Contract Number: W81XWH-17-P-0022 Support the (TCCCR) Task Area for Research and Development of Medical Equipment to Clear and Maintain a Combat Airway

A Report on Deliverable One: Determine Required Performance Characteristics [of Suction] for Management Of Prehospital Combat Casualty Care Injuries.

Report Author: Robert A. De Lorenzo, MD, MSCI, MSM, FACEP Department of Emergency Medicine UT Health San Antonio

22 February 2017

Table of Contents

Objective of the Report	4
Background	4
Combat Casualty Care and Suction	6
Combat Versus Civil Sector Out-of-Hospital Care	7
Tiered Organization of Military Healthcare Delivery	9
Summary of the Background Sections	11
Recommendations of Background Section	11
Tactical Combat Casualty Care (TCCC) Guidelines	11
Summary of the Tactical Combat Casualty Care (TCCC) Guidelines Section	13
Recommendations of the Tactical Combat Casualty Care (TCCC) Guidelines Section	13
Suction Devices for Emergency and Combat Casualty Care	13
Suction Device Categories	13
Key Mechanics of Suction	15
Summary of the Suction Devices for Emergency and Combat Casualty Care Section	17
Recommendations of the Suction Devices for Emergency and Combat Casualty Care Se	<i>ction</i> 18
Manufacturing Standards for Suction Devices	18
ISO 10079-1 Medical Suction Equipment	18
Food and Drug Administration Regulations	20
Summary of the Manufacturing Standards for Suction Devices for Use in Combat and Emergency Care Section	20
Recommendations of the Manufacturing Standards for Suction Devices for Use in Comba and Emergency Care Section	ət 21
Textbooks in Prehospital Combat Casualty Care	21
Summary of the Textbooks in Prehospital Combat Casualty Care Section	24
Recommendations of the Textbooks in Prehospital Combat Casualty Care Section	24
Peer-Reviewed Journals	25
Tubing and Tips	25
Portable Suction Devices	26
Fluid Viscosity and Particle Size	27
Other Performance Characteristics	27

Summary of the Peer-Review Journals Section	28
Recommendations of the Peer-Review Journals Section	29
Summary and Conclusions	29
Acknowledgements	30
Appendix A - Section Summaries and Recommendations	31
Appendix B - Key Task of the Report	35
Appendix C - Technical Approach	36
References	38

Objective of the Report

Determine required performance characteristics (primarily vacuum suction flow rate, pressure, and fluid/particle viscosity/size) for management of prehospital Combat Casualty Care injuries. This is a requirements-based analysis derived primarily from combat data and supplemented with physiologic data, medical literature and industry standards.

Background

Tactical airway management often determines survival in both trauma and medical patients. Skilled interventions often make the critical difference in survival for patients with actual or impending airway compromise. Managing airways in the tactical environment presents an additional level of unique and complex challenges for any emergency provider. Hazardous or confined spaces and hostile action inherently limit the ability to intervene with an artificial airway or assisted ventilation. Loss of patient airway in tactical and combat environments commonly occurs. The proximate cause can be direct trauma to the airway structures or indirectly from traumatic shock or brain injury and the subsequent loss of airway protective reflexes.

In the Vietnam War, 6% of all soldiers killed in action only had an airway obstruction. More recent conflicts, notably Operation Iraqi Freedom (OIF), have shown an increase in primary injuries to the airway. In OIF, 27% of wounded in action suffered injuries only to the head, neck or airway structures.¹ This increase in airway trauma is likely due to the excellent torso protection of body armor and a subsequent diversion of injuries towards less armored areas such as the neck and face. The Registry of Emergency Airways at Combat Hospitals study (REACH) shows that prehospital cricothyrotomies are performed ten times more often on the battlefield as compared to civilian trauma systems. (5.8% vs. 0.5%).¹ A recent study highlights the high incidence of combat airway injury in combat maxillofacial trauma.² In these and other trauma cases, airway management requires a low threshold for airway stabilization to include tracheal intubation and cricothyrotomy or tracheostomy. A major reason for this dramatically higher rate of surgical airways is poor visualization of the injured airway with current inadequate suction devices available on the battlefield.

Aspiration of as little as 25 mL (approximately ¼ mouthful) of vomitus can cause significant pulmonary aspiration injury, and a massive aspiration carries a mortality as high as 70%.^{3,4} Delays in suction can presumably increase the risk of aspiration,

obstruction-related hypoxia, and make visualized intubation of the trachea impossible, so the availability and performance of suction can be viewed as essential. Despite this, there is a paucity of high-quality evidence on the techniques of suction. A 2009 Cochrane review on suctioning of patients revealed limited scope of data.⁵ Practice guidelines from 2001 on hyperoxygenation, hyperinflation, use of a ventilator circuit adaptor and subglottic suctioning were validated. In the review, new evidence was identified with respect to indications for suctioning, open suction versus closed suction systems, use of medications and infection control. Virtually all of the data was focused on in-hospital suctioning of primarily mechanically ventilated patients. There were no high-quality reports focusing on prehospital or emergency care in the Cochrane review.

The combat experience of the last dozen years clearly demonstrates that airway obstruction is the leading cause of preventable combat casualty deaths behind only hemorrhagic shock. Between 6-10% of battlefield deaths could have been prevented with adequate airway management.⁶ Because of vastly improved body armor and the enemy's shift towards direct fire and improvised explosive devices, the injury pattern today is much different than in previous wars. Airway management in this austere environment is notoriously difficult for many reasons but especially because of inadequate airway equipment.

In comparison to the advances in many areas of prehospital equipment, the current suction devices on the market have not achieved the level of performance required in civilian prehospital care, let alone battlefield care. It is telling that a recent 5 page review article on an advances in technology and concepts in tactical combat casualty care, there was no mention of suction and only this to say about airway management advances in general:⁷

Airway Protection: A skill common to all physicians deploying on the MERTE Medical Emergency Response Team (MERT)] is that they must be proficient at airway assessment and competent to definitively secure an airway if required. Generally, this takes the form of a rapid sequence induction using direct laryngoscopy. Several rescue devices are also available as alternatives or for use in a failed intubation such as supraglottic airways, optical laryngoscopes, and cricothyroidotomy.

Perhaps reflecting the perceived lack of effectiveness of prehospital suction devices, Kozak reported on a survey of paramedics carrying suction equipment to the scene of medical aid calls less than 25% of the time, and once on scene, suction equipment was utilized on only 50% of advanced airway procedures.⁸ It seems the available off-theshelf devices do not possess the proper balance of tradeoffs between portability, effectiveness and cost to be effective in tactical care.

There is limited information on the types, if any, of portable suction units carried by combat medics in the far-forward combat area. Anecdotal information suggests that powered suction devices are simply too heavy to be carried in the combat medic's aid kit. Manual powered devices, while lightweight, offer limited capability and require the use of a hand or foot to operate, limiting efficiency of the provider. Fielding data from military logistics agencies on the number and types of suction units employed in the field is not available, and prior experience suggests even if obtained, the data shows only total purchases and not where and when fielded.

Existing portable suction standards are civilian-oriented, lack a detailed base of evidentiary support, and in any case do not satisfy the critical needs of combat casualty care. We propose a set of performance standards that meet the needs of prehospital combat casualty care that could support a future development of a portable suction design that meets all of the combat medic's needs.

