New York State Council on Human Blood and Transfusion Services

GUIDELINES FOR THE EVALUATION OF TRANSFUSION-ASSOCIATED INFECTIONS

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GUIDELINES FOR THE EVALUATION OF TRANSFUSION-ASSOCIATED INFECTIONS

INTRODUCTION

These guidelines were prepared by the New York State Council on Human Blood and Transfusion Services to:

1. encourage the reporting, to collection facilities, of cases of possible disease transmission by transfusion;
2. standardize the clinical and laboratory investigation of involved donors and recipients; and
3. provide guidance for the management of future donations by donors implicated in disease transmission.

Despite the high degree of sophistication of current methods of blood donor screening, there exists a possibility of transmission of infectious diseases by transfusion or for the occurrence of other adverse reactions. Transmission of infectious diseases may occur because the donation took place within the "window period" of detection for the pertinent infectious disease marker; no test is available for the agent that causes the disease; or other factors, including clerical and/or laboratory error. Infectious disease risks are listed in Appendix A. Other adverse reactions may occur because of unexpected interactions between donor and recipient blood (*e.g*., high titer of leukocyte antibodies).

A donor is “involved” with a transfusion-transmitted event if a donated component was transfused to the affected patient during an interval plausible for acquisition. An involved donor is “implicated” in a transfusion-transmitted event if the donor’s component is determined to be the likely cause.

The major benefit of reporting transfusion-associated disease to collection facilities is the potential for:

1. preventing future transmission by identification of implicated donors who may pose a higher risk of disease transmission;
2. interdicting other components from the implicated unit or units prior to transfusion; and
3. identifying patients who received components from the implicated donation or other potentially infectious donations from the implicated donor.

It is important that any communication to the donor that the donation may have transmitted a disease to a recipient be preceded by careful evaluation of the recipient, in order to eliminate clearly from consideration any conditions not associated with transfusion.

I. DONOR SCREENING

Screening of blood donors is a highly controlled process prescribed in regulations and standards. Only donations from donors who fulfill all required criteria are distributed for transfusion.

Although currently all blood collected in New York State for transfusion purposes is donated by volunteer donors, blood may be collected from paid donors if it is appropriately labeled as such. Collecting facilities provide donors with educational materials regarding both donor and recipient safety issues. In addition, donors receive information about the risks for human immunodeficiency virus (HIV) infection. In the course of the medical history interview, donors are asked about prior exposure to infectious diseases, medications, and risks for infectious diseases (*e.g.*, history of hepatitis, injected drug use, venereal diseases, antibiotic therapy). Provisions should be made to enable donors to self-exclude confidentially, at the time of donation or via a call-back system, donations that may be unsuitable.

The names of blood donors are compared to names in a local, regional, or nationwide donor deferral registry to identify those currently disqualified because of infectious disease risk (previous medical/behavioral risk history and/or test results).

Donors are subjected to an evaluation that includes temperature, pulse, blood pressure, screening for hemoglobin concentration or hematocrit, and examination of the antecubital areas to identify skin infections or evidence of illegal drug use. Units are collected aseptically and processed in a sterile, closed system.

Blood samples from each donor are subjected to a number of tests, including assays for blood group, antibodies to red blood cell antigens, and infectious disease markers. Test kits are manufactured under strict U.S. Food and Drug Administration (FDA) oversight. Each lot must pass an "FDA lot release panel" before sale to donor testing laboratories. Testing of donor samples is also performed under strict rules and oversight by regulatory agencies.

II. TRANSFUSION-TRANSMISSIBLE DISEASES FOR WHICH BLOOD DONORS ARE SCREENED

The following are important diseases and pathogens that can be transmitted by transfusion. All donors are screened for markers of these infectious agents.

A. HIV infection

1. Most cases are acquired by sexual contact, injected drug use, or other contact with blood or other body fluids.

2. Transfusion-associated cases (with any blood product) constituted only three percent of reported HIV infection cases acquired prior to the availability and implementation of screening tests in April 1985, and have been rare since initiation of universal donor screening.

3. No transmission of HIV by IM or IV immunoglobulins has been reported; pathogen reduction of human-derived clotting factor concentrates makes transmission unlikely.

