Carter BloodCare

To: Transfusion Services Managers
From: Hospital Relations
Date: February 27, 2025
Re: Deglycerolization of Frozen Red Blood Cells Saline Shortage

Background

The deglycerolization of frozen red blood cells requires 1.6% hypertonic saline (1.6% NaCl.) Due to hurricane damage at the manufacturing plant, there is a national shortage of 1.6% NaCl which may not be resolved until late March 2025. Most of the 1.6% NaCl in the US, including here at Carter BloodCare, expires 02/28/2025.

Please note, this does **not** impact liquid red blood cells and apheresis platelet washing which requires 0.9% saline.

We have been in contact with the Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration and have applied for a variance to use expired 1.6% NaCl. The FDA has stated that if blood establishments wish to temporarily use 1.6% saline beyond the expiration date, the responsible physician should make this determination, and document the reason for the deviation.

Impact to Clients

- Frozen products are typically rare and cannot be obtained easily, and Carter BloodCare's ability to use these rare products for patient care requires the use of 1.6% NaCl. Therefore, expired 1.6% NaCl will be used to deglycerolize frozen red blood cells if no other in-date hypertonic saline supply is available.

- Prior to the release of the thawed blood product, we will obtain a signature from the transfusing provider attesting to the medical necessity of the distributed product; and that the thawed blood product(s) requiring use of expired 1.6% saline are needed with sufficient urgency, and the benefits of the product(s) being transfused outweigh the risk(s) involved

- This planned deviation applies to each deglycerolization procedure that Carter BloodCare will perform using expired hypertonic saline until the shortage is resolved.

Thank you for your patience and understanding.

Questions and Additional Information:

Please contact hospitalrelations@carterbloodcare.org with any questions or concerns.

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STATEMENT OF MEDICAL NECESSITY FOR BLOOD PRODUCT DEVIATION

Date/Tech ID: _____

Patient Name: _____

Patient Identification #: _____

Patient ABO/Rh: _____

Name of Requesting Facility: _____

Product(s) Requested: _____

Reason for Deviation from Standard Operating Procedures:

Due to a national shortage, expired 1.6% saline was used to wash the product

Medical Necessity Documentation: (Completed By Attending Physician or Designee)

Current status of this patient's condition dictates that the blood product(s) listed above is needed with sufficient urgency, and the benefits of the product(s) being transfused outweigh the risk(s) involved. I acknowledge that the product(s) deviate(s) from the regulations required by FDA (21 CFR 606.171 [b]). I understand that close monitoring of this patient for transfusion – associated adverse events should still occur per the transfusing facility's blood administration policy.

_____

Attending Physician or Designee Signature Date

_____

Attending Physician or Designee Printed Name/Credentials

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