JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)

Airway Management in Prolonged Field Care (CPG ID:80)

This Role 1, prolonged field care (PFC) clinical practice guideline (CPG) is intended to be used after Tactical Combat Casualty Care (TCCC) Guidelines, when evacuation to higher level of care is not immediately possible

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PURPOSE

This Role 1, prolonged field care (PFC) clinical practice guideline (CPG) is intended to be used after Tactical Combat Casualty Care (TCCC) Guidelines, when evacuation to higher level of care is not immediately possible. A provider must first and foremost be an expert in TCCC, the Department of Defense standard of care for first responders. The intent of this PFC CPG is to provide evidence and experience-based solutions to those who manage airways in an austere environment. An emphasis is placed on utilizing the tools and adjuncts most familiar to a Role 1 provider. The PFC capability of airway is addressed to reflect the reality of managing an airway in a Role 1 resource-constrained environment. A separate Joint Trauma System CPG will address mechanical ventilation. This PFC CPG also introduces an acronym to assist providers and their teams in preparing for advanced procedures, to include airway management.

BACKGROUND

Airway compromise is the second leading cause of potentially survivable death on the battlefield after hemorrhage.[1] Complete airway occlusion can cause death from suffocation within minutes. Austere environments present significant challenges with airway management. Limited provider experience and skill, equipment, resources, and medications shape the best management techniques. Considerations include: limited availability of supplemental oxygen; medications for induction/rapid sequence intubation, paralysis, and post-intubation management; and limitations in available equipment. Another reality currently is limitations in sustainment training options, especially for advanced airway techniques. Due to these challenges, some common recommendations that may be considered "rescue" techniques in standard hospital airway management may be recommended earlier or in a non-standard fashion to establish and control an airway in a PFC environment. Patients who require advanced airway placement tend to undergo more interventions, be more critically injured, and ultimately have a higher proportion of deaths. The ability to rapidly and consistently manage an airway when indicated, or spend time on other resuscitative needs when airway management is not indicated, may contribute to improved outcomes.[2,3]

INDICATIONS FOR AIRWAY MANAGEMENT

DISRUPTED FACE OR NECK ANATOMY

If managing an isolated injury that disrupts face or neck anatomy, healthy adults may only need a mechanical airway placed and may not require assisted ventilation if they are not heavily sedated. Examples of conditions requiring early airway management include:

- Massive facial trauma
- Burns to the face or inhalation injury with hoarseness or stridor
- Massive neck trauma
- Expanding neck mass/hematoma
- Acute pharyngeal infection (Retropharyngeal abscess, peritonsillar abscess, epiglottitis)
- Foreign body aspiration
- Anaphylaxis (airway swelling)

INSUFFICIENT OXYGENATION OR VENTILATION

These indications may be apparent on initial evaluation or may emerge during the course of patient management. If the need to establish an airway develops more gradually, additional elective airway techniques can be employed. Interventions such as prolonged manual bag or mechanical ventilation require an airway intervention to ensure best overall management. Examples include:

- Chest wall and pulmonary trauma (blunt or penetrating) such as flail segments, pulmonary contusions (from blast, blunt or crush mechanism)
- Burns with greater than 40% body surface area
- Traumatic brain injury with decreased level of consciousness (GCS ≤ 8)
- Traumatic brain injury with suspected herniation requiring hyperventilation (target ETCO2 between 30 and 35)
- Procedural sedation or surgical procedure
- Respiratory failure from disease, infection, or injury:
  - Chemical or toxic inhalation injuries
  - Acute Respiratory Distress Syndrome (ARDS) from infection, massive resuscitation, drug-induced or other causes
  - Primary lung infection (pneumonia)
  - Massive pulmonary embolism
  - TRALI (transfusion related acute lung injury) or TACO (transfusion associated circulatory overload) due to massive transfusion

Table 1. TCCC Airway Management Adjuncts (Consider basic adjuncts first)

Device/ Techniques	Pros	Cons	Pharm Reqs to Maintain (0/+/++)	Skill Level (NM: Non-Medic; M: Medic)
Head-Tilt/ Chin-Lift	Easy	Requires hands-on continuously	0	NM
Recovery Position	Easy; tactically feasible (TCCC/MASCAL)	May limit patient assessment or ongoing management	0	NM
Sit Up/ Lean Forward	Easy and practical (may be position of comfort)	May indicate impending airway loss	0	NM
Nasopharyngeal Airway (NPA)	Easy	Risk of nose bleeds with placement	0	NM
Oropharyngeal Airway (OPA)	Easy	Not tolerated in conscious patient	+	NM
Supraglottic Airway (SGA)	Easy	Not tolerated in conscious patient	++	M

Device/ Techniques	Pros	Cons	Pharm Reqs to Maintain (0/+/++)	Skill Level (NM: Non-Medic; M: Medic)
Oral Endotracheal Tube (ETT) Airway	Familiar to trained providers; Definitive; No surgical incision needed	Skill sustainment challenging, requires neuromuscular blockade (rapid-sequence intubation) for best success, may require suction to visualize vocal cords, requires sedation (potential limitation in PFC)	++	M+
Cricothyrotomy (Cric)	Definitive; Better tolerated than Oropharyngeal (OP), SGA or ETT. May require less sedation to sustain once in place	Invasive procedure, high failure rate in some studies.[4,5]	+	M

For Pharm Reqs: Maintain: 0 = no additional medications; + = some or intermittent dosing medications required; ++ = continuous or multiple medications required

MACHINE, SUCTION, MONITOR, AIRWAY, INTRAVENOUS ACCESS, DRUGS

Checklists are commonly used in medical practice. In preparation for an advanced procedure (including securing an airway) using an acronym or other checklist approach will prove invaluable. One such acronym, originally developed as a simple pre-operative anesthesia checklist, is presented.
The MSMAID acronym (Machine, Suction, Monitor, Airway, Intravenous access, Drugs) organizes an approach to preparation for airway management and may also prove useful in preparation for other procedures.

The patient's condition dictates the available time for a provider to consider all items on this checklist. A rapidly deteriorating patient with airway disruption or compromise will need the airway procedure first and follow-on considerations later. If a patient can be more appropriately classified as semi-urgent (e.g., worsening respiratory status due to an underlying pulmonary cause) the provider will have more time to consider the algorithm and prepare. Logistic considerations, and sometimes considerable time constraints, will affect preparation for advanced procedures. Recommendations follow the "minimum, better, best" format.

MACHINE

(Equipment required post-intubation)

- **Minimum**: Bag-Valve-Mask (BVM) with positive end-expiratory pressure (PEEP) valve
- **Better**: Automated portable ventilator (preferably with PEEP); oxygen concentrator
- **Best**: Full-feature portable ventilator (e.g. several ventilatory modes, PEEP); supplemental oxygen if available

 Managing ventilators or advanced equipment unfamiliar to a provider presents challenges. Initiate telemedicine consultation for best guidance.

