

GUIDELINES FOR THERAPEUTIC APHERESIS CLINICAL PRIVILEGES

INTRODUCTION

The following Guidelines for the establishment of therapeutic apheresis (TA) clinical privileges, developed by the Clinical Applications and Standards Committee of the American Society for Apheresis (ASFA), are 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 professional knowledge. These Guidelines were published on September 14, 2005 and will be reviewed by the Board of Directors of ASFA bi-annually thereafter.

THERAPEUTIC APHERESIS SERVICE

1. Medical Director

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

Apheresis therapy is best provided by the 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 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;
- iv. expertise in the different applications of current modalities of apheresis therapy;
- v. expertise in the management of adverse effects of TA;
- vi. familiarity with the logistical, financial and personnel issues involved in the management of a TA service.

Many physicians, presently functioning as Directors, have acquired such expertise by accumulated experience prior to January 1, 2005 and are not subject to criteria listed below.

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Newly appointed 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 obtained a Hemapheresis Practitioner Certificate [HP(ASCP)]; AND/OR
- iii. have documented participation in continuing education specifically related to TA offered by ASFA, AABB, or equivalent organizations;
- iv. AND are board certified or board eligible;
- v. AND have participated in a minimum of 50 TA procedures involving 15 different patients (Note: participation should be documented).

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

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 always be feasible or practical. If the Director of the TA service is not credentialed in the facility, a designated physician on staff at the facility (see below for Qualified Designee description) should be responsible for the immediate patient management responsibilities. In such situations, the Director of the TA service should be available for consultation

2. Qualified Designee

Designated onsite physicians should receive formal documented training according to the written policies in the TA service SOP. 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 responsibility (such as those performed at the Director's home facility).

Onsite designees who do not have training and/or experience are not considered qualified under these Guidelines.

3. Additional Support Staff

The Director may also delegate responsibility for immediate management of adverse effects during TA in a hospital setting to licensed physicians who do not have special training in apheresis if the Director is available by phone and can return to the site in a reasonable period of time, if necessary.

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