Combat Casualty Care and Suction

Over the past 15 years of wars, between 5-10% of the combat casualty population required emergency airway management and 6% of casualties arrived at a combat support hospital (CSH) without a definitive airway despite needing one.¹ Ten percent of combat deaths had airway compromise as the primary cause of death.⁶

Gunshot wounds (GSWs) and explosions were the most common mechanism of injury causing death in the recent wars.⁹ Most potentially survivable deaths due to airway obstruction were caused by GSWs to the upper airway structures.^{9,10} In the civilian setting, GSWs to the face require emergency airway management 35% of the time.^{11,12}

Since the end of the Vietnam War, there have been significant changes in protective equipment, weaponry, and tactics increasing the proportion of injuries to the face and neck. Data from US military casualties treated by US naval personnel between 2004 and 2010 revealed 23% of all injured casualties had combat-related maxillofacial injuries, with 4% of total casualties having severe maxillofacial injuries.² Of those with severe injuries, 51% required intubation prior to reaching a Role III Military treatment facility, and 19% underwent eventual tracheotomy reflecting the severity of anatomical disruption.²

Maxillofacial trauma can cause airway obstruction and loss of airway protection by multiple mechanisms including prolapse of the tongue base or maxillary structures, edema of the pharyngeal tissues, or hematoma formation. Bleeding into the airway from open wounds of the face, head, and oropharyngeal area will likely be copious, owing to the rich vascular supply of the head and face. Bleeding from the neck can be brisk, given the large vessels located there, and can easily pool in the upper airway. Hemoptysis from pulmonary injury can further increase the rate and amount of bleeding into the upper airway. Although clinical data is not available, it is easily conceivable that 200-400 mL/min of blood can hemorrhage into the airway from major vessel disruption. Vomiting can introduce significant volumes of fluid and partially digested food into the airway. While there is wide variation, the typical human adult stomach has a 1 liter capacity, most of which can be emptied through emesis. While the nondistended adult pharynx is considerably smaller, averaging 23 mL and the oral cavity averages 40 mL, repeated bouts of emesis can refill these cavities.^{13,14} Others report a mouthful to represent 90 mL.³ Distension of these structure might nearly double the volume to approximately 100 mL.

Importantly a combat casualty is likely to have concomitant shattering of bones, broken teeth, and avulsed tissue fragments. and introduction of mud, gravel and other debris mixed in with the blood and secretions. Failure to rapidly clear the fluids and particulates from the casualty's upper airway will likely lead to rapid and severe morbidity or death.

Combat Versus Civil Sector Out-of-Hospital Care

The "Fundamentals of Combat Casualty Care" chapter in the US Army Borden Institute textbook *Combat Casualty Care: Lessons Learned from Operation Enduring Freedom and Operation Iraqi Freedom* provides the following explanation for the key differences between combat casualty care and civilian prehospital care.¹⁵

While some similarities exist, out-of-hospital emergency care in combat or other military deployment settings often radically differs from civil sector practice in the United States. Beyond the challenges of individual patient care, harsh weather conditions, and austere settings, combat casualty care providers providing out-of-hospital care face unique tactical challenges.

For example, in civilian sector EMS, a common accident scene might include an ambulance crew routinely consisting of two or even three emergency medical technicians (EMTs), with at least one being an EMT-Paramedic. Often, firefighters will be present, bringing additional capability. Their ambulance, in most cases, will be stocked with a generous selection of basic and advanced life

support devices, monitors, and pharmaceuticals. This will generally include battery-powered "luggable" (the size of a small suitcase) suction units. While first responders often operate in harsh weather and austere settings, they do not typically encounter hostile fire while providing care. Thus, civilian sector out-ofhospital emergency care practitioners are able to fully focus on patient care and will have ready access to relatively heavy, battery-powered equipment including suction devices.

In contrast, a combat medic or other combat casualty care provider typically has a far more restricted ability to carry equipment and supplies. In many cases all available medical equipment is carried on the medic's person, in a rucksack, or otherwise harnessed to them. In some situations a vehicle or forward-operating medical unit (e.g., battalion aid station) is nearby and this may increase the availability of bulky and heavy equipment. In any event, there is likely to be only one medic, but there may be many patients, often severely wounded by highexplosive ordnance, vehicle fires, or small arms fire. The medic is appropriately focused on patient care, but must also be cognizant that the overarching priorities are the unit's integrity and mission. While working, the medic may become the target of hostile fire, and may have to return fire.

As highlighted above, tactical combat casualty care poses additional unique challenges compared to civilian practice. Combat casualty care providers are more likely to encounter mass casualty incidents and patients with catastrophic wounds. The epidemiology of wounding in OEF and OIF reveals a high incidence of penetrating trauma and blast-related mechanisms of injury.¹⁶ Casualty evacuations will tend to be longer in distance, duration and complexity, often necessitating longer duration of patient care. This latter aspect has been codified into doctrine and now termed "prolonged field care." Implicit in this concept is the requirement to care for severely injured casualties for a prolonged length of time (e.g., 72 hours) with limited availability of trained personnel, equipment and supplies. Prolonged field care is a particular condition of special operations missions that have a small footprint of personnel and materiel often occur in remote corners of the globe, far from logistical centers and without rapid evacuation capabilities.

In addition to the individual challenges of combat casualty care, several systemic issues pose significant obstacles to the optimization of combat casualty care in the modern battlespace. The most pressing of these issues is a lack of effective clinical data collection in the forward setting. Outcomes research in EMS is sparse in both the civilian sector and combat settings. Randomized, controlled,

prospective trials are the exception rather than the rule.¹⁷ Much of what is available comes in the form of case reports or series, focusing on single aspects of out-of-hospital combat casualty care or case series resulting from individual engagements.^{18,19} This is also true of data and information on suction devices.

Tiered Organization of Military Healthcare Delivery

An internationally-recognized textbook on emergency medical services and prehospital care entitled *EMS: A Practical Global Guidebook* provides in the "Military EMS Systems" chapter an adapted description of the tiered organization of medical care on the battlefield.²⁰ Tiered layers of care is an important doctrinal concept when discussing the employment of combat medical providers and fielding of medical equipment is the "role" of the medical provider or unit.

The military Roles of Care (formerly referred to as "Levels of Care," and before that "echelons") system describes a graduated hierarchy of combat medical care and facilities Treatment capabilities are roughly standardized for each role of care across the services, in compliance with the Joint Chiefs of Staff doctrinal directives.

Role 1 is located closest to the fighting, and thus, Role 1 care is austere and its elements are light and mobile. It includes four distinct levels of care: (1) self- and buddy-aid, (2) combat lifesaving, (3) combat medic care, and (4) "aid station care." Generally speaking, tactical combat casualty care is the primary responsibility of these role 1 medical providers and facilities. Self- and buddy-aid is the care rendered by the casualty himself or by his compatriot. It is essentially first aid. Combat lifesaver care is care by specially trained combatants who have advanced first aid training. Combat medic care is rendered by the first-line medical provider. This individual can, in addition to advanced first aid, initiate intravenous fluids, insert thoracostomy needles, and insert basic and advanced airways. The combat medic is also the first provider in the line to possess formal training on the use of suction devices.

For the U.S. Army and Marines, the battalion aid station is the first medical "facility" casualties will encounter, and may be staffed by physicians or physician assistants. It is austere and highly mobile, with advanced trauma life support capabilities, including endotracheal intubation, tube thoracostomy, intravenous medication and other physician-directed medical care. The equipment list for a battalion aid station generally does include a powered suction device. Navy ships

have a rough equivalent in various satellite "battle dressing stations" located remotely from the primary shipboard medical department.

