

Request for approval of a trial study

This document follows Form #EMSA-0391

**EMS Medical Director:** Dr. Mark Luoto

**Local EMS Agency:** Coastal Valleys EMS Agency

**Proposed procedure:** Insertion of the LMA Supreme for airway management by flight paramedics.

**1) Description of procedure:** Insertion of the LMA Supreme supraglottic airway device for airway management. The insertion of any supraglottic airway whether for primary or secondary airway management is a blind technique. Confirmation is achieved utilizing pulse oximetry and capnometry.

**2) Description of medical conditions for which it will be utilized:** Airway management is of paramount importance in EMS. Patients experience the need for active management of their airways and support of their respiratory status for many medical and trauma conditions. Patients in this study will be experiencing respiratory failure or impending respiratory failure. For this study (REACH Air Medical Services ) the majority of these patients would be a failed RSI (rapid sequence intubation) where the providers were not able to get the patient intubated with an endotracheal tube. There are instances where they (the flight paramedic or nurse) would decide that the LMA would be the first choice. The rest of the patients would be resuscitated from cardiac arrest or near cardiac arrest for whom RSI is not indicated.

**3) Alternatives:** The gold standard for airway management continues to be endotracheal intubation. This is the primary method to be utilized in this study. Again there are many times when it is not possible to endotracheal intubate patients. Bag-Valve-Mask ventilation (BVM) is an acceptable alternative for short transports. BVM ventilation however, is not a feasible alternative for the majority of patients with longer transport times. Other supraglottic airway devices are utilized currently, but they are not utilized by our air medical services.

**4) Estimated frequency of use:** For the study (REACH Air Medical Services) in California about 2-5 times per month

**5) Other factors or exceptional circumstances:** Used as first choice airway at crew discretion.

**6) Supporting documentation:** Attached to this document via e mail is supporting documentation.

This includes articles and studies on, ease of insertion, use during CPR, use in the field, ability to do long term ventilation, use for difficult airways, effect on cerebral blood flow (LMA supreme has the least deleterious effect of all of the supra glottic devices), use for

RSA as opposed to RSI, how to select the correct size, ability to protect against aspiration ( LMA Supreme was slightly better protection than the other supra glottic airways).

**7) Recommended policies:** please see our LMA policy attached

- a) **Use:** as per the policy attached
- b) **Medical control:** Off line via our protocols and those of the LEMSA(see attached policy for Coastal Valleys Destination procedure). On line for scene calls is the base hospital if needed. For Inter Facility transfers, the sending and receiving physician. In the absence of all of the above REACH has an on call medical director 24/7/365 available to our crews.
- c) **Treatment protocol:** Attached
- d) **Quality assurance:** REACH Air Medical Services has a very robust chart review and CQI program. Most flights and clinical care are reviewed by one of our clinical managers within 24-48 hours. There are clinical criteria for medical director review and this is also done within 24-48 hours. There is also a mandatory call to the medical director on call for any patient deterioration. We also have the ability in our charting system to mandate MD review on specific criteria, we will add LMA-S use to this list. This will insure timely review of all cases involving the LMA Supreme. In addition, two of the investigators will perform CQI of the cases each month (Drs. Luoto and Rudnick). Any issues or concerns will be handled immediately and processed thru the normal CQI process at Coastal Valleys EMS agency procedures.

**8.Description of training and competency:** Each crew member will receive first time training from a video provided by LMA and competency testing with the device on a simulator. They then receive annual training in our clinical skills lab on simulation mannequins. There are also monthly airway drills that may involve the LMA Supreme.

**9) Copy of local EMS system evaluation and QI program plan:** Please find attached a copy of Coastal Valleys EMS agency policies. For cases that require further evaluation the LEMSA Medical Director for the affected area will be notified and given the opportunity to have the case put into their local CQI process if requested. .

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Assessment of Ease of Insertion and Success in use of the LMA-S by Paramedics in the Helicopter EMS (HEMS) environment.

## Introduction:

Emergent airway management of air medical patients is a time- and skill-critical intervention. The use of adjunct devices to assist in successful ventilation and oxygenation of patients is of the utmost importance. REACH Air Medical Services utilizes a nurse/paramedic patient care team, both of whom have received training in emergent advanced airway management. Our airway management tools include RSI (nurse administered medications) with endotracheal intubation; with both team members able to perform the physical intubation as well as back up supra-glottic airway (King Airway). Additionally our nurse crews are trained in surgical cricothyrotomy if endotracheal intubation or supra-glottic airway placement are not successful.

