PUTNAM COUNTY EMERGENCY MEDICAL SERVICES
STANDARD OPERATING GUIDELINES
COOKEVILLE TN (931)528-1555

Guideline name: Prehospital Blood Program	**Guideline Number:**	**Pages**:
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Written/revised by: Joe Smith, Tommy Copeland, Darren Ford		
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Purpose: The purpose of this policy is to establish guidelines and procedures for the safe and effective storage, monitoring, and administration of blood products by Putnam County EMS personnel in the prehospital setting.

Definitions:

1) Blood Assurance-Company that PCEMS partners with to obtain blood products.
2) Delta APRU- Blood management refrigerator that PCEMS currently carries.
3) Bloodhub- Ordering platform of Blood Assurance in which blood products are ordered online.
4) BloodCOMM- Software of Delta used to intake and track all blood products used by PCEMS.
5) PRBC- Packed Red Blood Cells
6) Fluke 62 Max+- Infrared thermometer used by PCEMS to measure temperature of blood products on intake.

Guideline:

7) Blood Assurance Delivery Options
   a) Routine- To be delivered within the next 24 hours
   b) ASAP- To leave Blood Assurance facility within 2 hours
   c) STAT- To leave Blood Assurance facility within 1 hour
   d) Scheduled- Standing orders to be delivered on certain days on certain routes from Blood Assurance facility while also picking up any returns, these orders will populate automatically on a set schedule agreed on between PCEMS and Blood Assurance.
8) Blood Assurance Order Type
   a) Standard- To order blood products
   b) Non-blood- To order thermometer calibration (if needed)
   c) Services- To order expired liquid plasma disposal (if needed)
9) Blood Receiving
   a) PCEMS will receive all blood shipments from Blood Assurance.
   b) PCEMS Officer receiving the blood will check the temperature immediately upon receipt using the Fluke 62 Max+ infrared thermometer.
      i) When using the infrared thermometer to measure blood product temperature, shoot the temperature on the red/yellow of the clear plastic bag. Taking the temperature on the label will always result in a lower and inaccurate reading.
      ii) Blood products with a temperature of <1°C or >10°C will be rejected and immediately returned to Blood Assurance courier. Blood products that are rejected will be recorded on the BloodCOMM software upon the initial inspection. Notify Blood Assurance immediately of any unacceptable units, and to determine if products need returned to Blood Assurance for evaluation.
   c) Blood products may be obtained from Blood Assurance's Cookeville location during their normal business hours on Monday, Wednesday, and Friday.
   d) All blood products will be logged into BloodCOMM using the appropriate procedure.
   e) Blood products will be placed in the Delta APRU on the Captain vehicle
   f) No blood products may be bartered, traded, or exchanged with any other entity outside of Blood Assurance.
10) Blood Storage

a) PCEMS will maintain 2 designated refrigerators to store blood products. The refrigerators will be the Delta APRU. Day-to-day operations of the storage and management of blood products will be the responsibility of the Shift Officer or designee.
b) Blood products will be maintained in the Delta APRU between 1-6°C or as outlined in the agency Blood Services Agreement with Blood Assurance.
c) BloodCOMM software provides continuous monitoring for the APRU refrigerator.
d) Temperature should be documented every 12 hours at a minimum. Daily checks will be performed on the BloodCOMM software.
e) Blood products should be stored in a separate area from temperature-controlled medications

11) Blood Ordering and Exchange
a) Any time blood product is transfused, wasted, destroyed or otherwise known that new blood products are needed the captain, or designee should immediately place an order with Blood Assurance for replacement. Blood ordering will be completed on Blood Assurance's Bloodhub website.
b) PRBC's will be exchanged no less than 21 days prior to expiration date with Blood Assurance. Liquid plasma will not be returned to Blood Assurance for credit but will be sent with Blood Assurance to be destroyed if it is not used by the expiration date.
i) If liquid plasma or PRBC's are to be destroyed, they will be discarded into the biohazard waste shed in an appropriate container. Any discarded or destroyed blood products will be documented in the BloodCOMM software. PRBC's will only be destroyed or discarded if it is rendered unusable due to being out of temperature range more than 30 minutes, are expired, or show signs of contamination/hemolysis. Please contact Blood Assurance prior to discarding PRBC's in case they wish for them to be sent back for testing. Notify Blood Assurance any time PRBC's or liquid plasma are thought to be contaminated or hemolyzed.

