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**FOR: JONATHAN WOODSON, M.D., ASSISTANT SECRETARY OF DEFENSE
(HEALTH AFFAIRS)**

SUBJECT: Supraglottic Airway Use in Tactical Evacuation Care 2012-06

EXECUTIVE SUMMARY

The Tactical Combat Casualty Care (TCCC) Guidelines for Tactical Evacuation (TACEVAC) Care outline stepped airway management interventions for a casualty with airway obstruction or impending airway obstruction. These include the chin lift/jaw thrust maneuver, nasopharyngeal airway and recovery position as first-line interventions. Should these prove unsuccessful, the Guidelines recommend the laryngeal mask airway (LMA) or Combitube™ (Combitube) device for supraglottic airway (SGA) interventions, endotracheal intubation or surgical cricothyroidotomy. Many new SGA devices have emerged since the development of the TCCC Guidelines. Evidence is inconclusive as to whether any one device is superior over another. Patient safety and provider competency literature suggests that provider experience may be a better indicator of safety and efficacy than individual device capabilities. Therefore, the Defense Health Board (DHB) recommends that the specific devices referenced in the TCCC Guidelines for SGA interventions during TACEVAC Care be removed.

INTRODUCTION

Charge

The TCCC Guidelines are a set of trauma care instructions customized for use on the battlefield during tactical field care and TACEVAC (**Attachment A**). The Committee on TCCC (CoTCCC), a Work Group of the DHB Trauma and Injury Subcommittee, performs a quarterly review of current evidence, emerging data and feedback from the field to ensure the TCCC Guidelines reflect evolving best practices.

The TCCC Guidelines provide a spectrum of airway management interventions for a casualty with airway obstruction or impending airway obstruction during TACEVAC. These include the chin lift/jaw thrust maneuver, nasopharyngeal airway and recovery position as first-line interventions, as well as the LMA and Combitube for SGA interventions, endotracheal intubation or surgical cricothyroidotomy, should the first-line approaches prove unsuccessful. In an effort to optimize appropriate use of the SGA and in light of various new SGA devices emerging on the market, the SGA component of this spectrum is being updated.

Methodology

Dr. Mel Otten, Trauma and Injury Subcommittee member, conducted a comprehensive literature review of airway management best practices. Using available evidence, Dr. Otten and Subcommittee member Dr. Frank Butler developed a white paper proposing that the CoTCCC revise the TCCC Guidelines for TACEVAC to allow the use of other SGA devices in addition to

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the LMA and Combitube. Dr. Otten presented the proposed revision at the May 2012 CoTCCC meeting, during which the CoTCCC deliberated the findings and unanimously agreed to forward it to the Trauma and Injury Subcommittee. The Subcommittee subsequently approved the recommended revision during its meeting and forwarded it to the Board for consideration. The Board conducted a comprehensive literature review which included an evaluation of levels of evidence in accordance with the Oxford Centre for Evidence-Based Medicine method¹ (**Attachment B**). Board members approved this revision, in the form of a recommendation, at the June 2012 meeting. While finalizing the recommendation to the Department, Dr. Dickey proposed text be added to encourage the Services to select a limited number of devices, emphasize the importance of training and to work toward standardization. Additionally, she recommended text regarding ongoing research and identification of best practices. In August 2012, the Board members agreed with Dr. Dickey's comments and changes, and approved the revised recommendation by unanimous vote.

EVIDENCE

Recently, many new SGA devices have emerged in an effort to optimize airway devices,^{2,3,4} and additional generations may be expected. Although current evidence does not support one device as being superior over another,^{5,6,7} patient safety and provider competency literature document that a device is likely to outperform others when utilized by a provider with more experience and training in using that device. Specifically, provider experience and skill strongly influence the effectiveness, efficiency and safety of devices and procedures.^{8,9,10,11,12,13,14,15} Those performed by more experienced and adequately trained providers are less likely to result in adverse events, including injuries resulting from device misuse or unfamiliarity. Expert feedback from the field from post-mortem examinations further underline the importance of ensuring SGA devices are used properly. These data suggest that providers should be trained specifically on the devices they would use in theater in order to enhance both Service member safety and treatment success.