PEEP is important for prolonged ventilation. PEEP is the pressure in the airway at the end of the expiratory phase which prevents the alveoli of the lung from completely collapsing. In a spontaneously breathing person, this pressure is maintained by closing the glottis, clearing the throat, coughing, sighing, etc. With an invasive airway, the glottis is bypassed with the tube and "natural" PEEP is lost. PEEP should therefore be introduced into the ventilated patient using a PEEP valve on the BVM or using the PEEP setting on a ventilator. When using BVM or ventilator, provide PEEP (recommended initial setting is 5cm H2O).[6]

SUCTION

- **Minimum**: Improvised suction (i.e. syringe + nasopharyngeal airway [NPA]) and patient positioning if not contraindicated
- **Better**: Manual suction bulb with adapter
- **Best**: Powered commercial suction with oral tip and in-line endotracheal tube suction adapter

Suction should be available when establishing and maintaining an airway to remove excessive secretions or blood. It is particularly important to utilize suction to facilitate view of the vocal cords during endotracheal intubation. In addition, suction should be available for routine patient care and maintenance requirement for any intubated patients. Suction should be utilized as needed to remove secretions, mucous or blood from the airway device or oropharynx. In the event of high airway pressures, suction may be used to remove mucus/mucus plugs or to clear obstructions. In the case of thick secretions, a saline flush of 1-2 mL followed by in-line suctioning of the endotracheal tube may be useful.
Note: *During in-line suctioning of tubes, the suction should only be applied when withdrawing the catheter and not upon initial insertion.*

MONITOR

(Monitoring and telemedicine support)

- **Minimum**: Pulse oximeter (SpO2), assistant to monitor respirations and record manual vital signs. Trending vital signs documentation. PFC flow sheet is recommended. Refer to PFC Documentation CPG.[7] Voice or data connections to perform telemedicine communication
- **Better**: Portable Capnometry (ETCO2)/capnography in addition to SpO2. Transmit photographs from smartphones or personal devices to augment telemedicine communications.
- **Best**: Automatic vital signs monitor with SpO2, ETCO2/waveform capnography, +/- electrocardiogram (EKG); Synchronous (real-time continuous) telemedicine using video or remote patient monitoring systems

Monitoring is the active process of assessing the patient throughout a procedure. It involves the gathering, documenting and interpretation of vital signs and other data, and the continuous assessment of their clinical status. Telemedicine can be an important adjunct and critical capability to employ when monitoring a patient undergoing complex procedures.

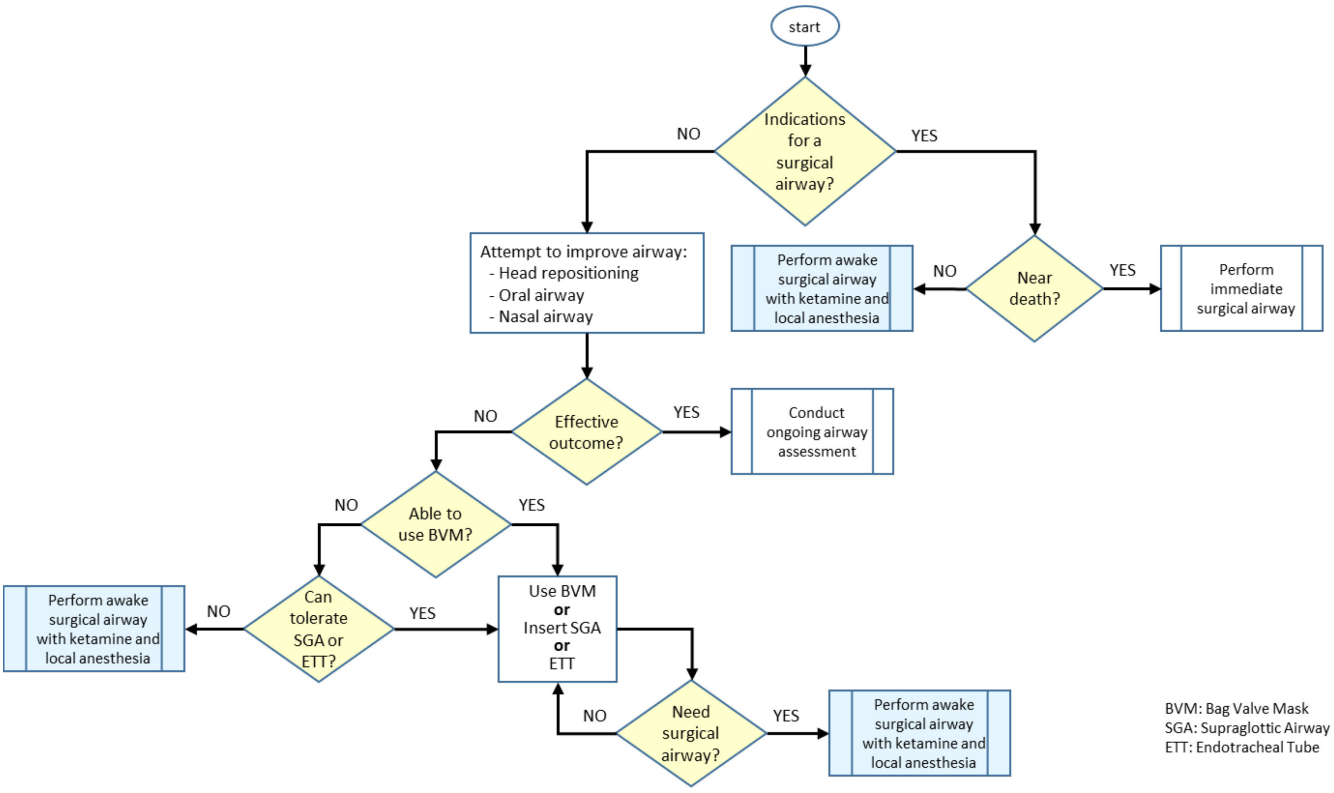
AIRWAY

- **Minimum**: Medic is prepared for a ketamine cricothyroidotomy.
- **Better**: Add ability to provide continuous sedation.
- **Best**: Add a responsible rapid-sequence intubation capability (to include chemical paralysis) with airway maintenance (to include suction) and continuous sedation.

Per the PFC Capabilities Position Paper, a definitive airway requires control of the patient's airway with an inflated cuff in the trachea. In addition, sedation is needed to keep the patient comfortable and sustain the airway.[8]

A proposed algorithm was developed by Mabry RL et al for an awake surgical airway (Figure 1).[9] This algorithm incorporates the skills recommended for Tactical Combat Casualty Care and presents the decision process deemed adequate (minimum standard) for definitive airway control in PFC. The airway algorithm is presented in its published form and surgical airway is synonymous with cricothyrotomy. As noted above, the indications for surgical airway include disrupted face or neck anatomy, as well as a need for prolonged positive pressure ventilation in a resource constrained PFC environment. Consider temporizing, if possible, with basic airway maneuvers or other airway adjuncts (e.g.; NPA, SGA). Please see Table 1.

Figure 1. An Awake Patient Surgical Airway Algorithm



Source: Mabry RL, Kharod CU, Bennett BL. Awake cricothyrotomy: a novel approach to the surgical airway in the tactical setting. Wilderness Environ Med. 2017;28(2S):S61-8. Adapted with permission from the Wilderness Medical Society. ©2017 Wilderness Medical Society.