Role 2 is a divisional level "clearing station" that is staffed by a medical company of physicians, nurses, and medics. Casualties are examined to determine treatment needs and evacuation triage priority. Emergency medical treatment, including initial comprehensive resuscitation, is provided, and is supported by limited radiographic, dental, and laboratory services with whole-blood transfusion capacity. Portable suction units are standard equipment in these units. The "clearing station" provides limited duration patient-holding capability for sick or injured personnel, roughly at the "general ward" level. Ship medical departments approximate this capability, as do the Marine Fleet Surgical Support Groups. Role 2 units can be supplemented with surgical capabilities such as a Forward Surgical Team

Role 3 is the first true "full service" medical facility that a casualty will encounter on the battlefield. At present, this is a U.S. Army "combat support hospital", the Air Force Theater Hospitals or Expeditionary Medical Support (EMEDS) facilities, the Navy fleet hospitals, and the major amphibious assault ships medical departments, if augmented by surgical support teams. Role 3 hospitals provide comprehensive resuscitative surgery and medical care. Medical providers at them include general surgeons, and both surgical and medical sub-specialists, with comprehensive anesthesia and nursing support. Patients who are unlikely to return to duty are evacuated as soon as possible from these facilities after stabilization. Several types of suction units are present in Role 3 facilities including hand-portable and cartable devices for emergency care and bedside use, larger non-portable suction devices for use in surgical operations.

Role 4 has been traditionally represented by comprehensive theater hospitals variously designated as General, Field, Theater Area, or Station Hospitals. These large and generally poorly mobile facilities are mostly obsolete. Exceptions include the Navy's two 1,000-bed hospital ships (USNS Mercy and USNS Comfort), Landstuhl Regional Medical Center in Germany, and any host nation hospitals with which the services may have developed official relationships. As in any modern hospital, an array of suction devices is available for use in all emergency, acute and critical care locations.

Role 5 represents fixed hospitals located outside the theater of operations in the continental United States. These are primarily military medical facilities, augmented within the United States by Veteran's Administration, and civilian

hospitals as part of the National Defense Medical System. Definitive and rehabilitative care of all types are found in role 5 facilities, and most have extensive medical education training programs.

Summary of the Background Sections

- Airway obstruction is the second leading cause of preventable battlefield death
- Suction is integral to management of airway obstruction.
- The nondistended volume of the human oropharynx is limited, approximately 65 mL. Distension might increase this volume to 100 mL.
- Up to 400 mL/min of blood and a total of 1 L of emesis can contaminate the upper airways.
- Airway secretions and blood will likely be mixed with bone fragments, broken teeth and other solids, making suctioning imperative.
- Powered suction is not available in far-forward combat casualty care areas.
- Limited information suggests manual suction devices are not carried or used by medics because of limited capability to evacuate secretions.
- The large size and heavy weight of existing powered portable suction units precludes their carry by combat medics.

Recommendations of Background Section

- Detailed fielding data on the types of suction in current use in far-forward combat environments would establish a clear baseline of current availability of suction devices.
- Combat casualty care provider (e.g., medic) user feedback would establish a clear baseline of prime user preferences.

Tactical Combat Casualty Care (TCCC) Guidelines

The inadequacy of applying a civilian trauma model to tactical situations has long been recognized. ^{18,21} The Tactical Combat Casualty Care (TCCC) program was initiated by the Naval Special Warfare Command in 1993, and later continued by the U.S. Special Operations Command (USSOCOM). This effort developed a set of tactically appropriate battlefield trauma care guidelines that provide combat casualty care providers with trauma management strategies that combine good medicine with good small-unit tactics.²¹ TCCC guidelines recognize that trauma care in the tactical

environment has three goals: (1) treat the casualty; (2) prevent additional casualties; and (3) complete the mission.

The overarching goal of the TCCC initiative was the combination of good tactics with good medicine. As the name implies, TCCC is practiced during combat missions. TCCC was originally conceived as comprising three phases: (1) care-under-fire; (2) tactical field care and (3) tactical evacuation care. Prolonged field care, while not a separate phase, can be conceived as a merging of tactical field care and tactical evacuation in the context of a long time duration, typically many hours to several days.

Current TCCC guidelines do not mention suction, and the relevant sections state in part:²²

Care Under Fire Guidelines

Casualty with airway obstruction or impending airway obstruction:

- Chin lift or jaw thrust maneuver
- Nasopharyngeal airway
- Allow a conscious casualty to assume any position that best protects the airway, to include sitting up.
- Place unconscious casualty in the recovery position.

Tactical Field Care Guidelines

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 the previous measures are unsuccessful, assess the tactical and clinical situations, the equipment at hand, and the skills and experience of the person providing care, and then select one of the following airway interventions:
 - Supraglottic airway, or
 - o Endotracheal intubation or
 - *Perform a surgical cricothyroidotomy...*

Again, no mention is made of suction or suction devices. We can presume that suction is critical for the management of a casualty with airway obstruction, but the omission

from the TCCC guidelines reflects the pragmatic assumption that no suction device is likely to be available to the combat casualty care provider.

Summary of the Tactical Combat Casualty Care (TCCC) Guidelines Section

- Airway management is emphasized as a high priority in TCCC guidelines.
- Management of secretions is emphasized with simple maneuvers such as recovery position emphasized.
- Suction is not mentioned as an intervention and the rationale for this is not specified.
- TCCC guidelines place a premium on small, lightweight and effective implements that can easily be carried by the combat casualty care provider; presumably current suction devices do not meet this threshold.

Recommendations of the Tactical Combat Casualty Care (TCCC) Guidelines Section

- Specifically query the Committee on Tactical Combat Casualty Care (CoTCCC) for their guidance on the use of suction
- Specifically petition the CoTCCC to place the need for far-forward suction capability on their list of priorities

Suction Devices for Emergency and Combat Casualty Care

Suction Device Categories

Suction devices for use in emergency and combat casualty care can generally be divided into three categories:

- 1. Manually powered devices
- 2. Electrically powered devices (usually battery powered)
- 3. Fixed vacuum system devices that rely on piped wall suction

For purposes of this report, the focus will be on the first two categories, as fixed systems are not relevant to the mobile needs of far-forward combat casualty providers. Suction units can also be subdivided into the following two categories based on the location of intended use:

- 1. Field devices that are intended to be carried by the individual prehospital provider. These devices are relatively lightweight and compact.
- 2. Portable or "luggable" devices that are intended to be carried in a transport vehicle or used a stationary machine in a temporary facility such as an aid station.

The following figures depict typical current examples of portable suction units.

Figure: Example medical suction devices, for use in the prehospital environment. From left, SSCOR QuickDraw Jr. Laerdal V-Vac and Ambu Rescue Pump.



Photo Credit: SSCOR, Sun Valley, <u>www.sscor.com</u>; Laerdal, Wrappinggers Falls, NY, <u>www.laerdal.com</u>; Ambu, Ballerup, Denmark, <u>www.ambu.com</u> COPYRIGHTED FIGURE – PERMISSION PENDING – NOT FOR PUBLICATION Figure: Example medical suction devices, for use in transport or other emergency care environments. From the left, Laerdal Suction Unit, Spencer Jet Compact, S-SCCOR VX-2.



Photo Credit: Laerdal, Wrappinggers Falls, NY, <u>www.laerdal.com</u>; Spencer USA, <u>www.spencer.it/en</u>; SSCOR, Sun Valley, <u>www.sscor.com</u> COPYRIGHTED FIGURE – PERMISSION PENDING – NOT FOR PUBLICATION

Key Mechanics of Suction

The Hagen–Poiseuille equation relates flow, pressure and the viscosity of a fluid. For a Newtonian (linear mechanics) fluid, flow rate is proportional to pressure and viscosity.

$$\frac{\mathrm{dP}}{\mathrm{dx}} = \frac{8\mu LQ}{\pi r4} = \frac{128\mu LQ}{\pi \,\mathrm{d4}} \cong \Delta P$$

Where

 $\frac{dP}{dr}$ and ΔP are the pressure change [dP/dx]

L is the length of tubing

μ is the dynamic viscosity,

Q is the volumetric flow rate,

r is the pipe radius,

d is the diameter

 π is the mathematical constant pi.