12) Blood Product Inventory and Inspection
a) The blood refrigerator will be stocked with 2 units of PRBC and 2 units of liquid plasma.
b) Delta APRU's will be exchanged at the beginning of each work week by the off-going and oncoming captains. A/B shift will be responsible for refrigerator 1 and C/D shift will be responsible for refrigerator 2. Thursday mornings should be the only time blood or plasma is moved from refrigerator to another refrigerator outside of a failure of a refrigerator.
c) All PRBC's and liquid plasma will be visually inspected at each shift change (every 12 hours) to assess for signs of contamination/hemolysis or evidence of damage to the product bags. Visual inspections will be documented on the BloodCOMM software.
i) Evidence of hemolysis, clotting, or contamination. Such evidence includes:
(1) PRBC- abnormal, dark, or purplish color, visible clots, cloudy appearance, bubbling, or foaming.
(2) Plasma- pink-to-red tinted supernatant, yellowing, cloudiness, bubbling, foaming, or milky white hue.
ii) Temperature compliance
(1) All temperatures must be documented in degrees Celsius and not vary more than 1 degree between readings of the infrared/laser thermometer and APRU temperature. All temperatures must be maintained between 1-6°C
d) Any refrigerator temperature spike (too hot or too cold) must be explained (for example – door left open, loading/unloading, performing alarm checks, etc.). This information will be documented on the BloodCOMM software.
e) If blood is found to be out of temperature:
i) If temperature range is exceeded for less than 30 minutes: blood must be transferred to a working APRU until returned to normal temperature range. The blood must regain normal temperature range within 30 minutes. Check for visual signs of hemolysis. Troubleshoot and document reason that blood exceeded temperature range.
ii) If temperature range is exceeded for greater than 30 minutes: discard blood immediately using appropriate biohazard precautions.

13) Delta APRU Validations
a) Validation guides, alarm testing procedures, and checklists can be found on the lieutenant server.
b) Validation types

i) Installation Validation
   (1) Installation validation demonstrates that the equipment is operated in environmental conditions that meet Delta Development's specifications. The installation validation must be completed prior to execution of the operational validation phase. The installation validation of the Delta APRU refrigerators will take place on initial installation and on an annual basis.

ii) Operational Validation
   (1) Operational validation demonstrates that the equipment is functioning within established limits as specified by Delta Development. The operational validation must be completed prior to the performance validation. Operational validation of the Delta APRU refrigerators will take place quarterly.

iii) Remote Monitoring (BloodCOMM) Validation
   (1) Remote monitoring validation demonstrates that the equipment is communicating to Delta Development's remote monitoring software, BloodCOMM. The remote monitoring validation should be completed in conjunction with the performance validation. The remote monitoring validation will take place quarterly.

iv) Performance Validations
   (1) Performance validation demonstrates that the equipment performs as expected for its intended use in the processes established by PCEMS, and that the output meets PCEMS specifications. It evaluates the adequacy of the equipment as used in specific processes that rely on PCEMS personnel, procedures, and supplies, in a normal working environment. Performance validations will take place quarterly.

14) Blood Refrigerator Alarms
   a) If an alarm is received from the APRU, that alarm must be attended to immediately
   b) Alarm validation of blood refrigerators must be performed quarterly
   c) Alarms on blood refrigerator will be set to alarm at less than 1.5°C and greater than 5.5°C, allowing for advanced notification for proper action to be taken prior to stored blood products reaching an undesirable temperature.
      i) If an alarm is activated, silence the alarm and look for obvious alarm causes, e.g. the door is ajar or power is interrupted.
      ii) Alarms should be documented with findings and corrections.
      iii) If alarm cause cannot be determined, remove the blood products from the refrigerator and place them in the other APRU refrigerator.