Positioning of the patient to help clear airway obstruction should be considered first, when possible. The simple option of placing the patient in a sitting position, placing the patient in the lateral "recovery" position, or head tilt-chin lift/jaw thrust maneuver may be enough to ensure adequate respirations. Simple adjuncts such as a nasal or oropharyngeal airway (in an unconscious patient) may be utilized in addition to proper positioning to help ensure a clear airway.

For those patients requiring active airway assistance, the first step should be inserting an NPA to open the airway. BVM ventilation is the next step in the algorithm and though it appears to be relatively simple, the procedure requires preparation, training and skill to perform correctly. A spontaneously breathing patient may prove challenging, but properly delivered, synchronous breaths may be the only requirement to assist a patient's respirations. Care should be taken to ensure proper volume and rate of bag-delivered breath. One hand should provide moderate pressure to the bag for no more than 50% of the volume of an adult bag or just enough to see the chest begin to rise at a rate of 12-16 breaths per minute (one breath every 4-5 seconds) initially. It is important to avoid hyperventilation through large or rapid breaths, particularly with traumatic brain injury (TBI) casualties, therefore ETCO2 monitoring is indicated for all patients requiring assisted ventilation and all patients with altered mental status (including both TBI casualties and sedated patients). BVM is an important airway management skill (see Appendix C: Bag-Valve-Mask Technique for a detailed description). It is highly recommended that all PFC training on airway skills cover BVM skills and techniques.

OP and SGA insertion can present a considerable noxious stimulus and may not be tolerated by conscious or even some semiconscious patients. Additionally, the dyssynchronous use of BVM ventilation may lead to poor patient cooperation, abnormal tidal volumes, gastric insufflation (and resultant regurgitation/aspiration), or other complications.

 ***The decision to perform a cricothyroidotomy is one that is sometimes difficult. When possible, in urgent but not emergency situations, a telemedicine call should be considered to help with medical decision making.***

An important adjunct to passing an endotracheal tube, either via the cricothyroid membrane or the oropharynx, is the use of a gum elastic bougie (sometimes also referred to as an Eschmann Stylet or, simply bougie). This device is simple, rugged and should be used to guide tube placement. The bougie is placed in the trachea before the endotracheal tube and may be used first to confirm proper positioning by either tactile discrimination (feeling the tube bump against the tracheal rings on introduction), or by encountering a hard stop when abutted against the carina. An endotracheal tube is then introduced over the bougie into the trachea. Lastly, the bougie is removed. A bougie may also be used to change tubes in the case of a tube malfunction. This may be accomplished by placing a bougie in a tube that is currently positioned, remove the tube over the bougie (ensuring the bougie remains in the proper position within the airway lumen), and replacing a new tube over that bougie. Remove the bougie, leaving the new tube in place. Confirmation procedures discussed below must be repeated once the new tube is in place.

Consistent with TCCC guidelines, the routine use of orotracheal intubation is not recommended as the minimum standard in PFC. This procedure requires considerable skill and sustainment;[10] and requires appropriate sedation for both rapid sequence intubation and post-intubation management. If a provider is appropriately trained, current and practiced in the procedure, and has the required support equipment and medications, then orotracheal intubation may be considered. Although preferred when

possible, training in orotracheal intubation is not required to obtain a definitive airway in the PFC operational setting. Consider basic measures first before proceeding to either type of invasive airway. Additional details on orotracheal intubation are included in the JTS Airway CPG.

Airway management in the tactical setting requires a different conceptual approach than airway management in the hospital, or even the civilian prehospital environment. Differences in epidemiology, injury patterns, equipment and environment must be considered if airway management is to be optimized. First, most military casualties requiring a prehospital airway have trauma to the head, face or neck. Surgical airway is often the final common pathway due to bleeding or distorted anatomy. In comparison, most airways in the civilian prehospital environment are placed in elderly people for cardiac arrest. When reliable suction and oxygen delivery are not available, or personnel are not experienced in rapid sequence intubation using neuromuscular blockade, a definitive airway will often mean a surgical airway.

Proper Tube Placement

- **Minimum**: Visualization of the tube passing through the vocal cords (in the case of endotracheal intubation); auscultation of epigastric region (should be silent) and bilateral lung sounds (should be present). Colorimetric capnography + endotracheal detection device (EDD). Easy bilateral rise and fall of the chest + misting of the tube + no signs of gastric insufflation. (Reassess frequently and have another medic double check if unsure.)
- **Better**: Minimum plus portable capnometer. Ultrasound if trained/available to guide and/or verify placement
- **Best**: Continuous ETCO2/waveform capnography

Verification of correct tube placement must be performed every time as incorrect tube placement may be fatal. The REACH study[5] showed that right mainstem and hypopharynx placement are the most common locations of incorrect placement of ETT. Esophageal intubation is also common. Subcutaneous placement of cricothyroidotomy tube may occur. Use capnography to verify correct tube placement as tube misplacement can be fatal. Auscultate, if possible, to verify bilateral breath sounds. If ultrasound is available, this can be used to further verify placement in the correct position.[11]

IV/IO ACCESS

- **Minimum**: If (IV) / intraosseous (IO) attempts fail or when unavailable: medication may be given intramuscularly or intranasally for immediate sedation to facilitate surgical cricothyroidotomy. Continue attempts at IV/IO access after airway has been controlled
- **Better**: 1-2 patent IV/IO
- **Best**: 2-3x patent intravenous IV/IO with additional IO device on standby

Though an important consideration to administer medications and fluids, do not delay an emergent airway to obtain IV/IO access in the instance you are the sole provider.

Ultrasound may be used to help identify small or deep veins. Ultrasound guided IV access may be attempted if trained. Other sites to consider for superficial IV attempts include the external jugular and saphenous veins. If appropriately trained, consider central venous access or venous cutdown.

DRUGS

Airway Placement

- **Minimum**: Local anesthetic for cricothyroidotomy (superficial skin anesthesia plus 1-2 mL injected through the cricothyroid membrane); or placement without medications in unconscious patient. **Note: most sedating agents can be given IM if IV/IO has not been established
- **Better**: Any IV/ IO sedating agent (opioid, benzodiazepine: reference the Analgesia and Sedation Management for PFC CPG for procedural doses of such agents).[12]
- **Best**: Procedural dose ketamine (1-2 mg/kg IV push) for ETT or cricothyroidotomy placement + local anesthetic (lidocaine) for cricothyroidotomy placement

Prolonged Sedation

(post-airway placement)

- **Minimum** (without IV access): Ketamine (sedation dose), 3-4mg/kg IM
- **Better**: IV/IO pushes of ketamine, opioid, and/or midazolam (alone or in combination as per the individual's scope of practice, experience and availability of medications)
- **Best**: Ketamine IV/IO Drip. Hydromorphone or alternate opioid IV/IO push for breakthrough pain and midazolam IV/IO push as needed for sedation

(Reference Analgesia and Sedation Management in PFC CPG for details and drug doses).[12]

Be cautious with sedation, advanced airway placement and positive pressure ventilation in patients who are hypotensive or under-resuscitated. Blood pressure can fall rapidly during airway management due to a variety of mechanisms.

