PENNSYLVANIA EMERGENCY HEALTH SERVICES COUNCIL

Your Voice In EMS

RECOMMENDATION FOR CONSIDERATION

Board Meeting Date: September 21, 2016

Subject: Addition of i-gel to EMS Scope of Practice and Required Equipment List

VTR#: 0916-01 Committee/Task Force: Medical Advisory

☒Recommended Goal ☐Recommended Policy Change ☐Other:

Recommendation:

The Department of Health should amend the scope of practice for providers at or above the AEMT level to include the use of the i-gel as an alternative/rescue ALS airway. Furthermore, the Department of Health should amend the list of minimum required equipment and supplies for agencies at or above the IALS level to include the i-gel as an option for the alternative/rescue ALS airway device requirement.

Rationale [Background]:

The i-gel, manufactured by Intersurgical LTD, is an FDA approved pharyngeal airway control device designed for use in a variety of patient care environments, including the emergency care setting. At first glance, the i-gel has a slight resemblance to the laryngeal mask airway, however the i-gel has no inflatable cuff, which makes insertion and positioning much easier. The device is also available in pediatric, infant and neonatal sizes, which provides an advanced airway management option other than traditional endotracheal intubation.

A Department-approved pilot program using the i-gel was conducted by the Second Alarmers Rescue Squad (SARS) with support from the Montgomery County EMS Office. During the pilot, 78 adult placement attempts were made on 70 patients resulting in 67 successful insertions (96% successful placement rate). There was no evidence of insertion associated airway trauma or other adverse effects noted during the pilot. The device was able to be successfully placed in cardiac arrest situations without interruption of chest compressions. SARS providers participating in the pilot indicated a high degree of satisfaction with the device.

In addition to the recommendations made above, SARS and the Montgomery County EMS Office request the Department of Health grant permission for SARS to continue to use the i-gel, guided by the pilot program criteria, until such a time when the device is added to the EMS provider scope of practice and list of required minimum equipment and supplies documents.

Medical Review [Concerns]:

This recommendation has the unanimous support of the PEHSC medical advisory committee.

Fiscal Concerns:

This device would be an additional option for agencies at or above the IALS level to consider when complying with the requirement for an alternative/rescue ALS airway. The EMS agency, in consultation with their medical director, should consider cost when considering any new device purchase. Information provided from the pilot project regarding comparative device cost revealed:

- Combitube: $63.99 each
- King LTS-D: $48.99 each
- I-GEL: $20.00 to $32.79 each (size dependent)

Educational Concerns:

The EMS medical director is responsible for educating their providers on the proper use of any approved medical device prior to its use. With regard to i-gel, the Montgomery County Office of EMS has offered to develop a provider education program in addition to other available education resources.

Plan of Implementation:

Upon acceptance of this recommendation, the Department of Health should:

1. Update the EMS scope of practice for providers at or above the AEMT level to include the i-gel.
2. Update the list of required equipment and supplies for agencies at or above the IALS level to include the i-gel as an option for the alternative/rescue airway device requirement.
3. Grant SARS permission to continue use of the i-gel, guided by the pilot program criteria, until such a time when the device is added to the EMS provider scope of practice and list of required minimum equipment and supplies.

The PEHSC Committee/Task Force offers consultation to the Department in regard to the content of this Vote to Recommend (VTR) and its attached documents. The PEHSC Committee/Task Force specifically offers staff or member support to participate in Department deliberations regarding this recommendation in an effort to convey committee/task force discussions.

Board Meeting Comments/Concerns:

None.

Signed:_____ Date_____

President

For PEHSC Use Only – PA Department of Health Response

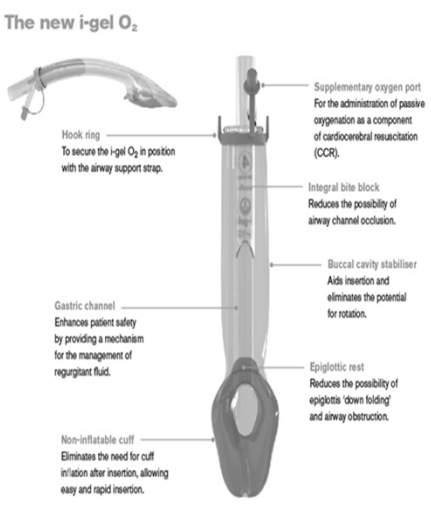
Accept:____ Table:____ Modify:____ Reject:____

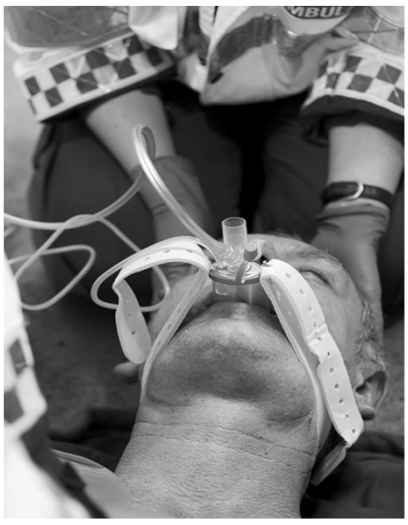
Comments:

