

EMERGENCY MEDICAL SERVICES AUTHORITY

10901 GOLD CENTER DR., SUITE 400
RANCHO CORDOVA, CA 95670
(916) 322-4336 FAX (916) 324-2875



DATE: March 19, 2014

TO: Commission on EMS

FROM: Howard Backer, MD, MPH, FACEP
Director

PREPARED BY: Sean Trask, Chief
EMS Personnel Division

SUBJECT: Trial Studies

RECOMMENDED ACTION:

Receive information regarding the status of current trial studies

FISCAL IMPACT:

No fiscal impact.

DISCUSSION:**Coastal Valleys EMS Agency**

On August 15, 2012, the EMS Authority received a trial study request from the Coastal Valleys EMS Agency to study the effectiveness of the Laryngeal Mask Airway-Supreme for use by flight paramedics with REACH Air Medical Services (REACH). As originally designed, this trial study would involve nine local EMS agency (LEMSA) jurisdictions with REACH operations. The EMS Authority requested that each participating LEMSA submit a protocol in their respective protocol format to the EMS Authority before starting the trial study in their jurisdiction. This is intended to protect the paramedics, the providers, the LEMSA, and the public in the event a particular case is reviewed. The EMS Authority approved the request to start the trial study in those jurisdictions where protocols were submitted and approved by the EMS Authority as opposed to waiting for all nine LEMSAs to submit their protocols. To date, the trial study has started in the Coastal Valleys, Sierra-Sacramento Valley, and Inland Counties EMS Regions. The remaining LEMSAs, Contra Costa County, Imperial County, Riverside County, Sacramento County, San Joaquin County, and North Coast EMS Agencies have not submitted local policies and therefore are not participating in this trial study. The 18-month report is due to the EMS Authority on June 1, 2015.

San Diego EMS Agency

On June 22, 2011, the EMS Authority approved a trial study for point of service testing of lactate by paramedics in San Diego County. This prehospital trial study is part of the Resuscitation Outcomes Consortium study of prehospital lactate for the identification of

shock in trauma patients that are routinely transported to two participating hospitals: UC San Diego Medical Center and Scripps Mercy Hospital. The first part of the trial study will be for paramedics to collect blood obtained from the stylet of the IV start on patients with major trauma for a point of care test. The second part of the trial study is that the receiving hospital will perform a second point of care blood test. Inclusion criteria includes patients meeting trauma triage criteria, systolic blood pressure ≤ 100 , placement of an IV, transported to a Level I or II Trauma Center or died in the field or en route (with systolic blood pressure ≤ 100 and after placement of an IV).

The purpose of this trial study is to determine if the addition of point-of-care lactate testing predicts the need for resuscitative care or death. This trial study was initiated on June 27, 2012 and stopped enrolling patients August 30, 2012. The 18-month report is due to the EMS Authority on August 1, 2013. Since this is a multicenter study, the data is still being analyzed by the University of Washington and the results will be released at a later date.

At the time this trial study was submitted for approval, point of care testing was not clearly defined in the paramedic scope of practice. Point of care testing has since been added to the basic paramedic scope in the revised Paramedic Regulations that became effective April 1, 2013, therefore no action from the Commission is necessary.