In all cases, monitor BP closely (every 1-2 minutes during the procedure, every 3-5 minutes for 15 minutes post-procedure). A BP drop may be brief (if due to vagal effects of epiglottis stimulation during ETT placement) or sustained (due to positive pressure ventilation, increased intrathoracic pressure and decreased venous return to the heart). Loss of sympathetic drive secondary to pain and sedation medications, and/or continued hypovolemia can also result in hypotension. Continue resuscitation with blood products (trauma patients) or crystalloid (non-trauma patients) if a hypotensive patient requires immediate airway interventions. Be prepared to support blood pressure with vasopressors (e.g. epinephrine bolus or drip) if trained or under direct telemedicine guidance.

Neuromuscular blockade (succinylcholine, rocuronium, vecuronium, etc.) is NOT recommended for use by the average practitioner of PFC. Though these are standard medications to use in rapid sequence intubation and ventilator management, their potential lethality in inexperienced hands does not justify routine recommended use. If trained and/or under direct supervision of telemedicine support, the use of neuromuscular blockade may be considered, subject to local medical direction and protocols.

PERFORMANCE IMPROVEMENT (PI) MONITORING

POPULATION OF INTEREST

1. All patients who received ETT/cricothyroidotomy/supraglottic airway/NPA

2. All patients with compromised airway (initial GCS < 8 or abbreviated injury scale (AIS) head and neck ≥ 3, or AIS face ≥ 3).

INTENT (EXPECTED OUTCOMES)

1. All injured patients who present with obtundation (GCS<8), apnea, respiratory distress or insufficiency, airway obstruction, or impending airway loss will have a secure and definitive airway established expeditiously upon arrival to a Role 2 or Role 3 if not done prehospital.

2. SpO2 is maintained ≥ 90%.

3. Patients with a definitive airway (endotracheal tube, cricothyroidotomy, tracheostomy) have ETCO2 monitoring to confirm airway placement.

PERFORMANCE/ADHERENCE METRICS

1. Number and percentage of patients in the population of interest who had a secure and definitive airway (endotracheal tube, cricothyroidotomy, tracheostomy) established or verified, or documentation of appropriate intervention.

2. Number and percentage of patients in the population of interest with SpO2 < 90%<80%, <70%, <60%.

3. Number and percentage of patients who had definitive airway (endotracheal tube, cricothyroidotomy, tracheostomy) with ETCO2 documented at the same role of care where the procedure is done.

DATA SOURCES

- Patient Record

- Department of Defense Trauma Registry (DoDTR)

SYSTEM REPORTING & FREQUENCY

The above constitutes the minimum criteria for PI monitoring of this CPG. System reporting will be performed annually; additional PI monitoring and system reporting may be performed as needed.

The system review and data analysis will be performed by the Joint Trauma System (JTS) Director, JTS Program Manager, and the JTS PI Branch.

RESPONSIBILITIES

It is the trauma team leader's responsibility to ensure familiarity, appropriate compliance and PI monitoring at the local level with this CPG.

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APPENDIX A: AIRWAY EQUIPMENT

AIRWAY EQUIPMENT:

- **Minimum** (Ruck/Aid Bag): Nasopharyngeal airway, Cricothyrotomy kit; BVM with PEEP valve
- **Better**: Minimum PLUS supraglottic airway, gum elastic bougie to facilitate intubation, nasogastric/orogastric tube
- **Best**: Better PLUS endotracheal tubes, direct laryngoscopy or video laryngoscopy equipment

WAVEFORM CAPNOGRAPHY:

- **Minimum**: Colorimetric ETCO2 detector
- **Better**: Portable capnometer
- **Best**: Waveform capnography on patient monitor

See Appendix G for Capnography Interpretation

HEAT-MOISTURE EXCHANGER:

Heat-Moisture Exchangers (HME) are small, relatively inexpensive, in-line ETT adjuncts that contain hygroscopic salts that utilize differences in vapor pressure, expired moisture content, and the patient's temperature to increase the humidity of inspired air. Increased moisture on inspiration helps maintain alveolar moisture. Capnography should not be positioned in-line following HME as these moisture devices can increase breathing resistance and work of respiration, as well as increase breathing apparatus dead space (especially in pediatric patients). This may lead to potential worsening hypercapnia and respiratory acidosis. Recommended order: endotracheal tube-capnograph-HME device (proximal to distal)

NASOGASTRIC/OROGASTRIC TUBE:

Placement of a nasogastric (NG) or orogastric (OG) tube should be considered following intubation of a patient in order to decompress gastric contents, prevent aspiration and gastric distention.

- If only supraglottic airway access is available, consider using a supraglottic device that incorporates an orogastric tube port.
- Always measure the distance from nose to stomach and note the distance prior to insertion, then verify epigastric sounds. Verify placement with second practitioner if sounds are questionable or difficult to auscultate.
- Do not feed, aggressively hydrate or give oral medications through an OGT or NGT without telemedicine guidance. Always reassess tube position prior to putting anything into stomach to ensure proper gastric placement. Feeding should not be considered until 72 hours after injury in the PFC environment. If volume instilled is too large or rate is too fast, there is increased risk for vomiting. If feeding or hydration is begun through an OGT or NGT, they must be accurate, measured, and monitored. Safe airway management takes precedence over nutrition.

SUGGESTED PACKING LIST

	Equipment	Notes
Minimum	Nasopharyngeal airway (NPA)	
	Oropharyngeal airway (OPA)	
	Cricothyroidotomy kit: a standardized kit should include at a minimum a #10 scalpel, a tracheal hook (or small, curved hemostat), an airway tube, a 10mL syringe, and a securing strap. The airway tube may be a prefabricated cricothyroidotomy tube such as that included in the Cric-Key (Control Cric), a Shiley tracheostomy tube, or a 6.0-sized endotracheal tube.	
	Bag valve mask (BVM)	
	PEEP valve: either separate device, or affixed to the BVM device	
	Capnography/capnometry device	
	Bougie	
Better	Additional endotracheal tubes	
	Portable suction device	
Best	Supraglottic airway: options include LMA (Size 4 if only one; size 5 for >90kg patient) or King-LT.	
	Waveform capnography	
	Commercial power suction device	
	Automatic (electronic) patient monitor	
	Direct laryngoscope: Macintosh blade size 3 or 4 for adults; Miller 1 or 2 for infants and small children as needed.	For those trained in endotracheal tube placement and opt to include equipment in their aid bag
	Endotracheal tubes: for cricothyroidotomies (6.0 mm tubes). Personnel trained in endotracheal intubation should also carry a 7.5 or 8.0mm tube for primary intubation. A 7.0 mm tube should be carried as a secondary ET tube in case of difficult intubation. (If pediatric trauma is common, consider adding smaller sizes, but these should be limited to the most common ages expected to encounter, and calculated on the classic rule of tube size = 4 + (age/4). Examples of what to carry include 4.0 mm uncuffed for infants, and 6.0 cuffed for older children).	For those trained in endotracheal tube placement and opt to include equipment in their aid bag
	Video laryngoscope: hand-held devices should utilize a blade with an angle that allows for direct laryngoscopy function should the video screen/battery fail during intubation.	For those trained in endotracheal tube placement and opt to include equipment in their aid bag
	Mechanical ventilator	
	Pediatric-sized equipment	
	Other equipment listed above but not carried due to cube/weight restrictions	