Thus, for a given length of suction tubing and diameter, flowrate is proportional to the pressure and inversely proportional to the fluid viscosity. For a given pressure, flowrate is proportional to the tube length and the 4th power of radius or diameter. This latter fact

underscores the importance of tube diameter to flowrate and small increases in tube cross section can result in large changes to flowrate.

Viscosity is the resistance to flow due to neighboring particles in a fluid. That is it is the "thickness" of the fluid. For example, water has a reference viscosity of 1 centipoise (cP) and blood typically 3-6 times as viscous at 37° C. Air, of course, is two orders of magnitude less viscous than water or nearly 74 times less viscous than blood. Thick mucus secretions can be 100-150 times as thick as the thickest blood.²³ Increased viscosity has the net effect of proportionally reducing flow rates for any given tubing diameter and length.



Figure: Flow of water compared to SAE 40 motor oil (simulating very thick mucus secretions) at different settings of the pressure regulator.

Photo Credit: Paulsen, AW: Are There Guidelines For Anesthesia Suction? APSF Newsletter, February 2015. Volume 29, No. 3, 41-64. Anesthesia Patient Safety Foundation, Indianapolis, IN. http://www.apsf.org/newsletters/html/2015/February/pdf/Feb2015.pdf COPYRIGHTED FIGURE – PERMISSION PENDING – NOT FOR PUBLICATION Table: Viscosity of various substances that may require suctioning during an anesthetic compared to the viscosity of SAE 40 motor oil.

Substance	Viscosity, cP at room Temp	Reference
Air	0.081	http://hyperphysics.phy- astr.gsu.edu/hbase/tables/viscosity.html
Water	1.0	http://hyperphysics.phy- astr.gsu.edu/hbase/tables/viscosity.html
Whole Blood	3.6 - 6.0	http://ltd.aruplab.com/tests/pub/0020054
Gastric Mucus	75 - 230	Curt JRN, Pringle R. Viscosity of gastric mucus in duodenal ulceration. Gut 1969;10: 931-934.
SAE 40 Motor Oil	650 -900	http://www.vp-scientific.com/Viscosity_Tables.htm
Sputum	148 – 15,000	Picot R, Das I, Reid L. Pus, deoxyribonucleic acid, and sputum viscosity. Thorax 1978;33:235-242, & Jenssen AO. Scanning of viscosity in sputum. Scand J Respir Dis 1976;57:31-36.

Adapted from Paulsen, AW: Are There Guidelines For Anesthesia Suction? APSF Newsletter, February 2015. Volume 29, No. 3, 41-64. Anesthesia Patient Safety Foundation, Indianapolis, IN.<u>http://www.apsf.org/newsletters/html/2015/February/pdf/Feb2015.pdf</u>

Interestingly, there is no mention in the manufacturing standards (see next section) or in other documents for a standard reflecting particulate matter. A combat casualty is likely to have severe injuries, with shattered bones, broken teeth, mud, gravel and tissue debris mixed in with the blood and secretions.

Summary of the Suction Devices for Emergency and Combat Casualty Care Section

• Suction devices can generally be divided into three categories based on their power source: manual, electrical (battery) and fixed vacuum systems.

- Flowrate is proportional to the pressure and inversely proportional to the fluid viscosity.
- Flowrate is proportional to the tube length and the 4th power of radius or diameter of the tube.
- Flowrate standards based on free flow of air are unlikely to be relevant to the suctioning of secretions and blood.

Recommendations of the Suction Devices for Emergency and Combat Casualty Care Section

• Flowrate performance should be measured using a fluid that has been shown to mimic the secretions and blood anticipated in a combat casualty.

Manufacturing Standards for Suction Devices

A review of the available literature reveals no standards, either proposed, validated or accepted for the performance of a portable suction device for use in combat casualty care. Similarly, there are no accepted standards to guide the performance suction for use in prehospital or emergency care. There are, however some sources that inform the discussion.

ISO 10079-1 Medical Suction Equipment

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. ISO normally focuses on technical and engineering aspects of a machine and in general, they do not address medical standards, *per se*. ISO is generally used by manufacturers seeking to document they have produced products that have met certain standardization guidelines. ISO is not normally considered applicable to the actual practice of patient care in the clinical environment.

ISO 10079 is a standard with the most recent available date of 2014-15 (the range reflects the different subparts of the ISO document).^{24,25,26} Compliance with ISO is voluntary but generally expected since unless a governmental body (e.g., Food and Drug Administration) requires it.

It is important to recognize that ISO 10079 covers suction devices in general, that is, it encompasses the universe of all medical suction devices. Suction devices for use in

prehospital care are just a subset and not all of ISO 10079 is relevant to this environment, let alone combat. In fact, much of the ISO standard represents good manufacturing practice, safety standards, and design implications that would all likely be transparent to the clinician. Nevertheless, the standard contains a number of relevant design and performance requirements for portable suction devices that may or may not apply to the combat casualty care environment. A select list of characteristics follows; readers are referred to the full ISO document for additional details.

- Dimensional Characteristics
 - Size: Device, including any carrying case or frame shall pass through a rectangular opening having dimensions of 600 mm × 300 mm (23.6 x 11.8")
 - $\circ \quad \text{Weight} < 6\text{kg} (13.2 \text{ lb})$
 - Effluent container > 300mL for field use, > 500 mL for transport use
 - Minimum inside diameter of suction tubing 6mm
- Performance Characteristics
 - Vacuum pressure: > 60 kPa (450 mm Hg)
 - Flow rate: > 20 L/min of air
 - Battery power: operate > 20 min @ free air flowrate > 20 L/min and a vacuum > 40 kPa (300 mm Hg)
 - Noise maximum 70 dBA

Thick mucus secretions can be 100-150 times as thick as the thickest blood. Yet the ISO standard is for the free flow of air. The graph in the previous section shows the effect of different fluids on the flow rate. The net result is a dramatic decrease in the effective flow rate to the order of 180 mL/min, which is likely to be inadequate in the case of copious fluids.

Interestingly, there is also no mention in the ISO standards or in other documents for a standard reflecting particulate matter. A combat casualty is likely to have severe injuries, with shattered bones, broken teeth, mud, gravel and tissue debris mixed in with the blood and secretions. Thus, it is unclear if devices that meet the ISO standard would be effective in battlefield medicine.

The key performance standards of vacuum pressure and flowrate are similarly not validated against the clinical needs of prehospital and combat casualty care. In this fashion, an interesting commentary on the performance standards can be found in a newsletter from Anesthesia Patient Safety Foundation.²³

ISO 10079 represents a minimum standard for portable manual and electrically powered suction devices. There is little indication in the standard that these minimums

are satisfactory for either prehospital or combat casualty care use. Of note, the size and weight standards are far above that expected to be hand-carried by a combat medic.

Food and Drug Administration Regulations

The Food and Drug Administration (FDA) classifies medical devices according to their hazard risk.²⁷ Devices are classified into one of three categories—Class I, Class II, and Class III. Class I devices are deemed to be low risk and are therefore subject to the least regulatory controls. Class II devices are higher risk devices than Class I and require greater regulatory controls to provide reasonable assurance of the device's safety and effectiveness. Class III devices are generally the highest risk devices and are therefore subject to the highest level of regulatory control. Class III devices must typically be approved by FDA before they are marketed. Class II devices are subject to much more stringent regulations that that of a Class I device.

Powered suction devices are considered a class II device by the FDA. Below are the several devices related to emergency suction devices and their classification.

