  – Conf. positive, RPR negative, past infection
  – Conf. positive, RPR positive, current infection depending on titer of RPR.
  – Re-entry after 1 year w/doctor’s note identifying the treatment used and that treatment was completed
Indate Product Retrieval, Lookback and Recipient Notification
What is it?

- **Indate Product Retrieval** - tracing products from donors who have subsequently tested positive on screening test for an infectious disease marker or CJD/vCJD risk

- **Lookback** - The process of tracing recipients of products from some of these donors

- Previously acceptable units may have transmitted disease if the donors were in the window period of infectivity or if there were no tests available at the time of donation
## Test Result Product Retrieval and Lookback

<table>
<thead>
<tr>
<th>Positive Test</th>
<th>Indate product Retrieval</th>
<th>Lookback Trace Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Ab</td>
<td>All products except pooled plasma</td>
<td>10 years or 1 year prior to last NR</td>
</tr>
<tr>
<td>HIV NAT</td>
<td>All products in prior 1 year except pooled plasma</td>
<td>1 year</td>
</tr>
<tr>
<td>HBsAg</td>
<td>All products except pooled plasma</td>
<td>none</td>
</tr>
<tr>
<td>HTLV</td>
<td>All products except any kind of plasma</td>
<td>none</td>
</tr>
<tr>
<td>HBc (Core)</td>
<td>All products except most recovered plasma</td>
<td>none</td>
</tr>
<tr>
<td>HCV Ab</td>
<td>All products except pooled plasma</td>
<td>As far back as electronic records available or 1 year prior to last NR</td>
</tr>
<tr>
<td>HCV NAT</td>
<td>All products in prior 1 year except pooled plasma</td>
<td>1 year</td>
</tr>
<tr>
<td>T. Cruzi</td>
<td>None</td>
<td>All</td>
</tr>
<tr>
<td>WNV</td>
<td>All in prior 120 days</td>
<td>None</td>
</tr>
</tbody>
</table>
# CJD/vCJD Product Retrieval and Lookback

<table>
<thead>
<tr>
<th>Deferral Category</th>
<th>Indate Product Retrieval</th>
<th>Lookback</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Blood Components</td>
<td>Plasma Derivatives</td>
</tr>
<tr>
<td>Donors dx with CJD</td>
<td>All products</td>
<td>Unpooled products only</td>
</tr>
<tr>
<td>Donors dx with nvCJD</td>
<td>same</td>
<td>All Pooled and unpooled products</td>
</tr>
<tr>
<td>↑ risk for CJD (1)</td>
<td>same</td>
<td>Unpooled products only</td>
</tr>
<tr>
<td>Has only 1 blood relative with CJD (2)</td>
<td>same</td>
<td>Unpooled products only</td>
</tr>
<tr>
<td>Lived in UK &gt;3 mo. (3) Transfusion in UK 5+ yrs in France/Europe Military bases in Europe</td>
<td>same</td>
<td>Unpooled products only</td>
</tr>
<tr>
<td>Received bovine derived injectable products from BSE countries (4)</td>
<td>same</td>
<td>Unpooled products only</td>
</tr>
<tr>
<td>Donors &lt;55 years with CJD</td>
<td>same</td>
<td>Unpooled products, refer to FDA for further action (5)</td>
</tr>
</tbody>
</table>
Notes on CJD/vCJD Product Retrieval and Lookback

• All CJD or nvCJD deferrals are permanent (indefinite) If a donor is not familiar with the term Creutzfeldt - Jakob disease it may be taken as a negative response.

• (1) Donors at increased risk for CJD include those who have:
  – received a dura mater transplant
  – received human pituitary hormones (now includes gonadotropins as well as growth hormones). If donor is not sure about human pituitary hormone treatment ask if they received the treatment by needle. If they did not, the donor is acceptable.
  – have 2 or more blood relatives with CJD.

• (2) Donor with only 1 blood relative with CJD – product retrieval only no recipient tracing or notification

• (3) Cumulative 3 months between 1980 and 1996. Includes travel to England, Northern Ireland, Scotland, Wales, the Isle of Man and the Channel Islands. Product retrieval only no recipient tracing or notification
• (4) Obtaining bovine derived injectable products from BSE countries is difficult to do. If the donor doesn’t know or is not sure, they are to be indefinitely deferred. Product retrieval only no recipient tracing or notification

• (5) FDA will evaluate on a case by case basis to determine if quarantine and withdrawal is indicated.

• All in-date product management notifications should be made within 1 week of the donor’s deferral for any of the above reasons. Lookback extends back as far as electronic records are available. Recipient notification for Lookback is at the discretion of the care providers.
Issues in Recipient Notification

- Must be tailored for the type of Lookback
  - Probability of Infection
  - Risk of secondary transmission

- Concept of window period or timing of new test introduction

- Recipient testing and follow-up
Summary

• Blood donor and recipient management are highly regulated activities
• The goal is to achieve a safe and adequate blood supply
Thank you!

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