15) MEQU °M Warmer System
   a) All blood products will be given through the MEQU °M Warmer system. This system will be carried by the captains in their response vehicle along with the blood products.
   b) The MEQU system consists of two components.
      i) The °M Warmer
         (1) The °M Warmer is a single patient use device. The °M Warmer can be used on the patient for up to 72 hours. The same device must not be reused or reattached to other patients. After use, the device must be disposed. Must be disposed of using standard biohazard precautions. There are no maintenance or calibration requirements due to this being a disposable piece of equipment.
      ii) The Power Pack
         (1) When the Power Pack has been used, it must be thoroughly cleaned. Cleaning should be performed immediately after the procedure to prevent soil from drying on the surface. The Power Pack is resistant to the most commonly used hospital cleaners and non-caustic cleaning agents for instruments. There are no maintenance or calibration requirements for the power pack outside of cleaning soil from the surface. If there is a failure of a power pack, it will be replaced.
   c) The power pack will be plugged into the °M Warmer to warm the blood products being transfused. The patient side of the °M warmer will be connected to the iv site and the opposite side of the °M warmer will be connected to the blood tubing.

16) Blood Transfusion
   a) Any time blood products are transfused, the uncrossmatched emergency blood release form must be filled out in its entirety ensuring all appropriate signatures are acquired.
      i) This form is to remain with the patient and the blood products being transfused. If able, a copy of this form should be made and scanned into the ePCR of the patient.

(1) If aeromedical flight is necessary, please take a picture of the uncrossmatched emergency blood release form after the receiving RN/medic has signed and attach that picture to the ePCR.

ii) If a mistake is made on this handwritten form, it must be marked through with a single line and the correction made in the nearest margin available with the date (MM/DD/YYYY) and initials of the crew member making the correction.

b) Prior to transfusing blood products, both crew members must agree that the information below is correct:
   i) Confirm the unit's expiration date
   ii) Confirm that the unit number(s) on the transfusion report and the unit number(s) on the blood product are identical
   iii) Confirm that the unit ABO/Rh on the bag and the transfusion report match and read as either O-negative or O-positive depending on which unit of PRBC's was selected to transfuse. Liquid plasma will be supplied in A or AB depending on availability.
   iv) When patient condition allows, draw sample of patient's blood into purple top tube and label with name, date, and time. This can be completed at any time but preferably prior to administering blood products and will be used by blood bank for purposes of identification of patient's native blood type.

c) Any adverse reactions encountered during the transfusion of blood products to a patient should be treated and information should be relayed promptly to the receiving clinician about details of the adverse reaction and treatments rendered.

d) All infused or infusing blood products bags and tubing must be left with the receiving facility. **DO NOT** discard these prior to arrival at the receiving facility.

e) When blood products are transfused, they must be documented in BloodCOMM.

17) Blood Product Disposal
   a) Any time a blood product is disposed of the following must be documented:
      i) Reason for disposal (expired, damaged, temperature, etc.)
      ii) Disposal method
      iii) Clinician disposing of the blood

18) Training
   a) All providers in charge of transporting blood products will be trained in all systems and procedures pertaining to blood products. This includes, but is not limited to BloodCOMM, Bloodhub, Delta APRU, MEQU °M Warmer System, and any other systems being used by PCEMS in the management of blood products.
      i) Trained providers will receive additional training if operating systems are updated by the manufacturer or changed by PCEMS.
      ii) Providers are prohibited from being charged with delivering blood products until they have been properly trained in all systems.
      iii) The Training Major will be responsible for keeping training records for audit purposes. These records will be stored in the medical records room for no less than 5 years.
         (1) This includes presentations, checklists, training rosters, and any other applicable documentation.
   b) All providers at a Paramedic level licensure or higher will be responsible for completing the required initial and annual training before initiating blood products in the field.
      i) The Training Major will be responsible for keeping training records for audit purposes. These records will be stored in the medical records room for no less than 5 years.
         (1) This includes presentations, checklists, training rosters, and any other applicable documentation.
      ii) Annual training will include:
         (1) Blood administration processes
         (2) Protocols review
         (3) Training on any devices/equipment used during the blood administration process
         (4) Any training deemed necessary by PCEMS or Blood Assurance that is necessary for the continued success of the prehospital blood program.