Device Nomenclature	Regulation Number	<u>Class</u>
Patient care suction apparatus	870.5050	II
Catheter and tip, suction	880.6740	II

Class II devices are medical devices which pose a higher level of risk to a patient and as such require additional regulation to ensure the safety and effectiveness of the device. Class II medical devices are devices, which if they fail, can cause injury but not death to a patient who uses them. The regulatory controls that are put into place include a premarket authorization, post market analysis, and adherence to national and international performance standards.

There are no specific FDA guidelines or regulations regarding emergency suction devices.

Summary of the Manufacturing Standards for Suction Devices for Use in Combat and Emergency Care Section

• Suction devices are FDA class II

- ISO 10079 provides detailed standards for suction devices intended for use in emergency and prehospital care.
- There are minimum performance standards for suction devices, but they have not been validated clinically or operationally, and may be inadequate for emergency and prehospital care.
- The standards are unlikely to be applicable to combat casualty care environments

Recommendations of the Manufacturing Standards for Suction Devices for Use in Combat and Emergency Care Section

• Establish clinical standards for suction use in prehospital and far-forward combat casualty care environments.

Textbooks in Prehospital Combat Casualty Care

In care-under-fire, combat medical personnel and their units are presumed to be under effective hostile fire, and the care they are capable of providing is very limited. In the tactical field care phase, medical personnel and their casualties are no longer under effective hostile fire, and more extensive care can be provided. In the tactical evacuation phase, casualties are transported to a medical facility by an aircraft, ground vehicle, or boat and there is an opportunity to provide additional medical personnel and equipment to further increase the level of care rendered.

Because the large size and heavy weight of battery powered suction units has generally precluded them from being included in the kit carried by ground combat medics, the use of powered suction devices has generally been omitted from standard texts and resources for TCCC. The sentinel 1999 textbook Tactical Emergency Care made reference to the management of secretions from a combat casualty through use of the recovery (lateral recumbent) position.²⁸ More recently, textbooks for the combat medic provide only slightly more detail on the use of portable powered suction equipment. For example, the 2012 US Army publication entitled *Tactical Combat Casualty Care: Lessons and Best Practices* makes no mention of suction and has just three paragraphs relevant to clearance of the airway:²⁹

In the tactical field care phase, direct initial management to the evaluation and treatment of the casualty's airway once all hemorrhage problems have been addressed. Intervention should proceed from the least invasive procedure to the

most invasive. Do not attempt any airway intervention if the casualty is conscious and breathing well on his own. Allow the casualty to assume the most comfortable position that best protects his airway, to include sitting upright.

Unconscious casualty without airway obstruction. If the casualty is unconscious, the most likely cause is either hemorrhagic shock or head trauma. In either case, an adequate airway must be maintained. If the unconscious casualty does not exhibit signs of airway obstruction, the airway should first be opened with a chin lift or a jaw-thrust maneuver. As in the care under fire phase, cervical spine immobilization is generally not required, except in the instance of significant blunt trauma.

If spontaneous respirations are present without respiratory distress, an adequate airway in the unconscious casualty is best maintained with a nasopharyngeal airway (NPA). An NPA is preferred over an oropharyngeal airway because it is better tolerated if the casualty regains consciousness and is less likely to be dislodged during casualty transport. After inserting the NPA, place the casualty in the recovery position to maintain the open airway and prevent aspiration of blood, mucous, or vomit.

Another recent textbook focusing on the combat medic and tactical combat casualty care provides one of the few references to suction. It is a 2009 edition entitled *68W Advanced Field Craft: Combat Medic Skills.*³⁰ In the section on airway management, it describes the technique of suctioning a casualty's oropharynx. However, on careful review the information differs little from that provided in standard civilian-style emergency medical technician (EMT) textbooks from which it appears to be derived. That is, the suction technique described is exactly the same as civilian EMT textbooks with adjustments made to photos to reflect military uniforms on the providers and casualties. No detail is provided on the equipment or performance requirements of the suction devices.

Figure: Technique of suctioning a casualty as detailed in a combat medic textbook.



Photo Credit: US Army. 68W Advanced Field Craft: Combat Medic Skills 1st ed. Jones & Bartlett Learning; 1 edition, 2009, Burlington, MA. COPYRIGHTED FIGURE – PERMISSION PENDING – NOT FOR PUBLICATION

A review of civilian EMT and paramedic textbooks as well as a select sample of textbooks in the fields of respiratory therapy, anesthesia, and emergency medicine reveals a paucity of information relevant to suctioning in tactical combat casualty care. One notable exception is Roberts and Hedges' Clinical Procedures in Emergency Medicine.³¹ It notes several points related to the performance of suction:

- A large bore dental-type tip should be used because it allows clearing of vomitus, hemorrhage, and secretions.
- 5/8 inch suction tubing should be used as larger diameters are more effective.
- Clogging is a common problem and devices such as traps can mitigate.
- Equipment that is always ready and is rapidly deployable from the stored state is essential.
- There are no contraindications to suctioning, however prolonged (>15s) suctioning can lead to hypoxia.
- To avoid hypoxia, consider supplemental oxygen during suctioning, or hyperventilate with oxygen before suction.
- Suction only under direct vision as blind suction can cause tissue damage or convert a partial obstruction to a complete one.

Summary of the Textbooks in Prehospital Combat Casualty Care Section

- Military and tactical combat casualty care textbooks generally omit suction as a topic.
- Select civilian medical textbooks make pertinent recommendations relevant to suction performance and characteristics.
 - Large bore tips and tubing improve suction performance.
 - Prolonged suctioning can lead to hypoxia.
 - Hypoxia can be avoided with supplemental oxygen or pre-hyperventilation with oxygen.
 - Clogging is a frequent problem but can be mitigated with traps.
 - Direct visualization is important as blind suctioning can worsen airway obstruction.
 - Equipment should be readily deployable for patient use.

Recommendations of the Textbooks in Prehospital Combat Casualty Care Section

• Textbooks focused on combat casualty care should address suctioning

• Recommendations from select civilian medical textbooks are relevant to tactical combat casualty care and should be considered for adoption

Peer-Reviewed Journals

There is limited peer-reviewed literature on the optimal suction performance characteristics related to vacuum suction flow rates, pressure, and the fluid viscosity and anticipated particle size that must be suctioned. There are no randomized controlled trials or other high-quality evidence that addresses the issues; nevertheless there is meaningful data that can be extracted from the non-clinical studies, narrative reviews case reports, and expert opinion in the literature.

Tubing and Tips

Vandenberg and Vinson in 1999 published a case series entitled *the inadequacies of contemporary oropharyngeal suction* in which they describe the general state of suction devices available for clinical use in the emergency department:³² It is unclear if the situation has improved since then as follow-up reports have not been published. The Vandenberg and Vinson paper primarily focuses on the tubing and tip diameter, noting that Hagen–Poiseuille equation strongly favors larger diameters. Vandenberg also criticizes the commonly used Yankaeur suction tip as not being designed for precision suctioning during tonsillectomies and other surgeries and not for the rapid evacuation of large quantities of obscuring fluids. He notes there are potentially better designs on the market and advocates for their use.

In two very similar follow-up papers, Vandenberg, et al studied the suction of various fluids simulating vomitus from human volunteers.^{3,33} Not surprisingly, they showed fluid evacuation times were 10 times faster using large bore (5/8 inch tip and ³/₄ inch tubing) versus small (standard Yankauer tip and ¹/₄ inch tubing) systems. Unfortunately, Vandenberg, et al's experimental setup used the wall suction available in hospital emergency departments so his results may not be applicable to the prehospital environment where battery or manually powered devices are the norm.