Practice effects may also compel providers to develop strong device preferences.¹⁵ Industry surveys and academic reviews highlight relationships between provider training and experience with device preference, selection, familiarity and perceived quality.^{15,16,17,18} Training greatly influences device selection, as physicians are more likely to use devices on which they are trained,¹⁷ particularly if recent.¹⁵ Providers hesitate to switch devices primarily because of the speed and proficiency attained in using those familiar to them.¹⁶

Since national standards and criteria are lacking for determining when new products should be deployed to replace existing ones,¹⁹ determining which devices should be fielded should take into account various logistical and practical considerations, including differences across the military Services. These include acquisition and procurement processes as well as equipping and fielding in theater.

SGA device selection is specific to each military Service. For example, the U.S. Army is currently using the King LT™ (King LT) rather than the Combitube in combat medic training and equipping.^{20,21} The U.S. Army started training medics to use the King LT, since it was demonstrated to be faster and more easily inserted than the Combitube in prospective observational studies^{22,23} examining their use by combat medics in training.²¹ As multiple types

of airway devices are being fielded, training and continued research on the optimal airway device are critical.²¹ In addition, challenges associated with the combat environment should be taken into consideration when evaluating device performance, as the environment in which the device is used impacts its safety and usability.²⁴

Provider type, supply options and available resources may also contribute to which airway device is used.²¹ A prospective observational study examining casualties presenting at combat support hospitals found that medics used the greatest variety of airway devices among all providers.²¹ The study also underlined that individuals are provided some degree of autonomy in selecting preferred airway devices, noting that in the combat setting, medical guidance in far-forward Army units lacks standardization, while training can be highly variable across units and individuals.^{21,25,26} Resources are typically limited for units that are further far-forward, constraining the types of devices available to providers in this setting.²¹

Other logistical and practical considerations should take into account differences in battlefield trauma care equipment procurement processes across the military Services. Cost-containment strategies pursued by civilian health care facilities underline benefits associated with standardizing medical devices. These include restricting the number of available device options by limiting the number of vendors, as well as negotiating lower prices and price ceilings.¹⁹ If current evidence does not support one device as being superior over another, then cost considerations alone indicate that one or two devices should be kept in the equipment inventory, and used in provider training and equipping. However, potential cost-containment practices such as purchasing large volumes of equipment to meet Service needs for several years, may introduce challenges resulting from the rapid, continuous evolution of medical best practices. As equipment investments by each military Service are significant, timely and adequate prehospital data collection, dissemination and analyses are critical in helping inform these expenditures.

LIMITATIONS

Although there are several studies of airway management devices and techniques, the current evidence base primarily consists of studies done in a controlled hospital environment (under anesthesia during elective surgery), on manikins, cadavers or in the civilian prehospital environment. The generalizability of these studies to the battlefield is limited, and the effectiveness of SGA devices in patients with direct airway trauma is not well studied.⁵ SGA device insertion and ventilation studies frequently lack the power required to examine survival rates.^{6,27} These studies are largely descriptive/observational or retrospective, providing primarily Level III and Level IV evidence based on the Oxford Centre for Evidence-Based Medicine grading scale.

Varying levels of provider training and experience across studies makes it difficult to compare outcomes. Industry and academic literature examining provider selection and preference for medical devices are often based on provider survey data (primarily Level III evidence). These reports demonstrate a positive correlation between device efficacy and safety, provider preference and familiarity. Retrospective studies of device-related injuries and patient safety using hospital and clinic records generally yield Level III evidence. Randomized controlled trials (where feasible) and comparable pilot studies are needed to compare SGA devices, airway

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management techniques and device effectiveness. Data collection forums, such as the Joint Theater Trauma Registry and other unit-based trauma registries, are imperative to enhancing outcomes-based research on optimal airway devices and techniques.

DELIBERATIONS

Members discussed implications pertaining to recommending the use of unlimited rather than a discrete number of SGA devices, until the evidence demonstrates that a particular device is superior. The Board considered issues pertaining to patient safety; potential adverse events; training and equipment standardization across the military Services; battlefield procurement processes; and prehospital data collection. In addition, members discussed potential benefits associated with limiting the number of SGA devices recommended in the TCCC Guidelines. These included enabling better use of training, as well as enhancing patient safety and treatment effectiveness, in allowing providers to acquire experience and proficiency by repeatedly using a specific device. However, members recognized that the current evidence base does not support the use of one SGA device over another, and that the collection and continuous evaluation of adequate prehospital data are necessary to identify an optimal device and develop evidence-based recommendations for its use. Although equipment standardization across the military Services is a desirable objective, the members understood that training plays a critical role in the near term when determinations are made regarding which SGA device would be best for use. Specifically, provider training and proficiency affect the likelihood that a device might fail, due to user error, or cause unintended adverse effects and patient harm. This is particularly critical, since training and proficiency levels vary across provider types and across the military Services.

