New York State Council on Human Blood and Transfusion Services

GUIDELINES FOR REMOTE BLOOD STORAGE

First Edition
2008

New York State Council on Human Blood and Transfusion Services
Wadsworth Center
New York State Department of Health
Empire State Plaza - P.O. Box 509
Albany, New York 12201-0509

First Edition 2008

Requests for copies of this publication may be directed to:

Blood and Tissue Resources Program
Wadsworth Center
New York State Department of Health
Empire State Plaza
P.O. Box 509
Albany, New York 12201-0509

Telephone: (518) 485-5341
Fax: (518) 485-5342
E-mail: btraxess@health.state.ny.us
Website: *www.wadsworth.org/labcert/blood_tissue*

NEW YORK STATE
COUNCIL ON HUMAN BLOOD AND TRANSFUSION SERVICES

Membership Roster – 2008

Donna Skerrett, M.D., M.S., Chairperson *
Director, Transfusion Medicine and
Cellular Therapy
New York Presbyterian Hospital –
Weill Cornell Medical Center
New York, New York

Joseph Chiofolo, D.O.
Medical Director, Transfusion Service
Winthrop University Hospital
Mineola, New York

William Fricke, M.D.
Director, Transfusion Service
Director, Hematology Laboratory
Rochester General Hospital
Rochester, New York

Alicia E. Gomensoro, M.D.
Director, Blood Bank
Maimonides Medical Center
Brooklyn, New York

Kathleen Grima, M.D.
Director, New York Blood Center
Clinical Services
White Plains, New York

David Huskie, R.N.
Petersburg, New York

Philip L. McCarthy, M.D.
Clinical Blood and Marrow
Transplant Director
Roswell Park Cancer Institute
Buffalo, New York

Lazaro Rosales, M.D.
Director, Blood Bank
SUNY Health Science Center at Syracuse
Syracuse, New York

Richard F. Daines, M.D.
(*Ex-officio*)
Commissioner
New York State Department of Health
Albany, New York

Jeanne V. Linden, M.D., M.P.H.*
Executive Secretary
Director, Blood and Tissue Resources
Wadsworth Center
New York State Department of Health
Albany, New York

* Member, Guideline Working Group

NEW YORK STATE
COUNCIL ON HUMAN BLOOD AND TRANSFUSION SERVICES

BLOOD SERVICES COMMITTEE

Membership Roster – 2008

Joseph Chiofolo, D.O., Chairperson
Medical Director, Transfusion Service
Winthrop University Hospital
Mineola, New York

Visalam Chandrasekaran, M.D.
Director, Medical Education
New York Blood Center – Center East
New York, New York

William Fricke, M.D.
Director, Transfusion Service
Director, Hematology Laboratory
Rochester General Hospital
Rochester, New York

Elizabeth S. Gloster, M.D.*
Blood Bank Director
Kings County Hospital Center and
SUNY Health Science Center at Brooklyn
Brooklyn, New York

Jeanne Linden, M.D., M.P.H.*
Director, Blood and Tissue Resources
Wadsworth Center
New York State Department of Health
Albany, New York

Patricia T. Pisciotto, M.D.
Chief Medical Officer
Northeast Division
American Red Cross
Farmington, Connecticut

Helen Richards, M.D.*
Blood Bank Director
Harlem Hospital
New York, New York

Joan Uehlinger, M.D. †
Director, Blood Bank
Montefiore Medical Center
Bronx, New York

Consultants

Timothy Hilbert, M.D., Ph.D., J.D.
Medical Director, Blood Bank
NYU Langone Medical Center
New York, New York

Pauline James, MBA, MS, MT(ASCP)BB
Blood Bank Manager
Kings County Hospital Center
Brooklyn, New York

Glenda Spencer, MT(ASCP)SBB
Transfusion Service Laboratory Manager
Rochester General Hospital
Rochester, New York

† Guideline Working Group Chairperson

* Member, Guideline Working Group

NEW YORK STATE
COUNCIL ON HUMAN BLOOD AND TRANSFUSION SERVICES

GUIDELINES FOR REMOTE BLOOD STORAGE

INTRODUCTION

The New York State Council on Human Blood and Transfusion Services is charged with setting standards and making recommendations regarding blood banking and transfusion-related services in New York State. This document is intended to assist hospital transfusion service directors and other hospital staff in developing and maintaining programs for blood storage outside the blood bank. Effective design of such a program requires a coordinated effort on the part of all participants, including the transfusion committee and the transfusion service director, to ensure that clinical needs are met through a well-considered plan. Written policies or procedures should specify responsibilities for particular activities. Although other hospital departments may be responsible for some elements of the program, the transfusion service director is ultimately responsible for the overall effectiveness of the program.