APPENDIX B: AIRWAY MANAGEMENT NURSING/CONTINUED CARE

Long-Term Airway Management, Nursing and Prolonged Field Care

Below is the recommended Prolonged Field Care Nursing Flowsheet to use as a guide.*

Patient ID:			Time	1hr	2hr	3hr	4hr	5hr	6hr	7hr	8hr	9hr	10hr	11hr	12hr	13hr	14hr	15hr	16hr	17hr	18hr	19hr	20hr	21hr	22hr	23hr	24hr
	Action (suggested interval)	Interval																									
Vitals	Check BP/HR/RR/T/SPO2/ETCO2 (Q1H)																										
	Check Peripheral Pulses (Q1H)																										
	Check Skin Temp and Color (Q1H)																										
	Check Lactate (Q4H)																										
	Check Blood Glucose (Q8H)																										
Ins/Outs	Check Drip Rates/Fluids In (Q1H)																										
	Check Urine Output (Q1H)																										
	Check Urine Dipstick (Q1H)																										
	Perform NG/OG Tube Care (Q2H)																										
	Perform Foley Care (Q24H)																										
	Flush PRN Locks (Q8H)																										
Pain/Sedation	Check GCS/RASS/PAIN (Q1H)																										
	Give Pain Rx (per Rx)																										
	Give Sedation Rx (per Rx)																										

Patient ID:			Time	1hr	2hr	3hr	4hr	5hr	6hr	7hr	8hr	9hr	10hr	11hr	12hr	13hr	14hr	15hr	16hr	17hr	18hr	19hr	20hr	21hr	22hr	23hr	24hr
HEENT	Perform Tube Suctioning (PRN)																										
	Perform Oral Suctioning (PRN)																										
	Perform Nasal Care/Moisten (Q4H)																										
	Perform Oral Care/Moisten (Q4H)																										
	Apply Lip Balm (Q1H)																										
	Apply Eye Ointment/Drops (per Rx)																										
	Brush Teeth (Q12H)																										
	Change All Tape (Q24H)																										
Respiratory	Check Ventilator Settings (Q1H)																										
	Auscultate Lungs (Q1H)																										
	Turn, Cough, Deep Breathe (Q1H)																										
	Check Chest Drainage (Q1H)																										
Integumentary	Check S/S Compartment Syndrome (Q2H)																										
	Reposition (Q2H)																										
	Check Padding (Q2H)																										
	Perform LE Massage (Q2H)																										
	Check Dressings (Q4H)																										

Patient ID:			Time	1hr	2hr	3hr	4hr	5hr	6hr	7hr	8hr	9hr	10hr	11hr	12hr	13hr	14hr	15hr	16hr	17hr	18hr	19hr	20hr	21hr	22hr	23hr	24hr
	Do A/P Limb ROM (Q8H)																										
	Wash and Dry Skin (Q24H)																										
	Perform Burn Skin Care (Q24H)																										
	Irrigate Wounds (Q24H)																										
	Debride Wounds (Q24H)																										
	Change Dressings (Q24H)																										
	Give Antibiotics Rx (Q24H)																										
Gastrointestinal	Give PPI Rx if Indicated (per Rx)																										
	Give Antiemetic Rx (per Rx)																										
	Auscultate Abdomen (Q2H)																										
	Palpate Abdomen (Q2H)																										
	Give Food/Nutrition (Q8H)																										
Extra Stuff	Check O2 Supply																										
	Check/change batteries																										
	Compression Socks/Stockings																										

AIRWAY-SPECIFIC PFC NURSING GUIDELINES/ASSESSMENT/TASKS

- Oral Suction (or in-line/tube suctioning, if placed) as indicated during routine patient assessments
- Nose and mouth moistened Q4H
- Lip Balm applied Q1H
- Teeth brushed Q12H - Prevents pneumonia and other infections.
- Auscultate lungs Q1H. If available, get a second medic to double check and verify if sounds are questionable or cannot otherwise auscultate. Extra diligence should be given to check for diminished breath sounds for suspected pneumothorax, as well as for pulmonary edema, especially if giving aggressive fluids in the case of a massive resuscitation, or replacement fluids. Consider ultrasound evaluation if available.

Naso/Orogastric Tube (NGT/OGT) and Abdominal Care

(as applicable)

- Consider placing an NG/OG tube for prolonged care of intubated/cricothyrotomy patient or those with an SGA in place (if a compatible port is available on the SGA).
- Abdominal palpation AND auscultation Q2H.
- Nutrition ONLY under telemedicine guidance (optional and not indicated in first 72 hours).

**Loos PE, Glassman E, Doerr D, et al. Documentation in prolonged field care. J Spec Oper Med. 2018; 18(1): 126-32.*

APPENDIX C: BAG-VALVE-MASK TECHNIQUE

Proper technique is essential to perform successful bag-valve-mask (BVM) airway management. Patients should be in the supine position, neck in a neutral position and the occiput slightly elevated (on a folded blanket, sheet, small pillow, etc.) to achieve a "sniffing position," with the opening of the ears at the same level as the sternal notch. Masks should be of the proper size and should be fitted to the face to obtain a seal. This is best achieved by first placing the tapered portion of the opening of the mask over the bridge of the nose, then covering the patient's mouth. If using the one-person method, the non-dominant had should use the "C & E" method with the thumb and index finger forming a C to cover the mask, and the middle, ring and small fingers forming an E on the bone of the mandible effectively lifting the jaw into the mask (rather than pressing the mask onto the face).

The other hand should gently squeeze the bag delivering a breath at a rate of one squeeze every 5-6 seconds. There should not be a leak around the mask, and you should be able to observe the rise and fall of the patient's chest. An ETCO2 monitor may be placed in-line with the bag and mask. PEEP should be used with the BVM and initially set to 5mmHg. Every attempt should be made to maintain a seal to ensure continued PEEP. If the patient is breathing spontaneously, careful observation and delivery of an assisted synchronous breath should be a priority.

Some additional considerations are below:

1. If unable to perform adequate single hand C & E clamp, use two handed technique with a second person to bag.
2. Don't press mask down onto face when performing C & E clamp, visualize you are lifting face into mask.
3. Be aware fingertips on "E-clamp" should be positioned on the bones of the mandible and not on soft tissue, which could possibly occlude the airway.
4. Use "BOOTS" to predict difficult face-mask seals: Bearded, Obese, Old, Toothless, Snoring. In addition, maxillofacial trauma and edema from burns may prevent effective ventilation by BVM.
5. NPA should be used to assist with face mask ventilations (unless obvious contraindications such as mid-face trauma). OPA are also effective in obtunded patients or those who have received chemical sedation or neuromuscular blockade.
6. For bearded patients, lubrication of mask may assist seal. Tegaderm occlusive dressings over beard may also help if available. (If Tegaderm is used in sedated patient, consider pulling off before medication wears off, to lessen pain).
7. Consider mask straps to make face-mask seal more "hands free", especially if a non-medic is assisting you with BVM.