19) Captain on the Ambulance

a) If a Captain must work the road for coverage, the administrator on call must be notified immediately. The AOC will determine the best method of insuring that the delivery of prehospital blood and plasma during the time that the captain is staffing the ambulance for coverage.

20) Continuous Quality Improvement of Blood Program
   a) The CQI division of PCEMS will do a clinical review of all responses where blood products are administered in the field. This will ensure that all blood transfusions meet established safety, regulatory, and clinical standards.
   b) Medical oversight
      i) The PCEMS Medical Director is responsible for clinical oversight of all prehospital blood transfusions. All transfusions will be reviewed by the CQI division under the Medical Director's authority. Those reviews include:
         (1) Reviewing every transfusion for clinical appropriateness and protocol compliance. This includes review of the ePCR and uncrossmatched blood release form.
         (2) Ensuring documentation meets the standards required by PCEMS, Blood Assurance, and state regulatory agencies.
         (3) Providing follow-up with PCEMS clinicians if issues, deviations, or concerns occur.
      ii) The PCEMS Medical Director is also responsible for approving protocols, revisions, educational updates, and quality improvement items.
   c) Transfusion Acceptability Review
      i) For each transfusion, the CQI division will evaluate:
         (1) Indications for transfusion
         (2) Correct product handling and storage
         (3) Administration technique
         (4) Response to transfusion
         (5) Any adverse transfusion reactions
         (6) Compliance with PCEMS Blood Administration Policy and Protocols
      ii) Findings will be documented and maintained in the CQI review process and maintained in CQI records.
   d) Transfusion Case Reviews
      i) Transfusions will require a case review if there are issues, deviations, or concerns found on the initial chart review. These will be reviewed with the clinicians responsible by the Compliance Major, and other members of the CQI division, PCEMS administration, or Medical Director.
   e) Monitoring Indicators
      i) The following performance indicators will be continuously monitored:
         (1) Number of transfusions performed
         (2) Accuracy of documentation (100% goal)
         (3) Adverse reactions
         (4) Protocol deviations
         (5) Provider competency compliance (training, annual skills review)
   f) Monitoring Program Effectiveness
      i) Outcome Measures
         (1) Effectiveness of the prehospital blood program will be evaluated using:
            (a) Patient physiological response (SBP, HR, mentation, perfusion)
            (b) Hospital feedback when available (e.g., labs, continued blood need, survival to OR/ICU)
               (i) PCEMS will request this information from receiving hospitals, but availability is dependent on hospital cooperation and permitted data-sharing
            (c) Time-to-blood metrics compared to historical non-blood resuscitation cases
            (d) Reduction in crystalloid administration
            (e) Prehospital mortality compared to previous datasets
      ii) Provider Feedback Loop
         (1) Education/Remediation will be based on QA findings and trends
            (a) Led at the direction of PCEMS Medical Director/CQI division
   g) Corrective and Preventative Actions

i) When Corrective and Preventative Actions are needed
   (1) A corrective or preventive action plan may be initiated if:
      (a) Improper storage temperature excursions
      (b) Deviations from medical protocols are identified
      (c) Documentation is incomplete
      (d) A transfusion reaction occurs
      (e) Wastage occurs
      (f) Repeated performance issues arise
ii) Corrective and Preventative Actions may include:
   (1) Additional provider training
   (2) Remediation sessions
   (3) Policy revisions
   (4) Adjustments to equipment or processes

h) Annual Program Review
   i) The Medical Director and PCEMS administration will conduct an annual review of the blood transfusion program.
      (1) Annual review includes changes in:
         (a) Protocols
         (b) Equipment
         (c) Blood Assurance recommendations
      (2) Findings will be documented and used to shape the next year's continuous quality improvement goals.

i) Policy Location
   i) This policy is visible to all employees of PCEMS on the Vairkko employee management system currently used by the organization.