Remote blood storage can be accomplished through the use of portable coolers and/or fixed refrigerators. The two approaches share common principles, including maintenance of suitable temperature (achieved by equipment validation and temperature monitoring), proper unit/patient identification, accurate tracking of blood disposition, and adequate training of staff involved in any aspect of the process. Computer-controlled features of automated blood storage and dispensing units may facilitate meeting these goals, but attention to design, implementation, and monitoring is still necessary. Because strategies for meeting these goals differ based on the particular approach, this document consists of two sections: one addressing coolers and the other, fixed refrigerators.

I. COOLERS

A. Cooler Validation

1. A written validation plan should be developed to determine the maximum number of units of each type of component that may be stored and the maximum duration of storage for each type of cooler. It is acceptable to set storage time limits for refrigerated components based on validation for red blood cells (RBCs), the component most sensitive to temperature fluctuations.

2. The maximum acceptable temperature for each type of component should be set (*e.g.,* 6º Celsius for RBCs).

3. The appropriate amount of coolant should be determined for each possible number of components. If the cooler design requires that coolant be added, generally the volume of coolant can be expected to equal approximately the volume of blood component(s).

4. Example procedure summary:
   Load cooler with coolant, blood component(s), and temperature-measuring device. Close the lid. Store at the maximum ambient temperature likely to occur

in the intended storage area. Measure or assess the adequacy of the temperature periodically (such as hourly) to determine the validated time limit for the number of units and amount of coolant tested. One method for measuring the temperature of blood units is to place the sensor end of a thermometer between the nonlabeled sides of two RBC units. Another option for assessing temperature is to use indicators, triggered at an appropriate temperature, applied to blood units.

5. Based on findings, the maximum duration of storage (including transportation time) should be established. The allowed duration of storage may be less than the maximum possible, to allow for minor variations. Applying the minimal time determined for any particular cooler to all coolers of the same type obviates the need to keep track of allowable time limits for individual coolers. Such time limits may vary based on the number of components to be packed. However, compensating for the volume of additional components with an additional volume of coolant, as well as selecting the shortest maximum time determined for any individual cooler, could yield a uniform maximum duration of cooler storage.

6. Once storage limits have been determined for a given type of cooler, a written procedure for qualification of individual coolers should be established, specifying the frequency of qualification, such as prior to initial use, annually, and as needed (*e.g.,* if coolant is observed to thaw prior to maximum storage time), action to be taken if a cooler fails qualification (*e.g.,* a single repeated test or removal from use) and required documentation. All coolers placed into service should carry a unique identification number or code to facilitate record keeping of qualification and performance, as well as tracking of coolers not returned in a timely fashion.

B. Temperature Monitoring

1. A procedure should be established for monitoring temperatures, including responsibility for and frequency of monitoring, as well as acceptable temperature limits.

2. Routine application of temperature indicators to components to be stored is one method for monitoring maintenance of acceptable temperatures. Assessment of coolant status upon return of coolers may be appropriate. Results of monitoring and any action taken in response should be documented.

C. Issuance of Blood for Remote Storage

1. A policy should specify the circumstances under which remote blood storage will be used and the types of blood components eligible for such storage.

2. A written procedure should be established for issuance of blood intended for remote storage, including required documentation.

3. Each cooler should contain blood intended for only one patient to reduce the likelihood of identification error.

4. Coolers should carry an external label or tag indicating the destination location, and the date and time by which blood must be used or the cooler returned to the blood bank for reissuance. When blood is intended for a particular patient, a label with the patient's name or other identifier may reduce the likelihood of administration to the incorrect patient.