In addition, the Board concluded: any recommendations advocating a specific SGA device be based on the best available evidence demonstrating its superiority; absent this evidence, the military Services should enhance the safety of Service members by selecting a limited number of devices and ensuring that the inventory, training and equipping practices are aligned and consistent with the devices selected; provider training be appropriate and realistic, and ensure the sustainment of acquired skills and proficiencies; SGA devices be evaluated on an ongoing basis, as new data emerge and recently developed devices are further tested; continued research and adequate prehospital data collection be ensured as they are vital for identifying best practices; and equipment inventories, as well as provider training and equipping, eventually be standardized across the military Services. Current initiatives to standardize training, such as the Tri-Service training provided for enlisted medical personnel at the Medical Education and Training Campus at Fort Sam Houston, Texas, may also serve as an impetus for the military Services to adopt a common equipment inventory and fielding practice in theater.

The Board also cautioned that inventory practices should account for the rapid, continuous evolution of medical best practices, where feasible. This would facilitate a timely adoption and fielding of optimal devices consistent with the best available scientific evidence. Based on emerging patient safety data, the Board noted that the issue of ensuring consistency regarding SGA device use across inventory, training and equipping practices may also be pertinent to other equipment fielded in theater.

CONCLUSION

Considering the evidence and its limitations, the Board concludes that there is no strong evidence to support the use of one SGA device over another.

RECOMMENDATIONS

The DHB recommends that:

1. The specific devices referenced in the TCCC Guidelines for SGA interventions during TACEVAC Care be removed.
2. Recommendations advocating a specific SGA device be based on the best available evidence demonstrating its superiority. Should such a device emerge, the military Services should ensure providers are trained on its use and are equipped to field it in theater.
3. Absent evidence indicating one device is superior over another, the military Services should enhance the safety of Service members by selecting a limited number of devices and ensuring that the inventory, training and equipping practices are aligned and consistent with the devices selected. Provider training should be appropriate and realistic, and should ensure the sustainment of acquired skills and proficiencies.
4. SGA devices be evaluated on an ongoing basis as new data emerge and recently developed devices are further tested.
5. Continued research and adequate prehospital data collection be ensured as they are vital for identifying best practices.
6. Equipment inventories, as well as provider training and equipping, eventually be standardized across the military Services. Current initiatives to standardize training, such as the Tri-Service training provided for enlisted medical personnel at the Medical Education and Training Campus at Fort Sam Houston, Texas, may also serve as an impetus for the military Services to adopt a common equipment inventory and fielding practice in theater.
7. Inventory practices should account for the rapid, continuous evolution of medical best practices, where feasible. This would facilitate a timely adoption and fielding of optimal devices based on the best available scientific evidence. Emerging patient safety data indicate that the issue of ensuring consistency regarding SGA device use across inventory, training and equipping practices may also be pertinent to other equipment fielded in theater.

In addition, the DHB recommends the Department incorporate the following proposed change (in **bold**) in the TCCC Guidelines for airway management during TACEVAC:

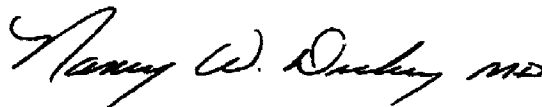
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Tactical Evacuation Care

1. Airway Management

- a. Unconscious casualty without airway obstruction:
 - Chin lift or jaw thrust maneuver
 - Nasopharyngeal airway
 - Place casualty in the recovery position
- b. Casualty with airway obstruction or impending airway obstruction:
 - Chin lift or jaw thrust maneuver
 - Nasopharyngeal airway
 - Allow casualty to assume any position that best protects the airway, to include sitting up.
 - Place unconscious casualty in the recovery position.
 - If above measures unsuccessful:
 - **Supraglottic airway** or
 - Endotracheal intubation or
 - Surgical cricothyroidotomy (with lidocaine if conscious).
- c. Spinal immobilization is not necessary for casualties with penetrating trauma.

FOR THE DEFENSE HEALTH BOARD:



Nancy Dickey, M.D.
DHB President

ATTACHMENTS:

- A. **TCCC Guidelines**
- B. **Oxford Centre for Evidence Based Medicine Levels of Evidence Table**

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