Larger tip diameters not only increase flow rates they likely reduce clogging. Kozak, et al described in 1997 that 62% of Los Angeles County paramedics surveyed reported clogging as a significant problem.⁸ Recently, Kei and Mebuster described an improvised setup including an 8mm endotracheal tube and infant meconium aspirator and showed in the laboratory that it reduced clogging when compared to the Yankauer

suction tip.³⁴ While it can be assumed that clogging is a potential pitfall of current suction devices, there are no scientific studies available that describe the clogging problem in specific terms.

Portable Suction Devices

There have been several reports comparing the suction performance of portable manual and battery powered suction devices intended for prehospital use. Rossi, et al were among the first and in 1992 evaluated several suction devices on the market at the time.³⁵ Sizes were modest (typically 20x10x20 cm) and weighed between 1-2 kg. Vacuum pressure ranged between 375 and 600 mm Hg. Water and salad oil were used as test fluids and water flow rates were measured between 7 and 67 L/min, a variation spanning nearly and order of magnitude. Simon, et al conducted a similar evaluation in 1993.³⁶ While all the devices tested are no longer commercially available, his report is instructive in that he did not establish performance standards based on clinical data or physiological inference.

Calkins, et al in 2002 evaluated manual and portable suction devices for use in prehospital combat casualty care.³⁷ They examined three commercially available devices, one modified device, a syringe, and two prototypes. He concluded that all were capable of generating suction pressure, but there were no controlled measurements of flow rates. Nevertheless they identified one device as superior in terms of size, weight, and performance. Like Vandenberg, et al before them, Calkins et al did not establish performance standards based on clinical data or physiological inference.

Arnstein in 1996 evaluated four manual (3 hand- and 1 foot-) powered suction devices.³⁸ Weights ranged between 0.2-1.9 kg and sizes were nominally 25x16x6 cm. He used volunteers to power the devices and performance testing was limited to vacuum pressure (range 197-525 mm Hg) and air flow (20-106 L/min). Similar to other suction device evaluations, an effort to establish performance standards based on clinical data or physiological inference was not completed.

While size and weight are important for portability and have big impact on combat casualty care providers who must often carry all of their gear, there is no literature describing the range of acceptable dimensions and weight. In articles that do report size and weight the inference is the user (or agency) purchasing and using the device will decide.

Fluid Viscosity and Particle Size

There are no clinical studies examining the viscosity and particle size of the fluids that are aspirated during prehospital or emergency care suctioning procedures for airway management. Data on the viscosity of human blood, gastric mucus and sputum is available (see table in the *Suction Devices for Emergency and Combat Casualty Care* section). There is no equivalent data for emesis. Given the significate range of foodstuffs and broad physiologic and circumstance differences between humans, there is probably no "typical" emesis and it may even be difficult to estimate a range of viscosities. This fact has not prevented investigators from devising their own version of test fluids, which generally range from water to commercially available condensed soups.^{3,32,36} Other fluids include charcoal suspended in sorbitol, salad oil, motor oil, and porcine blood.^{23,33,35,34}

Even less well studied is the particulate matter that can be mixed with the fluid. Partially digested food, broken teeth, shattered bone, avulsed tissue and gravel are all potential components of the material to be suctioned from a casualty. As mentioned, several authors have simulated this using commercially available condensed soups. One enterprising investigator used a coarsely blended mixture of a hamburger, French fries, and a soda to simulate emesis. The authors report the final mixture was primarily liquid in consistency with scattered solid food particles throughout.³⁴ While readily available and inexpensive, this substance is not validated nor standardized, and this remains an area in need of exploration. The issue is important as particulate matter can be particularly difficult to remove from the oropharynx with a suction device, and the particles can easily clog the inner workings of a machine, rendering it useless (at least until cleared). Trap devices can mitigate this problem, but like a collection container, they can fill and require emptying or replacement.

Other Performance Characteristics

The effluent container capacity defines the volume of secretions that can be suctioned before the container must be emptied or changed. Portable devices generally have small containers; there is not a recommendation based on clinical evidence. Rossi, et al recommend 200-300 mL, but give no justification.³⁵ Others report a range of capacity from 140-1000 mL, suggesting a lack of consensus on the appropriate capacity.^{36,38} Given the potential volume of blood, vomitus, secretions, mud and other fluids that can potentially befall a casualty, there is a need for data to better estimate the minimum capacity of portable suction devices.

Reliability and battery life are obvious and important performance characteristics for a portable device intended for prehospital use. There is no literature on toughness, lifespan, or battery life. Some testing for aviation has been reported but this is limited to electromagnetic interference and vibration testing. There is one report surveying suction device failures in EMS. In 2013 Rosavi, et al reported on inspections of suction units in a rural regional EMS system.³⁹ They reported that over a two-year period, 9,631 suction unit inspections were completed and there were 233 failures (2.4%). The majority (126, 54.1%) were due to battery failure. Seventy-three units failed due to other reasons (not recorded, switch failure, battery not seated). Ten inspections failed due to incorrect assembly, 19 due to defects with the suction canister and 5 due to kinked or disconnected suction tubing. This report underscores that reliability and fail-safe mechanisms of suction devices requires attention.

Of note, the literature does not shed light on the ergonomics and human factors aspects of suction devices. Factors such as balance, setup, controls, ease of use, and cleanup are important for all prehospital providers. Combat casualty care providers have the added requirements for noise and light abatement, owing to the tactical risk of giving up their position to the enemy, as well as more stringent requirements for size, weight and ruggedness.

Summary of the Peer-Review Journals Section

- There are no studies or expert opinions regarding the appropriate size and weight of portable suction units intended for prehospital care.
- Similarly, there is no data on vacuum suction pressure or flow rates.
- The Yankauer tip and small diameter tubing is ineffective for emergency care suction.
- Large bore tips and tubing improve suction performance.
- There is not a standardized fluid viscosity to test suction performance but investigators have used a range of simulated emesis fluids. There are no standards on particulate matter but experts opine that removal capacity is an important attribute of suction devices.
- Container capacity is not studied but ranges from 140 1000 mL.
- Reliability of suction machines may be inadequate; there is no data on ergonomics.
- There is no information on the specific needs of the tactical environment including ruggedness, and light and noise abatement.

Recommendations of the Peer-Review Journals Section

- Standards should be established relevant to combat casualty care for
 - Size and weight of portable suction machines
 - Suction tip and tubing diameter
 - o Minimum performance especially flowrates of validated simulated emesis t
 - Effluent container capacity
 - Reliability, ruggedness, and ease of use, and ergonomics
 - Noise and light abatement

Summary and Conclusions

Suction is a critical component of airway management, which is the second leading cause of preventable battlefield death. Current commercially available portable suction devices have not been scientifically validated for key performance measures relevant to prehospital care, let alone tactical combat casualty care. Current portable suction devices are not endorsed for combat casualty care and are considered too large and heavy to carry onto the battlefield anyway. As a result, the performance of suction itself is subsequently omitted as a care practice under current tactical combat casualty care (TCCC) treatment guidelines. It can be presumed that if a small, lightweight and effective device were available, the guidelines would change to reflect it.

Guidelines, regulations and the literature do inform some aspects of prehospital suction relevant to tactical combat casualty care. However, they also expose the gaps in knowledge and standards. While larger suction tip and tubing diameter improves suction performance, there are no standards for required vacuum pressures, flowrates or even the type of fluid and particulate matter that must be suctioned. Recommendations can be inferred from the literature, but the quality of supporting evidence is limited and subject to future research. In the interim, this report provides preliminary conclusions and recommendations regarding specific aspects of suction device performance.