REACH has recently changed from the King Airway to the LMA-Supreme (LMA-S). This decision was based on new features of the LMA-S designed to improve the ease of insertion in the pre-hospital setting, and minimize the risk of aspiration of stomach contents. While King Airway insertion was allowed by state regulation by both our nurse and paramedic, the LMA-S is currently not part of the State of California Paramedic Scope of Practice. Since the introduction of the LMA-S, an increasing body of research literature and experience has shown the LMA-S to be easier to use, quicker to insert, and superiorly effective in protection from aspiration to other supra-glottic devices. This change by REACH from the King to the LMA-S now presents an opportunity to assist the State of California with evaluation of paramedic use of the device and consideration of inclusion to the paramedic scope of practice.

Methods: Data will be collected from the electronic chart created routinely by REACH.

## Study Design:

This trial is a prospective, non-randomized, non-blinded study to evaluate the success in use of the LMA-S for advanced airway management by flight paramedics at REACH. This study is not a change from current care of the patient (as the flight nurse is currently inserting the LMA-S).

## Setting:

REACH Air Medical Services is a privately owned air ambulance that has been serving California for 25 years. The medical crew is comprised of a State of California licensed nurse and paramedic. REACH currently has bases of operation in the following locations in California;

Santa Rosa, Sonoma County

Lakeport, Lake County

Redding, Shasta County

Marysville, Yuba County

Sacramento (fixed wing aircraft) Sacramento County

Stockton, San Joaquin County

Concord, Contra Costa County

Thermal, Riverside County

Upland, San Bernardino County

El-Centro, Imperial County.

Each of these bases averages two flights per day for an average of 20 patient contacts per 24 hour period or 7,300 patient contacts per year. Of these, approximately two percent are in need of advanced airway management.

**Duration:**

The duration of the study will be 18 months

There will be periodic reviews every 6 months

Start date: TBD

End Date: TBD

**Inclusion Criteria:**

All patient greater than or equal to 1kg who need advanced airway management and where endotracheal intubation is not possible or fails. It is estimated 95% of the case this will be after a failed endotracheal intubation attempt. It is estimated less than 5% of the cases the LMA-S may be the first advanced airway used based on patient condition and air medical team judgment.

**Exclusion Criteria:**

Patients with an intact gag reflex and patients with severe caustic substance ingestion.

**Training:**

Each crew member will receive initial training from a video provided by LMA (<http://www.lmana.com/pwpcontrol.php?pwpID=6347>) and competency testing with the device on a mannequin or human patient simulator. They also receive ongoing training during our semi-annual clinical training labs as well as monthly airway drills (dependent on airway drill scenario).

**Protocol:**

See attached reference document.

**Data Collection:**

The following information will be obtained for each use of the LMA-S

-Age

-Sex

-Trauma or Medical patient

-estimated weight

-Date

-Flight number

-Indication for use

    Primary- Why endotracheal intubation was not done first

    Secondary- What were the reasons for unsuccessful endotracheal intubation( poor view, Cormack-Lehane scale, foreign material, Other)

-Blood pressure before LMA insertion

- Blood pressure after LMA insertion
- Heart rate before LMA insertion
- Heart rate after LMA insertion
- Respiratory rate before LMA insertion
- Respiratory rate after LMA insertion
- Pulse oximetry before LMA insertion
- Pulse oximetry after LMA insertion
- ETCO2 after LMA insertion
- Ease of insertion on a 1-5 Likert scale 1 being very easy and 5 being very difficult
- Success yes or no (as defined by confirmation methods)
- Number of attempts needed to insert the LMA-S (attempt is defined as passing any part of the LMA-S beyond the teeth)
- Time to complete insertion in seconds
- Any difficulties encountered (Narrative comment by the paramedic)
- If the paramedic was unable to get insert the LMA-S was anyone else later successful?
- if not successful with LMA insertion overall what was the final airway out come (Return to BVM, surgical?)

Results:

Pending.

Discussion:

Pending study

Limitations

Pending

Conclusion:

Pending.

References: