Oklahoma Stroke & Neurological Institute @ HILLCREST

February 27, 2018

Jeffrey Goodloe, M.D.
Emergency Medical Services
Medical Control Board
1417 North Lansing Avenue
Tulsa, OK 74106

RE: Medical Control Board Treatment Protocols

Dear Dr. Goodloe,

I am writing this letter on behalf of the Oklahoma Stroke & Neurological Institute at Hillcrest Medical Center. First, we would like to thank you for your participation in our recent survey of our stroke program. The relationship that we share is vital to the success we have obtained over the last three years. DNV has entrusted certified comprehensive stroke centers to educate and advocate EMS services for optimization of stroke services (i.e. tPA and Endovascular Treatment). We would like to take that opportunity to share the findings from the DNV.GL Comprehensive Stroke Center Certification annual review which was held on February 6th and 7th, 2018.

Upon review of the EMS System for Metropolitan Oklahoma City and Tulsa, 2018 Medical Control Board Treatment Protocols, we would greatly appreciate the immediate revision to the post tPA protocol to adhere to the Activase dosing and administration guidelines which specifically refers to the manufacturers dosing notes that **"a flush "i.e. 50cc Normal Saline" be infused post tPA at the same rate, using the same tubing used for the tPA infusion, to flush the line."**

As per DNV's findings in regards to our relationship with EMS, enclosed is the exact wording of their findings which are also attached.

> *During review of the EMS System for Metropolitan Oklahoma City and Tulsa 2018 Medical Control Board treatment Protocols Approved 9/13/17, Effective 1/15/18, replaces all prior versions Protocol 14I: page 14I.3 states:*
>
> *7. Infuse all Alteplase from tubing by infusing saline through same tubing set following Alteplase dose.*
>
> - *When bottle appears empty, there is still some Alteplase left in the tubing which must be infused.*
> - *Remove the IV tubing connector from the bottle and attach it to a newly spiked bag of normal saline and re-start infusion, TKO.*

Upon discuss with the EMS staff and stroke leadership there was not prior recognition of the incorrect flush infusion rate (at TKO {to keep vein open} rate) as stated in the above protocol. The hospital did not have documentation of the recognition of this error prior to the surveyors' review. EMS education to the providers will be occurring in the next several weeks with no stated plan to immediately correct this medication administration error, thus they will be teaching the incorrect flush process to the EMS providers.

We look forward to facilitating an immediate change to your current protocol. Our organization is willing to discuss this issue in person at a time of mutual convenience if need be. Once again thank you for being partners in our stroke program.

Sincerely,

Andre Fredieu, M.D.
Medical Director
Oklahoma Stroke & Neurological Institute

Jeffrey Dixon, M.D.
Medical Director
Emergency Department

Enclosure: DNV Report

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Certification Program Survey Report and Corrective Action Plan Submittal Form

DNV·GL

Organization: Hillcrest Medical Center - Tulsa, OK

NC Number	Process or Standard	Non-conformance category	DNV GL requirement(s) and other applicable standard(s)
NC-2-1	**Emergency Department** Protocols	☐ NC-1 Condition-level ☐ NC-1 ☑ NC-2 ☐ OFI	**PC.4 (CR.1) / (CR.2)**

Requirement (Description):

PC.4 EMERGENCY DEPARTMENT (ED)

CR.1 The CSC is responsible for developing and maintaining efficient pathways, protocols and processes to rapidly identify, evaluate and treat potential stroke patients.

CR.2 Emergency department practitioners and staff can demonstrate knowledge and understanding of the stroke protocol in place, including effective communication with EMS personnel, notification of the stroke team and initiation of the stroke protocol concurrent with the ED evaluation and management.

Note: Manufacturer's dosing information notes that a flush "eg 50cc Normal Saline" be infused post tPA at the same rate, using the same tubing used for the tPA infusion, to flush the line.

FLUSH IV TUBING

To ensure the full dose is delivered:

1. *Spike a small bag (e.g., 50 mL) of 0.9% Sodium Chloride, USP, with end of the Activase infusion set when the Activase vial is empty. The infusion should continue at the same rate* https://www.activase.com/iscstroke/dosing-and-administration/activase-administration

2. Activase [prescribing information] Activase (Alteplase) Dosing and Administration

The requirement was NOT MET as evidenced by the following:

During review of the *EMS System for Metropolitan Oklahoma City and Tulsa 2018 Medical Control Board Treatment Protocols Approved 9/13/17, Effective 1/15/18, replaces all prior versions Protocol 14I: page 14I.3 states:*
7. Infuse all Alteplase from tubing by infusing saline through same tubing set following Alteplase dose.
- *When bottle appears empty, there is still some Alteplase left in the tubing which must be infused.*
- *Remove the IV tubing connector from the bottle and attach it to a newly spiked bag of normal saline and re-start infusion, TKO.*

Upon discussion with the EMS staff and stroke leadership there was not prior recognition of the incorrect flush infusion rate (at TKO{to keep vein open} rate) as stated in the above protocol. The hospital did not have documentation of the recognition of this error prior to the surveyors' review. EMS education to the providers will be occurring in the next several weeks with no stated plan to immediately correct this medication administration error, thus they will be teaching the incorrect flush process to the EMS providers.

Corrective Action Plan due date: March 1, 2018

ORGANIZATION RESPONSE

Cause that led to the nonconformity:

Organization Corrective Action Plan (CAP):