APPENDIX D: SUPRAGLOTTIC AIRWAY PLACEMENT

SUPRAGLOTTIC AIRWAY (SGA) PLACEMENT CHECKLIST

- ☐ Open airway manually, measure and insert simple airway adjunct (NPA -or- OPA).
- ☐ Ventilate patient with bag-valve-mask (BVM) (attach supplemental oxygen, if available).
- ☐ If ventilations insufficient, or the patient is clearly unconscious and not breathing adequately, prepare for supraglottic airway insertion. Inspect SGA to ensure appropriate size. Lubricate airway to facilitate passage. Cricothyroidotomy kit should be prepared for use if SGA fails.
- ☐ Follow MSMAID and for induction, use ketamine (1-2 mg/kg IV/IO or 3-4mg/kg IM) if time permits and the recommended medications are available.

INSERTING THE AIRWAY:

- ☐ Properly position head in a neutral or "sniffing" position (neck extended, as on a pillow or small blanket while lying flat) and open airway.
- ☐ Remove oropharyngeal airway (OPA) if previously placed.
- ☐ Insert device to proper depth (may adjust later if need for improved ventilation).
- ☐ Inflate cuff, if applicable; inflate as per device-specific volume instructions and immediately remove syringe.
- ☐ Confirm placement with ventilation and auscultation over epigastrium, then bilaterally over chest, left lung then right lung. Get a second practitioner to double check and verify in sounds are questionable or cannot otherwise auscultate.
- ☐ Verify proper SGA placement by secondary confirmation such as capnography/capnometry or colorimetric device.
- ☐ Place orogastric tube and decompress stomach if available, and compatible with SGA device (has a port specifically for OGT placement).

SGA Size Chart

Estimated patient size	LMA	King LT*
Neonates/Infants (up to 5kg)	1	0
Infants 5-10 kg	1.5	1
Infants/Children 10-20kg	2	2
Children 20-30kg	2.5	2.5
Children 30-50kg	3	3*
Adults 50-70kg	4	4*
Adults 70-100kg	5	5*
Adults over 100kg	6	

APPENDIX E: CRICOTHYROIDOTOMY PROCEDURE CHECKLIST

PREPARE PATIENT

1. Pre-oxygenate patient if possible.
2. Inspect/assemble/test equipment for cricothyroidotomy.
3. Prepare site with alcohol and betadine -or- Chlorhexadine (Chlora-prep).
4. Follow MSMAID and for induction, use ketamine (1mg/kg IV/IO or 3-4mg/kg IM) if time permits and the medication is available.

For awake cricothyrotomy: Explain procedure to patient; *Use local anesthesia: lidocaine (1% or 2%), bupivacaine (0.25%, 0.5% or 1%); local through planned incision area AND approx. 1-2mL through cricothyroid membrane

PERFORM PROCEDURE

1. Stabilize thyroid cartilage and keep overlying skin taught. Maintain control with hand until the membrane incision is secured (step 8 below).
2. Locate cricothyroid membrane (Palpate for hyoid and tracheal rings. If unsure or difficult landmarks, then measure three finger widths above sternal notch for adults).
3. Make vertical incision through the skin over cricothyroid membrane.
4. Make horizontal incision through cricothyroid membrane, then immediately:
5. Open and maintain membrane incision with tracheal hook (or curved hemostat, bougie or blunt end of scalpel).
6. Insert endotracheal/tracheostomy tube into opening and direct tube caudad into trachea until the balloon is just inside the airway.
7. Inflate cuff and detach syringe (palpate bulb to ensure it's not under-inflated or over-inflated).
8. Maintain control of tube at all times to prevent dislodgement.
9. Attach waveform capnography, or capnometry, or colorimetric device to confirm proper placement of tube.
10. Being careful not to dislodge the tube, attach BVM with PEEP and further check placement (epigastric and bilateral chest) and adequacy of bilateral insufflation of lungs.
11. Remove BVM (if sufficient respiratory effort), assess respirations for adequacy (rate, rhythm, and quality), assist ventilations if needed.
12. Secure with sutures and tie with girth hitch passed around the neck if time permits. As a stopgap, may use chest seal or secure around the neck with tie, ensuring inflation bulb does not get caught.
13. Consider placing NG/OG tube if available.

APPENDIX F: POST CRICOTHYROTOMY/ENDOTRACHEAL INTUBATION CHECKLIST

POST CRICOTHYROTOMY/ENDOTRACHEAL INTUBATION CHECKLIST

- ☐ Double check placement with waveform capnography or capnometry, placed directly on ET tube adapter.
- ☐ Check proper tube depth (not main stem) by auscultating bilateral lung sounds
- ☐ Check that tube is secured (suture to skin + tie with girth hitch around neck, should be able to fit 2 fingers under the tube tie)
- ☐ Bag-valve-mask (BVM) with positive end-expiratory pressure (PEEP) valve @ 5 of PEEP at proper volume (one hand moderate squeeze) and proper rate (one squeeze every 5-6 seconds)
- ☐ Provide adequate analgesia and sedation (follow analgesia and sedation CPG)
- ☐ Calculate remaining medication and establish analgesia and sedation plan. A patient with a cricothyroidotomy may not require heavy continuous sedation.
- ☐ Raise the head and torso to 30 - 45°
- ☐ Filter and humidify the air with a heat moisture exchanger. Place HME in-line distal to $EtCO_2$ device.
- ☐ As needed, place in-line suction for the tube, and suction the mouth for any excess secretions
- ☐ Check cuff pressure (palpate bulb – should be moderately firm but still compressible)
- ☐ Place orogastric tube, if available.
- ☐ Put a BVM +PEEP valve at the bedside if using a mechanical ventilator.
- ☐ Decontaminate the mouth with chlorhexidine swab or toothbrush without paste as per the nursing care plan.

APPENDIX G: WAVEFORM CAPNOGRAPHY & PULSE OXIMETRY INTERPRETATION

WAVEFORM CAPNOGRAPHY (END TIDAL CO2 (ETCO2)) AND PULSE OXIMETRY (SPO2) INTERPRETATION

Detection of ETCO2 is the most reliable way to continuously monitor ventilation and therefore confirm placement of an advanced airway (the only exception is during CPR when ETCO2 may be undetectable). Waveform capnography is the preferred method to detect ETCO2, and with the development of small, portable devices, is the recommended technique even in austere field environments. Inexpensive colorimetric CO_2 detectors are available, however the color change method may be very difficult to visualize with poor lighting or night vision devices. Waveform capnography measures the end-tidal carbon dioxide that passes through the device as the patient exhales in real time since it is placed directly in-line with the endotracheal tube. ETCO2 may also be attached to a face mask to verify normal and spontaneous breaths, if an advanced airway has not been placed. With most portable, field capnographs, a number in mmHg will be appear on the display, which indicates the value of the CO_2 in the exhaled breath and can be an immediate confirmation of correct tube placement. If the airway was placed correctly, and the patient is ventilating normally, the capnograph should read between 35-45 mmHg. Some other examples include:

- ETCO2 = 0: the tube is not transmitting any CO_2: disconnected, tube placed in wrong position or has become dislodged. This may also occur if the patient is dead and there is no gas exchange.
- ETCO2 <35: Hyperventilation. The most common cause is over-bagging the patient, but may also indicate pain or anxiety. The only indication for "induced" hyperventilation is severe traumatic brain injury with signs of acute herniation, GOAL = 30-35 (no less than 30)
- ETCO2 >45: Retaining CO_2, ineffective ventilation may indicate oversedation, primary lung problem, brain injury, worsening obstructive disease (asthma). If the trend is rising, this is an indicator of need for active ventilation assistance (BVM or mechanical ventilator)

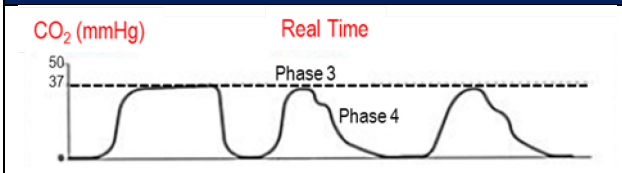
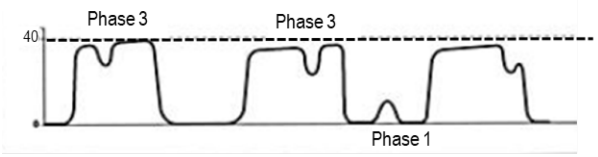
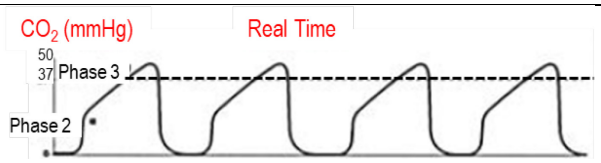
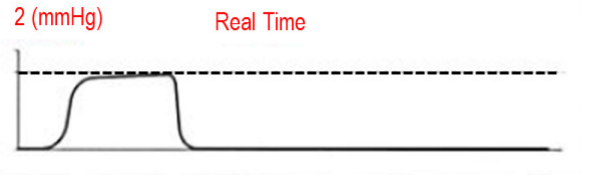
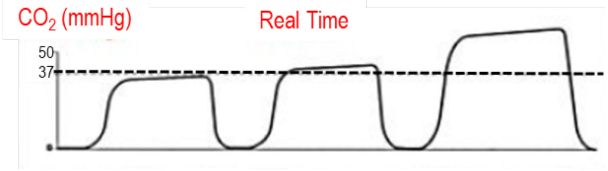
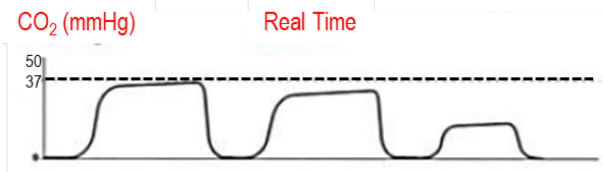
During CPR (as an indicator of effectiveness of chest compressions and return of circulation):

- ETCO2 < 10: there is no return of CO_2 to the lungs (no effective circulation). If CPR is initiated, it is ineffective
- ETCO2 = 10-20: EFFECTIVE CPR
- ETCO2 = 40 OR GREATER: You may see an abnormally high CO_2 reading immediately after return of spontaneous circulation (ROSC), for instance after a successful defibrillation or return of effective cardiac activity.

Monitor that can provide waveform capnography can provide much more insight into a patient's ventilation and oxygenation status. A quick reference to the most common waveforms is helpful to understanding the status of a patient.

Pulse oximetry is also of use in monitoring the oxygenation status of a patient. It can be an indirect measure of oxygen delivery to the tissues, and overall pulmonary function. Pulse oximetry monitors oxygenation by measuring absorbance differences between oxyhemoglobin and deoxyhemoglobin through the use of an infrared light. Pulse oximetry, however, has some important key limitations. A pulse oximetry reading indirectly reflects the patient's central (pulmonary) oxygenation status by measuring the peripheral oxygenation. This means that any intervention that addresses oxygenation in the lungs may not be detected by the pulse oximeter until 30-90 seconds after the intervention.

Additionally, if the patient is suffering from carbon monoxide or some other forms of poisoning, the pulse oximetry may read inaccurately. Also, a strong peripheral pulse and warm extremity are required to perfuse the capillary beds of the extremities and allow the pulse oximeter to obtain a valid measurement, therefore it may be difficult to measure in cold or hypotensive patients.

CAPNOGRAPHY (ETCO2) WAVEFORM	CHARACTERISTICS	CONSIDERATIONS
	**Cuff Leak** Waveform degrades sharply	• Check ET Tube for leak and replace as necessary (recommend exchange over a bougie)
	**Curare Cleft** Cleft or notch in waveform	• Represents asynchronous ventilation • Reassess patients level of sedation and augment as needed
	**Obstruction** Classic shark fin pattern	• Represents bronchospasm or airway obstruction • Assess for Hx of asthma, kinked ET tube, foreign body in airway or other anatomical airway obstruction.
	**Loss of Waveform** Normal waveform and then no waveform	• Assess for total airway obstruction, apnea, or cardiac arrest. • Assess ET tube for dislodgement and/or the need for suction • Check equipment for failure
	**Increasing ETCO2** Waveform increases in amplitude and width	• Assess for insufficient respirations, if breathing spontaneously, and treat underlying cause • Assess for respiratory failure • Assess for temperature increase • Consider increasing minute ventilation • Note: TQ release and sodium bicarbonate may cause a temporary increase in ETCO2
	**Decreasing ETCO2** Waveform decreases in amplitude and width	• Assess for tachypnea and treat underlying cause, if patient breathing spontaneously, • Assess for pulmonary embolism (If possible)

APPENDIX H: PEDIATRIC CONSIDERATIONS

PEDIATRIC CONSIDERATIONS FOR MSMAID & AIRWAY MANAGEMENT

MSMAID:

Similar to adult patients, the same preparatory steps should be followed prior to pediatric airway intervention. There are, however, significant differences with respect to equipment requirements and provider skill level. The core principles of MSMAID remain the same, with the following considerations:

- **Machine** – Continuous ventilation requires specific rate and volume based on the patient's age/size. Ensure your equipment (ventilator) and/or BVM can provide the required rate and volume prior to intubating or performing advanced procedures.[1,2]
- **Suction** – Similar to adults, ideally you can provide in-line suction, but you also will at a minimum need the correct size tubes to be able to provide suction
- **Monitor** – having pediatric sized equipment is essential as well as being able to adapt to pediatric sizes using adult monitors
- **Airway** – Multiple sizes of tubes are essential and proper pre-mission logistic planning includes pediatric supplies
- **Intravenous access** – Ensure you have pediatric sized needles with 24, 22, 20 and 18g as the primary access based on age of the patient. Pediatric intraosseous needles may be required.
- **Drugs** – Ensure you have a drug estimation guide, but always double check pediatric weight-based doses and measurements.

ADDITIONAL EQUIPMENT

1. Broselow Tape or similar height-based treatment aids.[3]
2. Video Laryngoscopy (VL) – While this is frequently an adjunctive (better/best) consideration for adult airway management, in the case of pediatric airways, VL has been shown in studies to out-perform direct laryngoscopy.[4-6]
3. Pediatric Kit – Pediatric airway equipment should be pre-packaged and set apart to allow for a rapid inclusion or addition to baseline airway kits.