Acknowledgements

The author wishes to acknowledge the administrative and editorial skill, tireless effort and patience of Heather Wantuch, MPA; and the technical advice, support and background information of Bruce Adams, MD, Yusheng Feng, PhD, and Lyle Hood, PhD.

Appendix A - Section Summaries and Recommendations

Summary of the Background Sections

- Airway obstruction is the second leading cause of preventable battlefield death.
- Suction is integral to management of airway obstruction.
- The nondistended volume of the human oropharynx is limited, approximately 65 mL. Distension might increase this volume to 100 mL.
- Up to 400 mL/min of blood and a total of 1 L of emesis can contaminate the upper airways.
- Airway secretions and blood will likely be mixed with bone fragments, broen teeth and other solids, making suctioning imperative.
- Powered suction is not available in far-forward combat casualty care areas.
- Limited information suggests manual suction devices are not carried or used by medics because of limited capability to evacuate secretions.
- Large size and heavy weight of existing powered portable suction units precludes their carry by combat medics.

Recommendations of Background Section

- Detailed fielding data on the types of suction in current use in far-forward combat environments would establish a clear baseline of current availability of suction devices.
- Combat casualty care provider (e.g., medic) user feedback would establish a clear baseline of prime user preferences.

Summary of the Tactical Combat Casualty Care (TCCC) Guidelines Section

- Airway management is given a high priority in TCCC guidelines.
- Management of secretions is emphasized with simple maneuvers such as recovery position emphasized.
- Suction is not mentioned as an intervention and the rationale for this is not specified.

• TCCC guidelines place a premium on small, lightweight and effective implements that can easily be carried by the combat casualty care provider; presumably current suction devices do not meet this threshold.

Recommendations of the Tactical Combat Casualty Care (TCCC) Guidelines Section

- Specifically query the Committee on Tactical Combat Casualty Care (CoTCCC) for their guidance on the use of suction.
- Specifically petition the CoTCCC to place the need for far-forward suction capability on their list of priorities.

Summary of the Suction Devices for Emergency and Combat Casualty Care Section

- Suction devices can generally be divided into three categories based on their power source: manual, electrical (battery) and fixed vacuum systems.
- Flowrate is proportional to the pressure and inversely proportional to the fluid viscosity.
- Flowrate is proportional to the tube length and the 4th power of radius or diameter of the tube.
- Flowrate standards based on free flow of air are unlikely to be relevant to the suctioning of secretions and blood.

Recommendations of the Suction Devices for Emergency and Combat Casualty Care Section

• Flowrate performance should be measured using a fluid that has been shown to mimic the secretions and blood anticipated in a combat casualty.

Summary of the Manufacturing Standards for Suction Devices for Use in Combat and Emergency Care Section

- Suction devices are FDA class II.
- ISO 10079 provides detailed standards for suction devices intended for use in emergency and prehospital care.

- There are minimum performance standards for suction devices but they have not been validated clinically or operationally, and may be inadequate for emergency and prehospital care.
- The standards are unlikely to be applicable to combat casualty care environments.

Recommendations of the Manufacturing Standards for Suction Devices for Use in Combat and Emergency Care Section

• Establish clinical standards for suction use in prehospital and far-forward combat casualty care environments.

Summary of the Textbooks in Prehospital Combat Casualty Care Section

- Military and tactical combat casualty care textbooks generally omit suction as a topic.
- Select civilian medical textbooks make pertinent recommendations relevant to suction performance and characteristics.
 - Large bore tips and tubing improve suction performance.
 - Prolonged suctioning can lead to hypoxia.
 - Hypoxia can be avoided with supplemental oxygen or pre-hyperventilation with oxygen.
 - Clogging is a frequent problem but can be mitigated with traps.
 - Direct visualization is important as blind suctioning can worsen airway obstruction.
 - Equipment should be readily deployable for patient use.

Recommendations of the Textbooks in Prehospital Combat Casualty Care Section

- Textbooks focused on combat casualty care should address suctioning.
- Recommendations from select civilian medical textbooks are relevant to tactical combat casualty care and should be considered for adoption.

Summary of the Peer-Review Journals Section

- There are no studies or expert opinions regarding the appropriate size and weight of portable suction units intended for prehospital care.
- Similarly, there is no data on vacuum suction pressure or flow rates.
- The Yankauer tip and small diameter tubing is ineffective for emergency care suction.
- Large bore tips and tubing improve suction performance.
- There is not a standardized fluid viscosity to test suction performance but investigators have used a range of simulated emesis fluids.
- There are no standards on particulate matter but experts opine that removal capacity is an important attribute of suction devices.
- Container capacity is not studied but ranges from 140 1000 mL.
- Reliability of suction machines may be inadequate; there is no data on ergonomics.
- There is no information on the specific needs of the tactical environment including ruggedness, and light and noise abatement.

Recommendations of the Peer-Review Journals Section

- Standards should be established relevant to combat casualty care for
 - Size and weight of portable suction machines
 - Suction tip and tubing diameter
 - o Minimum performance especially flowrates of validated simulated emesis t
 - Effluent container capacity
 - Reliability, ruggedness, and ease of use, and ergonomics
 - Noise and light abatement

Appendix B - Key Task of the Report

Determine required performance characteristics (primarily vacuum suction flow rate, pressure, and fluid/particle viscosity/size) for management of prehospital Combat Casualty Care injuries. This will be a requirements-based analysis derived primarily from combat data and supplemented with physiologic data, medical literature and where relevant, industry standards.

Appendix C - Technical Approach

Existing and projected (future) military medical requirements relevant to the expected combat and operational scenarios (such as prolonged field care) are identified. The required performance characteristics of a suction unit intended for prehospital combat casualty care is ascertained based on these anticipated operational scenarios. The key characteristics searched include vacuum suction flow rate, pressure, and capacity to evacuate the expected fluid/particle viscosity/size (e.g., saliva, blood, vomitus, mud, gravel, broken teeth) for management of prehospital Combat Casualty Care injuries. Source documents were extracted from 1980-present and analyzed for title content. If relevant, the article was reviewed in detail. Secondary references prior to 1980 were selectively searched based on the title and the likelihood of topical relevance. Specific sources searched include but are not limited to:

- Committee on Combat Casualty Care (CoTCCC)
- Medical literature using Medline or equivalent with search terms including
 - o Suction
 - o Vacuum
 - o Aspiration
 - o Airway, airway management
 - Airway obstruction
 - o Modifier terms including safety, efficacy, and performance
- Engineering literature using Academic Search (EBSCO), or equivalent using similar search terms as above
- Defense Technical Information Center (DTIC)
- Retrievable information from conferences and meetings focused on combat casualty care, prehospital care, and airway management.
- Government standards including FDA
- Industry and government standards clearinghouses including ISO

Where necessary to fill in information gaps, existing requirements were supplemented with proposed requirements vetted against local expert military and civilian medical consultations. UT Health San Antonio maintains a robust panel of US military experts in emergency medicine and prehospital care that can be consulted. Additionally, UT Health San Antonio is in close proximity to and maintains a healthy relationship with JBSA-Fort Sam Houston which is the US military's key hub of combat casualty care and trauma training, and UT Health San Antonio retains the ability to consult with the organizations and personnel within this installation as well as other US military installations worldwide.

The available information is organized, critically appraised, and synthesized into a narrative report that summarizes the performance characteristics for management of prehospital combat

References

1. Adams, B.D., Cuniowski, P.A., Muck, A., and De Lorenzo, R.A., Registry of emergency airways arriving at combat hospitals. J Trauma, 2008. 64(6): p. 1548-1554.

