

GUIDELINES FOR THERAPEUTIC APHERESIS ALLIED HEALTH STAFF

INTRODUCTION

The following Guidelines for therapeutic apheresis (TA) allied health staff, developed by the Allied Health 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 staff is the best provider of TA services and the importance of the maintenance of professional knowledge. It is also important to note that unlike donor apheresis procedures, TA procedures are performed on patients with underlying disease processes and physiologic abnormalities which have the potential to be exacerbated by the TA procedure. As a result, different educational and training requirements are necessary for the performance of TA procedures compared to donor procedures.

These guidelines were approved by the Board of Directors of ASFA and will be reviewed biennially by the ASFA Board of Directors.

THERAPEUTIC APHERESIS STAFF QUALIFICATIONS

Therapeutic Apheresis (TA) Service staff should consist of medical personnel qualified to perform TA procedures. These individuals will be called Apheresis Specialist in these Guidelines. Allied health staff eligible for consideration for being classified as an Apheresis Specialist should be one of the following*:

- 1) R.N. with current unrestricted license in the state in which they practice TA
- 2) MT (ASCP), BB (ASCP), or SBB (ASCP) certification. If practicing TA in a state that requires licensure of medical technologists, a current unrestricted license in that state is required.
- 3) Baccalaureate degree from a regionally accredited college or university with a combination of 24 semester hours (or 36 quarter hours) of biology and chemistry.
- 4) Allied health staff who has passed the American Society of Clinical Pathology (ASCP) examination for certification as Hemapheresis Practitioners (HP) would be considered qualified.
- 5) Other qualified medical personnel may include but not limited to LPN, MLT (ASCP), PBT (ASCP), AT (ASCP) with current unrestricted license/certification in the state in which they practice TA.

* State or local law, state licensing and credentialing and state nursing or pharmacology practice acts may limit who can perform certain medical procedures or components of procedures. Applicable local and state law must be considered in identifying Apheresis Specialists.

Apheresis Specialist should possess the following qualifications:

- 1) Operational knowledge with the specific instruments used by the TA service through documented training.
- 2) Knowledge of the basic principles of separation.
- 3) Knowledge of transfusion of blood components and the physiological renewal of blood components after removal or exchange.
- 4) Expertise in the management of adverse effects of TA and transfusion.
- 5) Documented formal training to the written SOPs and policies in use by the TA service. This includes orientation training and ongoing training.
- 6) Documented participation in continuing education specifically related to TA as offered by ASFA, AABB or equivalent organizations.
- 7) Documented annual competency in TA.
- 8) May perform TA procedures in more than one suitable medical facility (mobile service).
- 9) Under these guidelines personnel will not be considered qualified if there is no documentation of prior TA training and/or TA experience.

Training

Consistency in the delivery of required training is critical to the quality of the TA service. Each facility shall establish a training program to provide a system for the effective and consistent delivery of training for all staff. Completion of the training program will identify the ability of the staff to function independently, procedures that the individual is qualified to perform, and the instrumentation that may be used by the qualified individual.

The Training Program will:

- 1) Be subject to annual internal quality audits and regulatory/accreditation inspection processes.
- 2) Determine if all or a portion of the training may be omitted for new or transfer employees.
- 3) Document all training events that are missed during a leave of absence and will require completion of such training prior to the employee performing the associated task.
- 4) Require retraining for all tasks when a leave of absence is greater than one year.

After completion of the training program staff will be identified that are qualified to perform TA.

In order to be considered an Apheresis Specialist, the allied health staff will have had to have successfully completed the training program of the apheresis service for which they will be performing TA. This program of training may include training created and administered by the apheresis service, by instrument manufacturers or other vendors, or a combination of the two.

Competency

Competency assessments will verify that employees have and retain the necessary skills, judgment, and knowledge to perform the responsibilities specific to their position. Competency assessments also help to ensure that regulatory and accreditation requirements are met demonstrating the competency of personnel involved with the manufacture of products and/or patient/donor care activities at the six-month and twelve-month points within the first year of employment. It will also be used to build a program within the apheresis service to assess personnel for ongoing competency.

Initially, allied health staff must demonstrate competency at the completion of training. In order to continue be considered an Apheresis Specialist, the allied health staff will have to demonstrate continued competency.

Continuing Education

Knowledge within the field of medicine is continually expanding. This is true with regard to apheresis medicine and the performance of TA. In order to continue to be considered an Apheresis Specialist, the allied health staff will demonstrate continued growth in knowledge through documented participation in TA related education offered by appropriate professional organizations and providers. Each facility will maintain the necessary documentation of annual competency for TA personnel as defined by the facility which shall include at a minimum of three hours of Continuing Education credits (e.g. CEs, CNEs, CEUs, or other appropriate hours according to allied health staff position) related specifically to TA from accredited educational bodies as required by state and federal laws and regulations, and accreditation standards.

Responsibilities

The responsibilities of TA Allied Health staff will generally include, but need not to be limited to, the following:

- 1) Establish an appropriate clinical relationship with the patient to be treated- this could include answering questions and assisting in obtaining informed consent.
- 2) Create and complete a written record of each TA procedure.
- 3) Set up the apheresis instrument and assure proper function prior to beginning TA.
- 4) Assess patient just prior to TA, per SOP, to assure adequate hematocrit, vital signs, and overall clinical stability.
- 5) Establish vascular access and obtain any required samples.
- 6) Carry out requested TA procedure, maintaining fluid balance as ordered.
- 7) Monitor patient clinically, per SOP or special orders, during TA – this should include periodic recording of vital signs and monitoring for adverse effects of TA (e.g. citrate toxicity) and transfusion reactions.
- 8) Monitor instrument function, responding to alarms and maintaining vigilance for malfunctions (i.e. leak, return site hematoma) that may not trigger alarms.
- 9) Take corrective action for detected adverse effects or malfunctions to the extent qualified, or call for supervisor or physician assistance as needed.

- 10) Conclude procedure by returning patient blood (if appropriate), obtaining required samples, recording post- procedure vital signs, and assuring hemostasis at venipuncture site(s) and/ or antisepsis and patency at catheter access site(s).
- 11) Follow manufacturer's guidelines, regulatory/accrediting, agencies, OSHA/ERIKA, fire drills, internal/external audits

DISCLAIMER

It is the intent of the American Society for Apheresis (ASFA), the authors and the editors, to provide current and accurate information to the reader. Furthermore, ASFA, the authors and the editors disclaim any responsibility for any adverse event as a consequence, directly or indirectly, from the application of any suggested treatment, protocol, and/or procedure. Nor will ASFA, the authors or the editors accept responsibility for any undetected errors or misunderstanding of any information contained in this document. The apheresis principles, policies, and procedures described in this document must be prescribed by a qualified physician and administered under the supervision of a qualified physician (as outlined in the ASFA publication Organizational Guidelines For Therapeutic Apheresis Facilities and the ASFA Clinical Applications and Standards Committee) and in accordance with applicable Federal, State, and Local regulatory agency requirements.