GUIDELINES FOR PHYSICIANS OVERSEEING THERAPEUTIC APERATURESIS

INTRODUCTION

The following document for the establishment of Guidelines for Physicians overseeing Therapeutic Apheresis (TA) is intended to focus attention on two issues important in the quality of care: the recognition that a qualified physician is the best provider of TA services and the importance of the maintenance of TA professional knowledge. These Guidelines were published on September 14, 2005 and will be reviewed by Board of Directors of the American Society for Apheresis (ASFA) every two years thereafter.

THERAPEUTIC APERATURESIS SERVICE

1. Medical Director

A licensed physician, qualified by training and/or by experience, who will be called the Medical Director in these Guidelines, should oversee each TA Service.

Apheresis therapy is best provided by the Medical Director, or a qualified designee, as a consultative service to an individual patient.

To act as the leader of the TA Service and as a consultant to other physicians the Medical Director should possess the following qualifications:

i. detailed knowledge of relevant concepts in immunology and transfusion medicine, and of the basic principles of separation and transfusion of blood components and their physiological renewal after removal or exchange;

ii. operational familiarity with the specific instruments used by the TA Service;

iii. detailed knowledge of the diseases treated by TA and the clinical indications for TA in these diseases; familiarity with current relevant literature (e.g. current edition of ASFA guidelines on the use of TA)

iv. expertise in the different applications of current modalities of apheresis therapy;

v. expertise in the management of adverse effects of TA; and

vi. familiarity with the logistical, financial and personnel issues involved in the management of a TA service.
Physicians who presently function as Directors of TA services and have acquired such expertise by accumulated experience prior to January 1, 2005 are not subject to criteria listed below.

Newly appointed Medical Directors will generally be considered qualified if they:

i. have documented training in apheresis in a relevant accredited post graduate medical education (e.g. transfusion medicine, hematology/oncology, nephrology, clinical pathology); AND/OR
ii. have documented participation in continuing education specifically related to TA offered by American Society for Apheresis, AABB, or equivalent organizations;
iii. AND are board certified or board eligible;
iv. AND have participated in a minimum of 50 TA procedures involving 15 different patients (Note: participation should be documented).

Physicians who are appointed as Medical Directors with no documentation of prior training and/or experience will not be considered qualified under these Guidelines.

Medical Directors of TA Services that serve more than one facility, including mobile TA Services, should be members of the staff at all medical facilities served by their teams in order to provide consultation. However, due to local regulations and credentialing requirements such arrangements may not be always feasible or practical. If the Director of TA service is not credentialed in the facility, a designated physician on staff at the facility (see below for qualified designate) should be responsible for the immediate direct care patient management. In such situations, the Medical Director of TA service should be available for consultation.

2. Qualified Designee Overseeing TA procedures

Designated onsite physicians should receive formal documented training according to written policies/SOP in the TA Service. This structured training should include the observation of a minimum of 10 TA procedures involving 5 different patients for which the designated physician does not have management authority (such as those performed at the Director’s home facility).

Onsite designees Overseeing TA procedures who do not have training and/or experience are not considered qualified under these Guidelines.
3. Additional Support Staff (e.g. Mobile Apheresis Services)

After formulating the apheresis medicine treatment plan with the requesting physician by consultation, the Director, or his/her designee, may delegate authority for immediate oversight and management of the patient to the requesting physician who does not have specialized training in apheresis. Documentation in the Apheresis Medicine record should reflect this clinical delegation. Such activities may include any or all of the following: 1. ordering the procedure including blood components and derivatives, 2. medications, 3. vascular access, 4. laboratory monitoring, and 5. treatment of any adverse reactions. The medical oversight of the procedure remains the responsibility of the requesting physician before, during and after the procedure. Specific procedural oversight must be delegated to a physician (or his/her designee) with privileges at the facility where the procedure is going to take place and who is immediately available on site if not, by telephone, as long as emergency medical services are immediately available on site. If emergency medical services are not immediately available on site, the physician overseeing the procedure must be available on site. The Director, or his/her qualified designee, must also be immediately available by telephone for consultation.

DISCLAIMER

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