4. Screening includes testing for antibodies to HIV-1/HIV-2 and mini-pooled HIV nucleic acid testing (NAT).

5. The availability of FDA-approved NAT assays for HIV has eliminated the need for HIV p24 antigen screening.

6. Confirmed positive laboratory test results for HIV infection are reportable. Blood banks outside New York City reporting confirmed positive donor or patient test results, should contact the Bureau of HIV/AIDS Epidemiology at the NYSDOH at (518) 474-4284 to obtain the required form and instructions. Blood banks in New York City should contact the HIV Epidemiology and Field Services Program at the NYCDOHMH at (212) 442-3388. Donors should be informed of their HIV status in accordance with State regulations (10NYCRR Section 58-2.23).

7. Transfusion-associated cases should be reported to the collecting facility and the Blood and Tissue Resources Program.

B. Hepatitis B

1. Transmitted most commonly by sexual contact, injected drug use, needle sticks, or maternofetal transmission.

2. Very few of the cases reported every year are acquired by transfusion.

3. No transmission by IM or IV immunoglobulins has been reported; pathogen reduction of human-derived clotting factor concentrates makes transmission unlikely.

4. At present, screening includes HBsAg and anti-HBc; some facilities also use NAT.

5. Many persons have been vaccinated in the past and have antibodies to hepatitis B surface antigen (anti-HBs). Such persons do not carry antibodies to hepatitis B core antigen (anti-HBc), and should not be disqualified as blood donors under current testing algorithms.

6. Suspected or confirmed clinical cases and positive laboratory test results for HBV infection are reportable to the local health department, based on the patient's or donor's county of residence. Current laboratory reporting guidance is available from the sources given in Appendix B. A source listing, by county, New York State county health department contact information is provided in Appendix C.

7. Transfusion-associated cases should be reported to the collecting facility and the Blood and Tissue Resources Program.

C. Hepatitis C

1. Most cases are associated with contact with another person's blood through injected drug use. Some cases occur through maternofetal transmission or needlesticks in healthcare workers. The frequency of sexual transmission is low.

2. Pathogen reduction of human-derived clotting factor concentrates makes transmission unlikely.

3. Donor screening includes antibodies to hepatitis C virus (anti-HCV) by enzyme linked immunosorbent assay (ELISA) and mini-pooled HCV NAT. Repeatedly reactive anti-HCV results may be confirmed by recombinant immunoblot assay (RIBA).

4. Suspected or confirmed clinical cases and positive laboratory tests results for HCV infection are reportable to the local health department, based on the patient's or donor's county of residence. Current laboratory reporting guidance is available from the sources given in Appendix B. A source listing, by county, New York State county health department contact information is provided in Appendix C.

5. Transfusion-associated cases, very rare since the introduction of HCV testing, should be reported to the collecting facility and the Blood and Tissue Resources Program. Cases attributable to transfusions prior to availability of HCV testing may be recently recognized and diagnosed.

D. Human T-cell lymphotropic virus type I and type II (HTLV I/II)

1. Most cases are acquired through breast milk, sexual contact (primarily male to female), or injected drug use. Some cases have occurred in health care workers through needlesticks.

2. Confirmed transfusion-transmitted disease is rare.

3. The viruses are cell associated. Transmission has not been reported in association with frozen plasma or with red blood cell components stored for at least 28 days.

4. Blood donor screening tests for antibodies to HTLV I/II are very sensitive, but have a high rate of false-positive results. No FDA-licensed confirmatory test is available at present. A determination of presumptive HTLV infection is based on detection of antibodies to HTLV on ELISA screening, confirmed by a second ELISA test from a different manufacturer.

5. Many blood collecting facilities perform supplemental testing using immuno-fluorescence assay (IFA), Western blot, and/or radioimmunoprecipitation assay (RIPA) to aid in donor notification and counseling. Polymerase chain reaction (PCR) testing may also be performed.

6. HTLV infection is not currently reportable to the local health department.

7. Transfusion-associated cases should be reported to the collecting facility and the Blood and Tissue Resources Program. (See Appendix D.)

E. Syphilis

1. No transfusion-transmitted case of syphilis has been reported in the United States in more than 40 years.

2. The absence of disease transmission may be due to the low frequency of the disease in the blood donor population and a relatively small period of asymptomatic spirochetemia in infected persons. Studies have suggested, although not proven

conclusively, that storage conditions of both red blood cells and platelets are not compatible with extended survival of the organism.

3. Counseling messages for donors with confirmed positive screening test results should reflect the low likelihood of actual acute infection. A current rapid plasma reagin (RPR) titer is very helpful in differentiating between true- and false-positive results.

4. Suspected or confirmed clinical cases and positive laboratory test results for syphilis are reportable to the local health department, based on the patient's or donor's county of residence. Current laboratory reporting guidance is available from the sources given in Appendix B. A source listing, by county, New York State county health department contact information is provided in Appendix C.

