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: 1) recognition that specially trained staff provide the best TA services and 2) recognition that continued education maintains 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 alone.

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. Registered Nurse (RN) or Licensed Practical Nurse (LPN) with current, unrestricted license in the state in which they practice TA.
2. Current certification through American Society for Clinical Pathology (ASCP) for Medical Technologist (MT), Technologist in Blood Banking (BB), Specialist in Blood Banking (SBB), Medical Laboratory Technician (MLT), Phlebotomy Technician (PBT), or Apheresis Technician (AT).
   a. Due to varying state requirements, may require a current, unrestricted license.
3. Allied health staff who has passed the ASCP examination for certification as Hemapheresis Practitioners (HP) or Qualification in Apheresis (QIA).

Note: Institutional credentialing policy; state or local statues and/or ordinances; state licensing; and state nursing or pharmacology practice acts may limit who can perform certain medical procedures or components of those procedures. Regulatory guidance must be considered in determining the role and scope of each Apheresis Specialists.

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. This program of training may include training created and administered by the apheresis service and/or educator, by instrument manufacturers or other vendors, or a combination of the two. The Training Program should be subject to annual internal quality audits and regulatory/accreditation inspection processes. If determined any portion of the training may be omitted due to past experience or knowledge, competency (see below) should be assessed and documented. Completion of the training program will help ensure the ability of the staff to function independently and should be assessed by documenting competency (see below).
The training program should include the following:

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, collection or exchange.
4) Knowledge of management for adverse effects of TA including transfusion of blood products for prime and/or replacement fluids.
5) Documented formal training to the written SOPs and policies in use by the TA service.

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 by demonstrating the ability and/or knowledge of personnel.

Initially, allied health staff must demonstrate competency at the completion of training and subsequently, at minimum, annually to be considered an Apheresis Specialist. For any extended leave of absence greater than 1 year, consider retraining or document competency for all tasks. Document all training/competency events that are missed during a leave of absence and require completion prior to the employee performing the associated task.

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, experts in the field, and/or 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.

1) Documented participation in continuing education specifically related to TA as offered internally or by ASFA, AABB or equivalent organizations, including apheresis industry sponsored events offering credits.
   a. For collections: Ongoing training in current GxP, e.g. Good Manufacturing Practices (cGMP)

RESPONSIBILITIES

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

1) Provide physical assessment, knowledge assessment, education and participate in the process of ensuring informed consent prior to procedures.
2) Create and complete a record of each TA procedure.
3) Set up the apheresis instrument and ensure proper function prior to beginning TA.
4) Assess patient just prior to TA, per SOP, to assure criteria for a safe treatment is met: adequate hematocrit, vital signs, and overall clinical stability.
5) Establish vascular access and/or verify adequate central venous catheter. Obtain required samples.
6) Carry out ordered TA procedure, maintaining fluid balance as ordered.
7) Monitor patient clinically, per SOP or special orders, during TA – this should include consistent recording of vital signs and monitoring for adverse effects of TA (e.g. citrate toxicity, transfusion reactions, etc...).
8) Monitor instrument function, responding to alarms and maintaining vigilance for malfunctions (e.g. 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 provider 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 and any regulatory/accrediting agencies. Consider The Joint Commission, Foundations for Accreditation of Cellular Therapy, and Occupational Safety and Health Administration.

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