5. Consideration should be given to establishing a process for facilitating identification and use of autogeneic units prior to allogeneic units, and short-dated units prior to longer-dated units, when applicable (*e.g.,* "use first" labels).

D. Use of Remotely Stored Blood

1. A written policy should specify identification and tracking procedures for remotely stored blood to ensure that blood components are administered to the correct patient.

2. A written policy should detail the circumstances under which blood may be returned to a cooler and used subsequently.

3. A written procedure should detail responsibility for prompt removal of unneeded units from the patient care area and their return to the blood bank. Ensuring prompt removal is an important safeguard to reduce the likelihood of administration to the incorrect patient.

4. If group O RBCs are to be stored remotely on a routine basis for on-demand emergency use prior to availability of group-specific blood, consideration should be given to establishing a written policy regarding authority to initiate use of such units, responsibility for their removal, the documentation required, a mechanism for notifying the blood bank in a timely fashion once the blood is used, and responsibility for initiating replenishment of the established supply level.

E. Return of Coolers and Unused Blood

1. A written procedure should specify responsibility for return of coolers to the blood bank.

2. The Transfusion Service should establish a policy detailing parameters for acceptability of returned units for reentry into inventory.

3. A written procedure should specify the manner and frequency of cooler cleaning.

F. Reconciliation of Blood Unit Disposition

1. A written procedure should detail procedures for and responsibility for documenting the disposition of blood components stored remotely. A process to monitor compliance should be established and documented.

2. The Transfusion Committee should review the remote blood storage process periodically, as well as the use of units stored remotely.

II. REMOTE REFRIGERATORS

A. Equipment Validation

1. Refrigerators should be designed for blood storage or be validated to maintain acceptable temperatures uniformly to prevent hemolysis due to freezing.

2. Based on established procedures for blood storage refrigerators in the blood bank, a written procedure for validation and preventive maintenance of remote refrigerators should be established. The procedure should specify responsibility for validation and preventive maintenance, and provide for all necessary documentation.

3. The acceptable refrigerator temperature range should be determined (*e.g.,* 1-6º Celsius).

B. Monitoring

1. A procedure should be established for monitoring temperatures of remote refrigerators, including responsibility for and frequency of monitoring.

2. Continuous or periodic recording of temperatures should be performed, consistent with procedures in place for other blood storage refrigerators. Results of monitoring and any action taken in response should be documented.

3. Only blood components should be stored in designated remote refrigerators. A procedure should be established to specify responsibility for monitoring compliance.

C. Issuance of Blood for Remote Storage

1. A policy should specify the circumstances under which remote blood storage will be used and the types of blood components eligible for such storage.

2. A written procedure should be established for issuance of blood intended for remote storage, including required documentation.

3. Responsibility for placing blood in remote refrigerators should be specified.

4. Consideration should be given to establishing a process for facilitating identification and use of autogeneic units prior to allogeneic units, and short-dated units prior to longer-dated units, when applicable (*e.g.,* “use first” labels).

D. Use of Remotely Stored Blood

1. A written policy should specify identification and tracking procedures for remotely stored blood to ensure that blood components are administered to the correct patient.

2. A written policy should detail the circumstances under which blood may be returned to a remote refrigerator and used subsequently.

3. A written procedure should detail responsibility for prompt removal of unneeded units from the patient care area and their return to the blood bank. Ensuring prompt removal is an important safeguard to reduce the likelihood of administration to the incorrect patient.

4. If group O RBCs are to be stored remotely on a routine basis for on-demand emergency use prior to availability of group-specific blood, consideration should be given to establishing a written policy regarding authority to initiate use of such units, responsibility for their removal, the documentation required, a mechanism for notifying the blood bank in a timely fashion once the blood is used, and responsibility for initiating replenishment of the established supply level, ensuring removal of units prior to their expiration, and rotation of units based on expiration date, if such rotation is to be performed.

E. Return of Unused Blood

The Transfusion Service should establish a policy detailing parameters for acceptability of returned units for reentry into inventory.

F. Reconciliation of Blood Unit Disposition

1. A written procedure should detail procedures for and responsibility for documenting the disposition of blood components stored remotely. A process to monitor compliance should be established and documented.

2. The Transfusion Committee should review the remote blood storage process periodically, as well as the use of units stored remotely.