5. Transfusion-associated cases should be reported to the collecting facility and the Blood and Tissue Resources Program.

F. West Nile virus (WNV) infection

1. Most cases are acquired through the bite of an infected mosquito.

2. Transmission via blood transfusion and organ transplantation has been documented.

3. Current screening of blood donors by NAT has greatly reduced, but not eliminated, the risk of transfusion-transmitted WNV infection.

4. Suspected or confirmed clinical cases and positive laboratory results for WNV infection are reportable to the local health department, based on the patient's or donor's county of residence. Current laboratory reporting guidance is available from the sources given in Appendix B. A source listing, by county, New York State county health department contact information is provided in Appendix C.

5. Transfusion-associated cases should be reported to the collecting facility and the Blood and Tissue Resources Program.

6. Health department programs that can assist in investigations or receive reports can be found in Appendix C.

III. OTHER DISEASES TRANSMISSIBLE BY TRANSFUSION

A. Babesiosis

1. A rare, acute "malaria-like" infection caused in the northeastern United States by *Babesia microti*. It invades erythrocytes; parasites may be observed in peripheral blood smears.

2. Transmitted by the *Ixodes scapularis* tick.

3. Endemic areas in the eastern United States include eastern Long Island, Connecticut, and Massachusetts. Areas at risk for infection are expanding (*e.g.,* the lower Hudson Valley).

4. Usually produces no disease or mild disease in immunocompetent humans, but can cause severe illness in those who are splenectomized, elderly, or otherwise immunosuppressed.

5. Exposed individuals may be identified by the presence of IgM and IgG antibodies to *Babesia* in indirect immunofluorescence assays and confirmed by research-based NAT for parasitic nucleic acid.

6. An asymptomatic carrier state has been demonstrated in infected blood donors for periods exceeding a year. Implicated and confirmed-positive donors should be deferred.

7. Suspected or confirmed clinical cases and positive laboratory test results for *Babesia* infection are reportable to the local health department, based on the patient's or donor's county of residence. Current laboratory reporting guidance is available from the sources given in Appendix B. A source listing, by county, New York State county health department contact information is provided in Appendix C.

8. Transfusion-associated cases should be reported to the collecting facility and the Blood and Tissue Resources Program.

B. Chagas disease

1. Caused by the protozoan *Trypanosoma cruzi*, transmitted by insects of the Reduviidae family (kissing bugs); also transmissible by blood transfusion and organ transplantation, and may be transmissible by tissues containing intact cells.

2. Highly prevalent in areas of Mexico, and Central and South America; confirmed cases are uncommon in the United States.

3. A limited number of cases have been reported in association with blood transfusion and organ transplantation in North America during the last 25 years, almost exclusively in immunocompromised patients.

4. Infection produces acute fever in about one-third of cases. Acute infection is usually mild or even asymptomatic in immunocompetent persons.

5. About 20 percent of those infected develop heart disease (*e.g.,* cardiomegaly, cardiac failure) or gastrointestinal disease (megaesophagus and megacolon). No effective treatment is currently available to eradicate the organism. A chronic carrier state may persist indefinitely.

6. Infected individuals may be identified by observation of the protozoan in peripheral blood smears and biopsy specimens (in a few acute cases), and by detection of antibodies by enzyme immunoassay or indirect immunofluorescence.

7. Chronically infected persons likely have intermittent parasitemia, and about 50 percent of recipients of blood donated by chronically infected individuals acquire the infection. Thus, implicated donors must be permanently deferred from donating blood.

8. Donor screening using an FDA-approved enzyme immunoassay was implemented widely in February 2007.

9. Transfusion-associated cases should be reported to the collecting facility and the Blood and Tissue Resources Program. (See Appendix D.)

C. Bacterial contamination

1. Thought to be currently the most frequent infectious disease risk of blood transfusion.

2. Most commonly associated with contamination during blood collection (skin or environmental bacteria) or, less frequently, during manipulation of components (*e.g.,* preparation of platelet pools).

3. Risk of transfusion-transmitted bacterial infection is higher for platelets because room temperature storage conditions facilitate bacterial proliferation.

4. In rare occasions, it is associated with asymptomatic bacteremia in the donor (*e.g*., *Yersinia*).

5. Typical reaction is characterized by chills, high fever, rigors and shock in the first few minutes of transfusion; transfusion must be immediately discontinued.