ESSENTIAL MEASUREMENTS AND FORMULAS

Unlike adult airways that are narrowest at the level of the vocal cords (and therefore visible during DL or VL) pediatric tracheas are narrowest at the infraglottic level (19). In consideration of this, the following formulas and treatment aids are presented to best estimate tube sizes and measurements:

1. ETT size: age/4 +3.5. [7]
2. ETT insertion depth (for children over 1 year of age) in centimeters: age/2 + 13
3. ETT insertion depth (for children under 1 year of age) in centimeters: weight/2 + 8
4. Tidal volume: 5-8 cc/kg, rate concordant with pre-arrest breathing or rate prior to intervention. PALS recommends initial rate of at least 10-12 breaths/minute.[1,2]
5. Use caution with BVM, especially if improvising with adult BVM. Inflate gently only until the chest begins to rise. Surgical Airway Management

LMAs should be the first choice in all children prior to consideration of surgical intervention. Surgical airways should NOT be attempted on children younger than 12 years of age given the maturity of the thyroid cartilage and the cricothyroid membrane. It should never be attempted in children where the thyroid cartilage cannot be palpated. For children needing advanced airway intervention younger than 12 years of age, a combination of bag-valve-mask ventilation or placement of a supraglottic airway is recommended.[8,1]

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APPENDIX I: AIRWAY MANAGEMENT (USING MSMAID) IN PROLONGED FIELD CARE: SUMMARY TABLE

GOAL/CAPABILITY	MINIMUM	BETTER	BEST
MACHINE: Equipment needed post-intubation	Bag-Valve-Mask (BVM) with PEEP valve	• Automated portable ventilator (preferably with PEEP) • Oxygen concentrator	• Full-feature portable ventilator (e.g.; several ventilatory modes, PEEP) • Supplemental oxygen if available
SUCTION	• Improvised suction, such as using syringe + nasopharyngeal airway (NPA) • Patient positioning if not contraindicated	• Manual suction bulb with adapter	Powered commercial suction with oral tip In-line endotracheal tube suction adapter
MONITOR: Monitoring and telemedicine support	• Pulse oximeter (SpO2) • Assistant to monitor respirations and record manual vital signs • Trending vital signs documentation • Voice or data connections to perform telemedicine communication	• Portable Capnometry ETCO2) /capnography in addition to SpO2 • Transmit photographs from smartphones or personal devices to augment telemedicine communications	• Automatic vital signs monitor with SpO2, ETCO2/waveform capnography, +/- electrocardiogram (EKG) • Synchronous (real-time continuous) telemedicine using video or remote patient monitoring systems
AIRWAY	Ketamine cricothyroidotomy	Add ability to provide continuous sedation	Add a responsible rapid-sequence intubation capability (to include chemical paralysis) with airway maintenance (to include suction) and continuous sedation
AIRWAY: Verify proper tube placement	• Visualization of the tube passing through the vocal cords (in the case of endotracheal intubation) • Auscultation of epigastric region (should be silent) and bilateral lung sounds (should be present) • Colorimetric capnography + endotracheal detection device (EDD) • Easy bilateral rise and fall of the chest + misting of the tube + no signs of gastric insufflation	• Minimum plus portable capnometer • Ultrasound if trained/available to guide and/or verify placement	Continuous ETCO2/waveform capnography
IV/IO ACCESS	• If IV/IO attempts fail or when unavailable: medication may be given intramuscularly or intranasally for immediate sedation to facilitate surgical cricothyroidotomy • Continue attempts at IV/IO access after airway has been controlled	1-2 patent IV/IO	2-3x patent intravenous (IV) / intraosseous (IO) with additional IO device on standby

GOAL/CAPABILITY	MINIMUM	BETTER	BEST
DRUGS: Airway placement	• Local anesthetic for cricothyroidotomy (superficial skin anesthesia plus 1-2 mL injected through the cricothyroid membrane) • Placement without medications in unconscious patient • Also: most sedating agents can be given IM if IV/IO has not been established	Any IV/ IO sedating agent (i.e. opioid, benzodiazepine)	• Procedural dose ketamine (1-2 mg/kg IV push) for ETT or cricothyroidotomy placement • Local anesthetic (lidocaine) for cricothyroidotomy placement
DRUGS: Prolonged sedation (post-placement)	No I.V. access: ketamine (sedation dose), 3-4mg/kg IM	IV/ IO pushes of ketamine, opioid, and/or midazolam (alone or in combination as per the individual's scope of practice, experience and availability of medications)	• Ketamine I.V./ IO Drip • Hydromorphone or alternate opioid IV/IO push for breakthrough pain • Midazolam IV/IO push as needed for sedation
Airway Equipment	• Nasopharyngeal airway • Cricothyrotomy kit • BVM with PEEP valve	• Minimum PLUS supraglottic airway • Gum elastic bougie to facilitate intubation • Nasogastric/orogastric tube	• Better PLUS endotracheal tubes • Direct laryngoscopy or video laryngoscopy equipment
Waveform Capnography	Colorimetric $EtCO_2$ detector	Portable capnometer	Waveform capnography on patient monitor

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APPENDIX J: ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGS

PURPOSE

The purpose of this Appendix is to ensure an understanding of DoD policy and practice regarding inclusion in CPGs of "off-label" uses of U.S. Food and Drug Administration (FDA)–approved products. This applies to off-label uses with patients who are armed forces members.

BACKGROUND

Unapproved (i.e. "off-label") uses of FDA-approved products are extremely common in American medicine and are usually not subject to any special regulations. However, under Federal law, in some circumstances, unapproved uses of approved drugs are subject to FDA regulations governing "investigational new drugs." These circumstances include such uses as part of clinical trials, and in the military context, command required, unapproved uses. Some command requested unapproved uses may also be subject to special regulations.

ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGS

The inclusion in CPGs of off-label uses is not a clinical trial, nor is it a command request or requirement. Further, it does not imply that the Military Health System requires that use by DoD health care practitioners or considers it to be the "standard of care." Rather, the inclusion in CPGs of off-label uses is to inform the clinical judgment of the responsible health care practitioner by providing information regarding potential risks and benefits of treatment alternatives. The decision is for the clinical judgment of the responsible health care practitioner within the practitioner-patient relationship.

ADDITIONAL PROCEDURES

Balanced Discussion

Consistent with this purpose, CPG discussions of off-label uses specifically state that they are uses not approved by the FDA. Further, such discussions are balanced in the presentation of appropriate clinical study data, including any such data that suggest caution in the use of the product and specifically including any FDA-issued warnings.

Quality Assurance Monitoring

With respect to such off-label uses, DoD procedure is to maintain a regular system of quality assurance monitoring of outcomes and known potential adverse events. For this reason, the importance of accurate clinical records is underscored.

Information to Patients

Good clinical practice includes the provision of appropriate information to patients. Each CPG discussing an unusual off-label use will address the issue of information to patients. When practicable, consideration will be given to including in an appendix an appropriate information sheet for distribution to patients, whether before or after use of the product. Information to patients should address in plain language: a) that the use is not approved by the FDA; b) the reasons why a DoD health care practitioner would decide to use the product for this purpose; and c) the potential risks associated with such use.