New York State Council on Human Blood and Transfusion Services

GUIDELINES FOR IRRADIATION OF BLOOD AND BLOOD COMPONENTS

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NEW YORK STATE COUNCIL ON HUMAN BLOOD AND TRANSFUSION SERVICES

GUIDELINES FOR IRRADIATION OF BLOOD AND BLOOD COMPONENTS

I. INTRODUCTION

Transfusion-associated graft-vs-host disease (TA-GVHD) is a serious risk for certain severely immunosuppressed or immunodeficient patients. Cellular components for at-risk patients should be irradiated with a minimum of 2,500 cGy (rads) prior to transfusion. Medical evidence suggests that irradiation is not necessary for plasma components that have been frozen, such as frozen plasma (FFP/FP24) and cryoprecipitate. TA-GVHD has been reported in immunocompetent recipients who have received HLA-matched components or blood from a donor who has a similar HLA haplotype, such as a close relative. Scientific evidence suggests that donor lymphocytes of similar HLA type are not perceived as foreign and therefore are not destroyed by the recipient's immune system. Leukoreduction does not adequately reduce the risk of TA-GVHD.

- The risk of developing TA-GVHD depends on a combination of factors, including the number and viability of contaminating lymphocytes in the component, the receptiveness of the recipient's immune status to support engraftment, and the degree of immunologic (HLA) disparity between donor and recipient.

- Acute TA-GVHD is caused by engrafted donor lymphocytes that produce an almost invariably fatal syndrome. Signs or manifestations usually include dermatitis, high fever, hepatitis, severe gastrointestinal symptoms, and bone marrow suppression. However, all of these signs may have various other causes in such patients. In the adult, symptoms arise within four to 30 days after transfusion, and death usually ensues within a month. The median time to onset of symptoms has been reported to be longer in the neonate (28 days) versus adult (8 days) and the time to death also longer for neonates (51 days) versus adults (21 days). Therefore in the neonate presenting symptoms may occur quite a time span from the transfusion episode and TA-GVHD may not be considered in the differential diagnosis. The disease cannot be treated effectively.

- Irradiation with 2,500-3,000 cGy (rads) has not been demonstrated to alter significantly the lifespan or function of platelets or polymorphonuclear leukocytes. Irradiation does reduce red blood cell (RBC) viability, and the expiration date for irradiated RBCs is the usual expiration date of the unit, or 28 days from the date of irradiation, whichever is earlier. There is also a more rapid accumulation of potassium in extracellular fluid of stored red blood cells as a result of membrane damage.

- At present, no data are available to support the concern that administration of irradiated blood components may carry any immediate or long-term risks other than those associated with similar non-irradiated components.

- Irradiated units are not radioactive and require no special handling.

- Irradiated units may be used for patients other than the intended patient. There is no evidence that this practice is harmful. The reduction in shelf life must be observed.

II. RECOMMENDATIONS

Recommendations for irradiation of cellular blood components with a minimum of 2,500 cGy (rads) have been based on increased risk of TA-GVHD in association with the immune status of the recipient (as a result of either an inherent T cell defect of the disease state or acquired defect secondary to therapy) and/or due to the component being transfused.

A. Patients for whom irradiation is recommended include:

1. patients who have had or who may be having a hematopoietic progenitor cell transplant, either allogeneic or autogeneic, including those with aplastic anemia, thalassemia, certain malignancies, and other conditions;

2. patients with a congenital T-cell immunodeficiency syndrome or suspected of having a T-cell deficiency while diagnostic tests are being performed;

3. fetuses receiving intrauterine transfusions, to continue with all subsequent cellular transfusions in these infants post-delivery (either exchange transfusion or routine transfusion);

4. premature infants <1,200 g birthweight;

5. patients with Hodgkin disease;

6. hematologic malignancies undergoing aggressive chemotherapy; and

7. patients treated with purine analogue drugs (fludarabine, cladribine and deoxycoformicin).

   NOTE: *Irradiation of blood components should be considered for patients undergoing intensive chemotherapy or immunosuppressive therapy for oncologic or non-oncologic conditions, including patients who have received a solid organ transplant and are on immunosuppressive therapy.*

B. Components for which irradiation is recommended include:

1. HLA-matched or crossmatch-compatible platelets, even if the patient is immunocompetent;

2. cellular components from blood relatives, even if the patient is immunocompetent; and

   NOTE: *There may also be increased risk of GVHD for patients transfused with blood from other members of a genetically related group.*

3. all granulocyte components, even if the patient is immunocompetent.

C. Products that should NOT be irradiated include:

   1. peripheral blood stem cells;
   2. bone marrow;
   3. donor lymphocytes; and
   4. cord blood

D. Blood banks must have a written policy regarding use of irradiated blood components and a written procedure for irradiation and component issuance. The blood bank should have a process to ensure and document that irradiation is performed whenever indicated. Clinicians should notify their blood bank of any patients who should receive only irradiated cellular blood components to facilitate identification of patients for whom irradiation is indicated. All irradiated components must be appropriately labeled.

E. Equipment for irradiation of blood and blood components must be appropriately licensed and calibrated, with preventive maintenance documented as recommended by the manufacturer.

F. Verification of dose delivery should be performed periodically as specified by the manufacturer.

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