6. Diagnosed by culture of the blood component transfused and the recipient's blood. Segments associated with contaminated units are usually sterile. Diagnosis is frequently complicated by contamination during collection of samples, or by antibiotic therapy of the recipient.

7. Tracing and identification of other components from the same collection is indicated.

8. Careful consideration of the risk of bacteremia is extremely important in qualifying autogeneic donors.

9. Measures to decrease the frequency of bacterial contamination

   a. Careful evaluation of autogeneic and allogeneic donors for risk of bacteremia (very important).

   b. Adequate skin preparation of blood donors; dimpled sites should be avoided. Green soap should not be used as a cleansing agent.

   c. Diversion of first 10 to 50 mL of blood collected, using special collection pouches.

   d. Use of detection methods for bacterial contamination in platelet components. Units identified as contaminated with bacteria should not be released for allogeneic or autogeneic transfusion. Consideration may be given to deferral from future donation, as determined by the medical director, for particular organisms. Donor deferral for exogenous skin contaminants is not a productive

practice. In cases of asymptomatic bacteremia (*e.g.,Yersinia enterocolitica* and *Salmonella*), donor deferral is sometimes prudent, even for autogeneic donors.

e. Culture, after a day of storage during which bacteria have had an opportunity to proliferate, or prior to release, is superior to insensitive surrogate markers, such as pH and glucose (percentage remaining following consumption by bacteria).

f. Pathogen inactivation/reduction methods (research).

g. Careful inspection of all blood and blood components, prior to release for transfusion, for grossly visible abnormalities, such as discoloration and clots. Bacterial contamination may be associated with changes in the appearance of the blood component (*e.g.,* darkening of color, clotting, or aberrant platelet swirling, if assessed by a trained observer), but observation alone is not considered an adequate bacterial detection method.

10. Follow-up of suspected cases of bacterial contamination

The following approaches may facilitate investigation of cases of suspected bacterial contamination of blood products:

a. Transfusion should be discontinued; components and, in the case of derivatives, all associated containers, should be returned to the blood bank, using care to avoid external contamination.

b. As soon as feasible, specimens for blood culture should be collected from the recipient.

c. Specimens from unused portions of the blood product should be collected aseptically for culture. Culture of tubing segments is not useful because of the low levels of bacterial contamination at the time of blood collection. Gram stain on specimens from the component bag may be informative if positive, but are insensitive. It should be noted that contaminants may be introduced during specimen collection from the component bag or during the culturing process.

d. Patient records, including blood cultures, should be reviewed for other causes of septicemia not related to transfusion. Antibiotic treatment may mask symptoms associated with bacterial transmission by transfusion.

e. If unit and patient cultures are both positive, bacterial isolates from the blood component and patient should be subjected to comparative analysis (*e.g*., serotyping, biotyping, phage typing, etc.)

f. Contamination of other intravenous fluids should be considered.

g. Transfusion-associated cases should be reported to the collecting facility and the Blood and Tissue Resources Program.

D. Transfusion-related acute lung injury (TRALI)

Note: Although not caused by an infectious agent, TRALI is included in this guideline because some of its symptoms are similar to those caused by infectious agents and therefore require a similar evaluation.

1. A leading cause of transfusion-associated fatality.

2. Serious acute reaction to blood transfusion; often associated with donor antibodies to HLA antigens or to specific granulocyte antigens, although recipient antibodies may contribute in some cases.

3. Characterized by cough, dyspnea, hypoxia, chills and fever, and hypotension in the absence of fluid overload or congestive heart failure (*i.e.,* non-cardiogenic pulmonary edema).

4. Symptoms arise within six hours of transfusion.

5. Most patients recover within days of the event; however, mortality may reach five to ten percent.

6. Diagnosis is clinical, and may be complicated when the recipient has been multiply transfused. HLA or granulocyte antibody studies of donor(s) and the patient may be useful if positive, but are not essential for diagnosis.

7. Follow-up of suspected TRALI cases

   a. Transfusion should be discontinued and all component containers returned to the blood bank.

   b. As soon as feasible, specimens should be collected from the recipient for HLA and neutrophil antibody studies and for HLA typing. The collecting facility should obtain HLA and neutrophil antibody studies on the donor. Testing should be performed by an experienced laboratory; the collection facility may be helpful in referring these specimens for testing. The collecting facility should be notified as soon as possible regarding likely TRALI cases so that testing of donors for HLA and granulocyte antibodies may be conducted expeditiously.

   c. Donors involved in the event should be temporarily deferred until the antibody and leukocyte studies are completed. Permanent deferral from donation of components containing a high volume of plasma is indicated for donors implicated by the presence of anti-leukocyte antibodies to antigens present in the affected recipient.

   d. High plasma-volume components include plasma and frozen plasma from whole blood or collected by apheresis, apheresis platelets, buffy coat-derived platelets resuspended in plasma from one of the donors in the pool, and whole blood.

   e. Low plasma-volume components are acceptable for transfusion because, even if the donor has leukocyte or HLA antibodies, such components should contain fewer antibodies than a high plasma-volume component from a single donor.