2. Keller, M.W., Han, P.P., Galarneau, M.R., and Brigger, M.T., Airway Management in Severe Combat Maxillofacial Trauma. Otolaryngol Head Neck Surg, 2015. 153(4): p. 532-537.

3. Vandenberg JT. Lutz RH. Vinson DR. Large-diameter suction system reduces oropharyngeal evacuation time. Journal of Emergency Medicine 1999; 17(6):941-944.

4. DePaso WJ: Aspiration pneumonia. Clin Chest Med 1991; 12: 269-284.

5. TJ Overend, CM Anderson, D Brooks, et al. Updating the evidence base for suctioning adult patients: A systematic review. Can Respir J 2009;16(3):e6-e17.

6. Sebesta, J., Special lessons learned from Iraq. Surg Clin North Am, 2006. 86(3): p. 711-726

7. Blackbourne, LH, Baer, DG, Eastridge, BJ, et al: Military medical revolution: Prehospital combat casualty care Journal of Trauma and Acute Care Surgery: 2012; 73(6): S372–S377

8. Kozak, K, Ginther BS, Bean WS: Difficulties with portable suction equipment used for prehospital advanced airway procedures. Prehospital Emergency Care 1997; 1(2): 91-95.

9. Eastridge BJ, Mabry RL, Seguin P, et al: Death on the battlefield (2001–2011): Implications for the future of combat casualty care. Journal of Trauma and Acute Care Surgery, 2012. 73(6): p. S431-S437.

10. Mabry, R.L., Edens, J.W., Pearse, L., Kelly, J.F., and Harke, H., Fatal airway injuries during Operation Enduring Freedom and Operation Iraqi Freedom. Prehosp Emerg Care, 2010. 14(2): p. 272-277.

11. Kellman, R.M. and Losquadro, W.D., Comprehensive airway management of patients with maxillofacial trauma. Craniomaxillofac Trauma Reconstr, 2008.

12. Demetriades, D., Chahwan, S., Gomez, H., Falabella, A., Velmahos, G., and Yamashita, D., Initial evaluation and management of gunshot wounds to the face. J Trauma, 1998. 45(1): p. 39-41.

13. Grauer D, Cevidanes LSH, Styner MA, Ackerman JL, Proffit WR. Pharyngeal airway volume and shape from cone-beam computed tomography: Relationship to facial morphology. Am J Orthodontics Dentofacial Orthopedics. 2009; 136(6):805-814.

14. Oliver RG, Evans SP. Tongue size, oral cavity, and speech. Angle Orthodont 1986; July: 234-243.

15. Gerhardt RT, Mabry ML, De Lorenzo RA, Butler FK: Fundamentals of Combat Casualty Care, in Katz D, Eastridge B (editors): Combat Casualty Care: Lessons Learned from Operation Enduring Freedom and Operation Iraqi Freedom, Borden Institute, Ft. Detrick, MD, 2012

16. Eastridge BJ, Costanzo G, Jenkins D, et al: Impact of joint theater trauma system initiatives on battlefield injury outcomes. Am J Surg. 2009 198(6):852-7.

17. Gerhardt RT, De Lorenzo RA, Oliver JE, et al. Out-of-hospital combat casualty care in the current war in Iraq. Ann Emerg Med 2009; 53(2):169-714.

18. Butler FK, Holcomb JB, Giebner SG, McSwain NE, Bagian J: Tactical Combat Casualty Care 2007: Evolving Concepts and Battlefield Experience. Milit Med 2007; 172(S):1-19.

19. Mabry RL, Holcomb JB, Baker AM, et al. United States Army Rangers in Somalia: an analysis of combat casualties on an urban battlefield. J Trauma 2000; 49:515–528, discussion 528-529.

20. De Lorenzo RA, Lairet J, Mothershead J, Holliman CJ: Military EMS Systems, in Tintinalli JE, Cameron P, Holliman J, Tintinalli JE (editors): EMS: A Practical Global Guidebook. Peoples Medical Publishing House of China, 2010.

21. Butler FK, Hagmann J, Butler EG: Tactical Combat Casualty Care in Special Operations. Mil Med 1996;161(Supp):1-16.

22. Committee on Tactical combat Casualty Care. Tactical Combat Casualty Care Guidelines for Medical Personnel, dated 03 June 2016. <u>https://www.jsomonline.org/TCCC</u>.

23. Paulsen, AW: Are There Guidelines For Anesthesia Suction? APSF Newsletter, February 2015. Volume 29, No. 3, 41-64. Anesthesia Patient Safety Foundation, Indianapolis, IN.

24. International Organization for Standardization: ISO 10079-1:2015 Medical suction equipment — Part 1: Electrically powered suction equipment. https://www.iso.org/obp/ui/#iso:std:iso:10079:-1:ed-3:v1:en. 25. International Organization for Standardization: ISO 10079-2:2014 Medical suction equipment — Part 2: Manually powered suction equipment. <u>https://www.iso.org/obp/ui/#iso:std:iso:10079:-2:ed-3:v1:en</u>.

26. International Organization for Standardization: ISO 10079-3:2014 Medical suction equipment -- Part 3: Suction equipment powered from a vacuum or positive pressure gas source. <u>https://www.iso.org/obp/ui/#iso:std:iso:10079:-3:ed-3:v1:en</u>.

27. Food and Drug Administration, US Department of Health and Human Services, <u>www.fda.gov/MedicalDevices</u>.

28. De Lorenzo RA, Porter RS: Tactical Emergency Care. Brady (Prentice Hall), Upper Saddle River, NJ, 1999.

29. US Army. Tactical Combat Casualty Care: Lessons and Best Practices. Center for Lessons Learned, Ft. Leavenworth, KS. <u>www.call.army.mil</u>.

30. US Army. 68W Advanced Field Craft: Combat Medic Skills 1st ed. Jones & Bartlett Learning; 1 edition, Burlington, MA, 2009.

31. Reardon RF, Mason PE, Clinton JE: Basic Airway Management and Decision Making, in Roberts JR, et al: Roberts and Hedges' Clinical Procedures in Emergency Medicine, 6th ed, Chapter 3, 39-61.e4. Elsevier, Amsterdam, Netherlands, 2013.

32. Vandenberg JT. Vinson DR. The inadequacies of contemporary oropharyngeal suction. [Case Reports. Journal Article] American Journal of Emergency Medicine. 17(6):611-3, 1999 Oct.

33. Vandenberg JT, Rudman NT, Burke TF, Ramos DE. Large-diameter suction tubing significantly improves evacuation time of simulated vomitus. Am J Emerg Med. 1998 May;16(3):242-4.

34. Kei J, Mebust DP: Comparing the Effectiveness of a Novel Suction Set-up Using an Adult Endotracheal Tube Connected to a Meconium Aspirator vs. a Traditional Yankauer Suction Instrument. J Emerg Med. 2016; 14: S0736-4679(16)30717-X. [Epub ahead of print].

35. Rossi R, Jäger G, Ahnefeld FW, Pfenninger E: Efficiency of suction pumps for the emergency medicine setting. Arch Emerg Med. 1992 Mar;9(1):44-50.

36. Simon EJ, Davidson JA, Boom SJ: Evaluation of three portable suction devices. Anaesthesia. 1993 Sep;48(9):807-9.

37. Calkins MD, Reese K, Costello M, Mu T, Bentley TB: Evaluation of possible battlefield suction pumps for the far-forward setting. Mil Med. 2002 Oct;167(10):803-9.

38. Arnstein FE: A practical evaluation of four human-powered portable airway aspirators. Anaesthesia. 1996 Jan;51(1):63-68.

39. Risavi BL, Sabotchick KJ, Heile CJ. Portable suction unit failure in a rural EMS system. Prehosp Disaster Med. 2013;28(4):388-390.