Date of Department Response:_____

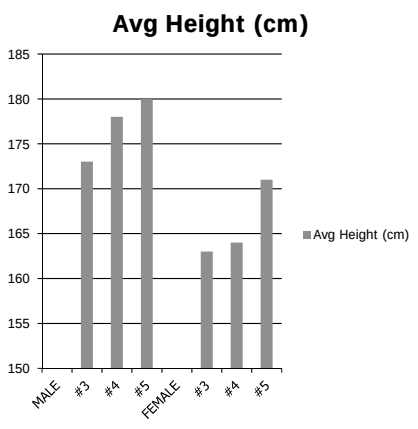
i-gel Study

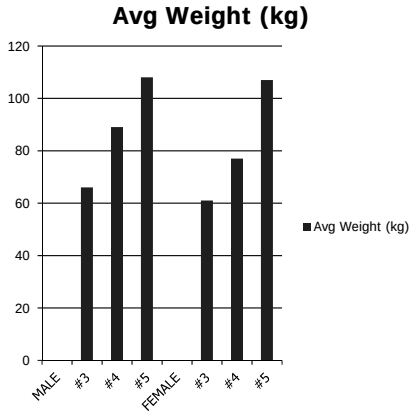
i-gel





Size Matters





Weight based size selection for i-gel use in study confirmed to be independent from height of patient

Trial Data Collection Tool

SECOND ALARMER'S RESCUE SQUAD / PENNSYLVANIA DEPARTMENT OF HEALTH
i-gel® AIRWAY TRIAL UTILIZATION REPORT

Date of Service:	**PSAP Number:**
Provider:	**Unit #:**
Estimated Weight: lbs.	**Estimated Height:** ft, In
<< Pre-Insertion Status >>	**<< Post-Insertion Status >>**
☐ Normal Respirations / Eupnea ☐ Abnormal	☐ Normal Respirations / Eupnea ☐ Abnormal
Tidal Volume:	**Tidal Volume:**
☐ Optimal ☐ Sub-Optimal	☐ Optimal ☐ Sub-Optimal
Rate:	**Rate:**
☐ Fast ☐ Normal ☐ Slow ☐ Apnea	☐ Fast ☐ Normal ☐ Slow ☐ Apnea
Fluid In Airway?	**Fluid In Airway?**
☐ None ☐ Blood ☐ Vomit ☐ Emesis	☐ None ☐ Blood ☐ Vomit ☐ Emesis
Upper Airway Trauma?	**Upper Airway Trauma?**
☐ None ☐ Penetrating ☐ Burns ☐ Edema	☐ None ☐ Penetrating ☐ Burns ☐ Edema
Pre-Insertion GCS:	Post-Insertion GCS:
Pre-Insertion SpO_2: Pre-Insertion $ETCO_2$:	Post-Insertion SpO_2: Post-Insertion $ETCO_2$:
<< Pre-Insertion Treatment >>	**<< Post-Insertion Treatment >>**
Oxygenation:	Passive: ☐ No O_2 ☐ O_2 Flow Rate: lpm
☐ None ☐ NC ☐ NRB ☐ BVM	Bag/Valve: ☐ No O_2 ☐ O_2 Flow Rate: lpm
Suction Information	AutoVent: Rate: Volume: Adult Ped
☐ Catheter Size: fr	**Suction Information**
☐ Yankauer	Visualization Of Fluid In Gastric Channel? ☐ Yes ☐ No
Sedation Medication:	☐ Suctioned Via Gastric Channel ☐ Suctioned Via Airway Channel
☐ None ☐ Valium ☐ Versed ☐ Ketamine	**Sedation Medication:**
<< i-gel® Insertion Information >>	☐ None ☐ Valium ☐ Versed ☐ Ketamine
Placement Successful? ☐ Yes ☐ No	Other Meds Via i-gel®:
Total Number Of Attempts:	
Estimated Total Time For Placement: Seconds	
Were Different Sizes Used? ☐ Yes ☐ No	
Attempt Sequence:	
Initial Attempt Size: ☐ 3 ☐ 4 ☐ 5	
Intermediate Attempt Sizes: ☐ N/A ☐ 3 ☐ 4 ☐ 5	
Final Size: ☐ 3 ☐ 4 ☐ 5	
i-gel® Secured: ☐ Factory Strap ☐ Tape ☐ Not Secured	
Misc. Comments:	

Study Demographics

- 121 Total Patients
  - 78 Male
    - Average Age: 67 (Min: 21 / Max: 98)
    - Average Weight: 93kg (Min: 48kg / Max: 168kg)
  - 43 Female
    - Average Age: 73 (Min: 24 / Max: 96)
    - Average Weight: 74kg (Min: 40kg / Max: 170kg)