Low plasma volume components include red blood cells, whole blood-derived platelets, and cryoprecipitate.

f. Suspected cases should be reported to the collecting facility and the Blood and Tissue Resources Program.

IV. BLOOD COLLECTION FACILITY AND HEALTH DEPARTMENT NOTIFICATION OF POSSIBLE TRANSFUSION-ASSOCIATED INFECTIONS

Notification of blood collection facilities, either directly or through an intermediary distributor, of potential disease transmission by transfusion should be preceded by a careful, but expeditious, investigation and data collection. The physician must also notify the local health department (based on the patient's residence) if the infection is a reportable communicable disease. (Current laboratory reporting guidance is available from the sources given in Appendix B. For information on reporting communicable diseases, see: *www.nyhealth.gov/nysdoh/cdc/main.htm*). The physician caring for the patient who received the transfusion(s) and the blood bank director must cooperate for accurate determination of the etiology.

A. Responsibilities of the treating physician

1. Diagnosis of the transfusion-associated infection, based on clinical and laboratory findings.

2. Notification by clinicians of transfusion-associated infections should be based on a confirmed infectious disease clinical diagnosis, not solely on test results.

3. Review of prior history and laboratory tests; identification (if possible) of negative test results prior to the transfusion event, or of stored samples that can be tested for the infectious agent.

4. Investigation of prior risks of exposure to the etiologic agent, including identification of risks, contact with blood, and prior history of transfusion. This investigation may be conducted in conjunction with the local and/or state health department, depending on the infectious disease.

5. Cooperation with the blood bank director and with the collecting facilities in clarifying the transfusion-associated event.

B. Responsibilities of the transfusion service director of the transfusing facility

1. Development of a standard operating procedure for evaluation of transfusion-associated infections.

2. In individual cases, review and evaluation of all clinical and laboratory data.

3. Determination of the ID#, expiration date, source, and date of transfusion of all blood products received by the patient.

4. Notification of the transfusion committee.

5. Submission of a report to the collecting facility(ies).

6. Transfusion-associated cases should be reported to the collecting facility and the Blood and Tissue Resources Program. (See Appendix D.)

7. Making reports and supporting documents available for inspection by regulatory agencies.

8. Maintaining confidentiality of the recipient (reports to the collecting facilities should not identify the recipient by name).

C. Suggested formats for notification

1. Notification of local health departments must be made in the appropriate format (For information on reporting communicable diseases see: *www.nyhealth.gov/nysdoh/cdc/main.htm* and Appendix B). Notification of the collecting facility, either directly or through an intermediary distributor, may be accomplished using the form enclosed in Appendix E, or by a document containing the same information. The report should be addressed to the medical director of the facility. Timeliness is of the utmost importance, in order to permit the collecting facility to quarantine or recall as-yet-untransfused products from the same donor.

2. The report should contain the following elements:

   a. Identification of reporting facility and blood bank director

   b. Patient identification code

   c. Disease or agent for which transmission is suspected

   d. List of products transfused, including:

      1. Product type

      2. Expiration date

      3. Unit #/Lot #

      4. Date transfused

      5. Summary of patient's clinical and laboratory history

      6. Summary of evidence indicating that the patient's symptoms are not likely due to an etiology other than transfusion transmission, including laboratory data and patient risk review.

D. Evaluation by collection facilities

1. Collection facilities should develop a standard operating procedure for evaluation of possible transfusion-associated infections. Upon receipt of such notification, the collecting facility should review the report to determine:

a. Completeness of the information or the need for additional information

b. Need to quarantine and recall in-date components

c. Need to recall donor(s) for interview and testing/retesting

d. Need to defer implicated donor(s) from future donations

e. Need to notify physicians of recipients of other components from the same donor(s)

2. These are complex decisions that must take into account the likelihood of disease transmission by transfusion instead of by other routes, particularly in the case of infectious diseases. The following are the major factors to consider in deciding whether to contact a donor:

   a. Number of units transfused/blood donors involved

      For transfusion-transmitted diseases, the probability that each donor is involved is directly related to the number of units transfused and the number of donors involved. Collection facilities may establish limits for the search of implicated units.

   b. Donation and test result history of each donor

      About 85 percent of volunteer blood donors are repeat donors (*i.e*., they have donated previously). In the case of suspected infectious disease transmission, especially infections with a long incubation period, donors have often returned and donated again by the time the case is reported. Thus, a review of donor records, the identification of donations that tested negative for infectious disease markers after the implicated donation, and an absence of similar reports associated with other donations constitute strong evidence that the donor is unlikely to be implicated in disease transmission of agents for which donors are routinely tested.

E. Management of blood donors and blood donations implicated in disease transmission

Events that fall within the parameters established by their standard operating procedure should be fully investigated by collection facilities. The following actions are suggested:

1. For possible transmission of agents for which donors have been screened, collection facilities should:

   a. Place the involved donors in a surveillance file; verify whether the donors were involved in other incidents of transmission of the same disease.

   b. Place in-date units from these donors in quarantine; if appropriate, seek plasma-containing units for testing.

   c. Review the donation records of the involved donors.

d. Recall and retest donors who have not donated since the involved donation, and interview, if appropriate.

e. If appropriate, defer from future donations all donors implicated as the source of a transfusion-transmitted infection.

f. Perform lookback when indicated, as determined by the medical director.

g. Notify the blood bank director of the transfusing facility of the investigation's results.

2. At the discretion of the collection facility medical director, donors who are not implicated as the source of a suspected transfusion-transmitted infection, for example, by subsequent negative infectious disease tests, may be removed from the surveillance files and their components may be released from quarantine.

3. For transmission of infectious diseases for which donors have not been screened (*e.g.,* malaria, babesiosis), collection facilities should:

   a. Place in-date units from these donors in quarantine.

   b. Review the donation records of the involved donors.

   c. Recall and test donors, if a suitable test is available.

   d. Defer from future donations all donors who test positive for the infectious agent.

   e. Notify the blood bank director of the transfusing facility of the investigation's results, if applicable.

V. RECORDS

The blood bank of the transfusing facility, as well as the collecting facility, must maintain records of the investigation and of corrective action taken if the investigation reveals a deviation from standard practice.

APPENDICES

Appendix A

Infectious Disease Risks of Blood Transfusion

Primary risks in immunocompetent recipients
- Bacterial contamination (Gram-negative bacteria)
- Hepatitis B
- Hepatitis C
- HIV-1

Additional risks in immunocompromised recipients
- Cytomegalovirus
- Bacterial contamination (Gram-positive bacteria)
- Parvovirus B19
- Epstein-Barr virus

Very rare risks
- Babesiosis (*Babesia microti*)
- Chagas disease (*Trypanosoma cruzi*)
- Malaria (primarily *P. malariae* and *P. falciparum*)
- West Nile virus
- Hepatitis A
- Syphilis (*Treponema pallidum*)
- Variant Creutzfeldt-Jakob disease
- HIV-2
- HTLV-I/II
- Leishmaniasis (visceral *Leishmania tropica* and possibly *L. donovani*)
- Human granulocytic anaplasmosis

Theoretical, but unreported, risks
- Creutzfeldt-Jakob disease
- Human monocytic ehrlichiosis
- Lyme disease (*Borrelia burgdorferi*)
- Toxoplasmosis (*Toxoplasma gondii*)

Table 1. **Estimated residual risks of some transfusion-transmissible viruses***

VIRUS	RECENT RISK ESTIMATE RANGES
HIV-1	**1/1,400,000 – 1/2,400,000 units**
HCV	**1/872,000 – 1/1,700,000 units**
HBV	**1/144,000 – 1/400,000 units**
HTLV	**1/524,000 – 1/2,993,000 units**

*After implementation of HIV/HCV NAT

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Appendix B

List of Reportable Diseases

For the following diseases, report diagnosis in patients and positive test results in donors (even if asymptomatic) to appropriate local health department based on the patient's or donor's county of residence, and to the collecting facility if transmission via transfusion is likely implicated. Current laboratory reporting guidance can be found in the guidance booklet, Laboratory Reporting of Communicable Diseases, available on the Wadsworth Center's website at *www.wadsworth.org/labcert/regaffairs/clinical/commdiseaseguide.pdf*, or by contacting the Wadsworth Center's Clinical Laboratory Evaluation Program at (518) 485-5378 (phone), (518) 485-5414 (fax), or *CLEP@health.state.ny.us* (e-mail). Information is also available on the Bureau of Communicable Disease Contol's website at *www.health.state.ny.us/diseases/communicable/reporting/information.htm*. NYS county health department contact information, by county, is available at *www.health.state.ny.us/nysdoh/lhu/map.htm*.

Amebiasis
Anthrax
Arboviral infection
Babesiosis
Botulism
Brucellosis
Campylobacteriosis
Chancroid
Chlamydia trachomatis infection
Cholera
CJD, vCJD
Cryptosporidiosis
Cyclosporiasis
Diphtheria
E. coli O157:H7 infection
Ehrlichiosis/Anaplasmosis
Encephalitis
Giardiasis
Glanders
Gonococcal infection
Group A streptococcal (invasive)
Group B streptococcal (invasive)
Haemophilus influenzae (invasive)
Hantavirus disease
Hemolytic uremic syndrome
Hepatitis A; B; C
Histoplasmosis
HIV-1 or HIV-2 infection*
Hospital associated infections
Influenza, laboratory-confirmed
Legionellosis
Listeriosis
Lyme disease
Lymphogranuloma venereum
Malaria
Measles
Melioidosis
Meningitis
Meningococcemia
Mumps
Pertussis
Plague
Poliomyelitis
Psittacosis
Q fever
Rabies
Rocky Mountain spotted fever
Rubella
Congenital rubella syndrome
Salmonellosis
Severe Acute Respiratory Syndrome (SARS)
Shigellosis
Smallpox
Staphylococcal enterotoxin B poisoning
Streptococcal infection (invasive)
Syphilis
Tetanus
Toxic shock syndrome
Trichinosis
Tuberculosis, current disease
Tularemia
Typhoid
Vaccinia disease
Viral hemorrhagic fever
West Nile virus infection
Yersiniosis

*** HIV:** In contrast to other reportable agents, HIV is reportable only to the New York State Department of Health (NYSDOH) or the New York City Department of Health and Mental Hygiene (NYCDOHMH). For blood banks outside New York City reporting confirmed positive donor or patient test results, contact the Bureau of HIV/AIDS Epidemiology at the NYSDOH at (518) 474-4284 to obtain the required form and instructions. For blood banks in New York City, contact the HIV Epidemiology and Field Services Program at the NYCDOHMH at (212) 442-3388.

Appendix C

Health Department Programs That Can Assist in Investigations or Receive Reports

Bureau of Communicable Disease Control
New York State Department of Health
Room 651, Corning Tower
Empire State Plaza
Albany, NY 12237
Phone: (518) 473-4439
Fax: (518) 474-7381
E-mail: tdg01@health.state.ny.us
Website: *www.health.state.ny.us/diseases/communicable/reporting/information.htm*

Bureau of HIV/AIDS Epidemiology
(518) 474-4284

A comprehensive list of New York State county health departments and contact information is available at: *www.health.state.ny.us/nysdoh/lhu/map.htm.*

Bureau of Communicable Diseases
New York City Department of Health and Mental Hygiene
Room 331, Box 29
125 Worth Street
New York, NY 10013
Phone: (212) 788-9830
Fax: (212) 788-4268
Website: *www.nyc.gov/html/doh/html/home/home.shtml*

HIV Epidemiology and Field Services Program
(212) 442-3388

Blood and Tissue Resources Program
New York State Department of Health
Wadsworth Center
Empire State Plaza
P.O. Box 509
Albany, NY 12201-0509
Phone: (518) 485-5341
Fax: (518) 485-5342
E-Mail: btraxess@health.state.ny.us
Website: *www.wadsworth.org/labcert/blood_tissue/index.htm*

Appendix D

Additional Diseases/Agents for Which Notification of Collecting Facilities is Recommended

In addition to the agents/diseases listed in Appendix B, the following should be reported to the collecting facilities:

Chagas disease
Cytomegalovirus
Epstein-Barr virus
HTLV
Leishmaniasis
Parvovirus B19
Septicemia
Toxoplasmosis

In addition to infectious diseases, TRALI should be reported to the collecting facility, as described on page 9.

Appendix E

Sample Form for Notification of Collection Facilities

REPORT OF POST-TRANSFUSION ADVERSE EVENT - PART 1

I. HOSPITAL INFORMATION

Date _____

Reporting Facility _____

Blood Bank Director _____

Address _____

Telephone # ( ) Fax # E-mail

II. CLASSIFICATION OF ADVERSE EVENT

ACUTE		**POSSIBLE INFECTIOUS DISEASE/AGENT**	
☐ Bacterial contamination	☐ Hemolytic reaction	☐ HBV	☐ HCV
☐ Graft vs. host disease	☐ Transfusion-related Acute lung injury (TRALI)	☐ HIV-1/HIV-2	☐ HTLV-I/II
☐ Anaphylactic reaction	☐ Other	☐ Other	

III. PATIENT INFORMATION

Hospital code/ID/MR# _____ Age _____ Sex ☐ Male ☐ Female

Country of origin _____ Pregnancy history _____

Previous transfusion ☐ Yes ☐ No Previous transfusion reaction ☐ Yes ☐ No

Type of reaction _____

Primary diagnosis _____

Indications for transfusion _____

Patient's clinical condition at time of transfusion _____

Patient's current status _____

IV. IMPLICATED BLOOD PRODUCTS INFORMATION (Attach additional forms if necessary)			Total # of Units Transfused	
Date & Time of Transfusion	**Hospital #**	**Blood Supplier's #**	**Exp. Date**	**Product Type**

V. CLINICAL DESCRIPTION OF TRANSFUSION-RELATED EVENT
(Use separate sheet of paper, if necessary)

VI. LABORATORY RESULTS RELATED TO THE PATIENT
(Please indicate if blood cultures or serological tests were/are being performed)
(Use separate sheet of paper, if necessary)

VII. LABORATORY RESULTS RELATED TO THE PRODUCTS
(Use separate sheet of paper, if necessary)

VIII. REACTIONS - ADDITIONAL INFORMATION
(Complete all that apply)

a) Could the event have been related to causes other than the implicated transfusion(s) (*e.g.,* septicemia related to primary disease or surgery, anaphylactic shock, volume overload)?

_____

b) If TRALI is suspected, do the CVP readings and chest X-ray results support the diagnosis?

_____

c) What time period elapsed between the issuance of unit(s) by the blood bank and the actual transfusion? _____

d) Was the transfusion discontinued? _____ Were the units returned to the blood bank? _____

e) Did the physical bag and/or contents present any abnormality on visual inspection? _____

_____

f) Color of supernatant of peripheral tubing? _____

g) What time period elapsed between the end of the transfusion and culture of the product?

_____

h) ***Was a clerical check performed?*** _____

IX. Hemolysis

a) Was the patient in surgery when hemolysis was noted?

_____

1. On or after using a bypass pump? _____
2. Cardiac valve replacement? _____

_____

3. Was a blood recovery device used? _____ Was the blood washed? _____ Unwashed? _____

b) Was the blood warmed in some way? _____ Method: _____

c) Was the blood stored in a non-temperature-controlled refrigerator? _____

_____

d) Was the blood transfused under pressure?_____

e) Was the blood given with other fluids or medications? _____ Specify: _____

_____

f) How many of the units were frozen deglycerolized red cells? _____

g) Does the patient have extensive muscle injuries or crush injuries? _____ Specify: _____

_____

h) Is there a history of disease associated with hemolytic anemia? _____

_____

i) Is the patient infected with an organism causing hemolysis? *(e.g., Clostridium, Plasmodium, Babesia)*

_____

_____

X. POSSIBLE TRANSMISSION OF INFECTIOUS DISEASE - ADDITIONAL INFORMATION

a) ***Analyte*** _____ ***Test date*** _____

b) Is it known whether the patient was negative for the implicated infectious agent prior to the transfusion event? _____Has this been documented? _____

c) Could the event be related to causes other than the implicated transfusion(s)? _____

_____

d) Has the patient been assessed for risks of exposure (*e.g.,* IV drug use, tattoos, acupuncture, ear piercing, venereal disease, sexual contact with infected partner, etc.)? _____

e) Has the patient received human-derived clotting factor concentrates in the past? _____

_____

f) Was the patient exposed to blood in the past (*e.g.,* needlestick, spill, etc.)? _____

XI. GENERAL ADDITIONAL INFORMATION - COMMENTS OR FINDINGS

a) Have you sent the units/products to the blood supplier(s) for further testing?

b) Are pre-transfusion and/or post-transfusion specimens from the patient available for studies?

At this stage of the investigation, what is the director's opinion of the relationship between the transfusion(s) and the adverse event?

Person completing this form: _____

Title: _____

Phone: _____

Signature of Blood Bank Director: _____

Date form completed and submitted: _____

Reporting Facility: _____ Date: _____

MR#/Hospital Code/ID: _____

REPORT OF POST-TRANSFUSION ADVERSE EVENT CONTINUATION PAGE