ETT vs. i-gel at Second Alarmer's Rescue Squad

ETT success rate during the i-gel study:

During the study 63 attempts were performed on 54 patients:

39 successful intubations. (72% Successful placement rate)

- Of the 39 Successful intubations
  - 5 Patients required 2nd attempt for successful intubation
  - 4 Patients had 2 attempts without success, and were subsequently managed successfully with an i-gel

i-gel success rate during study:

During the study 78 attempts on 70 patients resulting in 67 successful insertions. (96% Successful placement rate)

- Of 67 Successful insertions, 8 required a 2nd attempt. (resizing)
- The 3 unsuccessful cases were also not able to be intubated in the field and required the patient to be managed by alternative means.

(initial 12 month period of the study used as a snapshot)

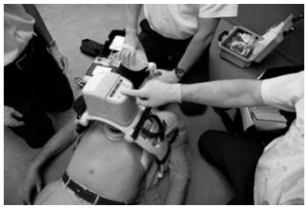
Additional data

Airway trauma from the device?

- There were NO incidence of trauma or adverse effects to patient's airways caused by the i-gel noted during the study

Building on the new CPR Concept: continuous, high quality, uninterrupted compressions

- Lucas device applied immediately delivering ***continuous*** uninterrupted compressions
- Establish a humeral head IO for medications
- Size and place an i-gel airway with passive O_2 at 8 lpm (50% FiO_2) without interruption of compressions
- Move to ambulance, place on ventilator and monitor $ETCO_2$



Resuscitation

High quality CPR / chest compressions.

- Unlike traditional intubation, it was observed that the i-gel could be inserted concurrently with chest compressions in progress and that there were no interruptions due to airway management.

Promising Resuscitation Rates Based on CARES data

2015 overall ROSC rates

- Second Alarmer's: 33.9%
  - 35 out of 103 patients
- MontCo Region: 28%
- PA State: 28%
- National: 32.9%

It is understood that data was not collected to directly link the use of the i-gel with improved ROSC rates. However, we believe the CARES data shows that the use of the i-gel is not detrimental to ROSC rates.

Challenges

Abnormal airway anatomy

- Patients with surgically altered airways (example: old/closed tracheal stoma)
  - Obtaining an initial seal and maintaining a seal due to altered anatomical structures.
  - One patient where it was not possible to obtain a seal, was also not able to be intubated in the field and proved to be a challenge for the anesthesiologist in the hospital using fiber optic techniques.
- The manufacturer was contacted and considers the following as potential contraindications for use of the i-gel:
  - Trismus (clenched jaw), limited mouth opening, pharyngo-perilaryngeal abscess, trauma or mass
  - While not specifically listed they believe that a surgically altered airway would fit under the 'trauma or mass' classification

Modification During Trial

Securing the i-gel adequately was identified as a issue early on in the trial

- Identified as insufficient pressure maintained after placement and/or i-gel migrating up the airway – both due to limitations of original factory retaining strap
- Discussed the issue with manufacturer and found simple solution – add more holes to strap – which was then implemented by the manufacturer

Discussion Points

Patient Safety

- From our data, and experience, the i-gel is safer for pre-hospital use than traditional intubation, King LT/LTS or Combitube:
  - If ETT placement in esophagus not recognized, the patient is not being ventilated
  - With the Combitube, if the wrong tube is used, the patient is not being ventilated
  - King LT airway devices have the potential to be inserted at improper depths (too shallow, too deep, or even in the trachea). Any of these situations would prevent ventilation of the patient
  - ***The i-gel cannot be inserted in the esophagus (too deep). Additionally. if the i-gel is not fully seated (too shallow), the patient can still be ventilated and receive passive oxygen as if they had an oral pharyngeal airway in place***
  - There is a potential for the King devices to rotate in the upper airway and occlude the ventilation ports
  - ***The i-gel buccal cavity stabilizer prevents the device from rotating in the upper airway***

Discussion Points

Time needed for placement

- Providers reported an average placement and oxygenating time of 15-30 seconds during the study. We feel that the i-gel placement is considerably faster then endotracheal intubation.
  - Time started at the moment the device package was opened.
  - Because we do not use the King airways, we were unable to determine if there was a significant difference in placement time between the King and i-gel. However, current literature/studies show that the i-gel is slightly faster due to the lack of need for inflation.

Financial Impact

- Retail cost:
  - Combitube: $63.99 each
  - King LTS-D: $48.99 each
  - i-gel O_2 Resus Pack: $32.79 each
    - 51% less than the Combitube
    - 33% less than the King LTS-D

With the financial challenges that EMS services face these days, cost savings is a consideration.

Conclusion

- There will always be a need for rapid control of the airway in emergent situations. i-gel placement is faster than intubation and has shown an improved successful placement rate.
- There is still a place for intubation in the ALS skill set, however, it should probably be utilized with consideration of i-gel capabilities