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Support the (TCCCR) Task Area for Research and Development
of Medical Equipment to Clear and Maintain a Combat Airway

**A Report on Deliverable Four:
Develop a specifications list for a portable, lightweight
prehospital suction device**

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Objective of the Report

Develop a specifications list for a portable, lightweight prehospital suction device. Using market research that includes key stakeholder input (e.g., military experts and field medics), develop a list of key operational and ergonomic specifications for the combat suction device including weight, size, power requirements, etc. Support each specification using relevant stakeholder data or standards derived from industry or medical literature sources.

For purposes of this report, specifications will refer to the characteristics normally provided by device manufacturers in their product literature. Specifically, this includes physical characteristics such as weight and size, effluent container capacity, and power supply. It also includes performance data such as maximum vacuum pressure, flow rate of air or other fluids, and battery life. Other factors that may be included include controls, human interface, and ergonomics.

Background

[Readers are referred to the following for a more detailed overview and background on portable suction for use in prehospital combat casualty care: *A Report on Deliverable One: Determine Required Performance Characteristics [of Suction] for Management Of Prehospital Combat Casualty Care Injuries*. 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. Report Author: Robert A. De Lorenzo, MD, MSCI, MSM, FACEP, Department of Emergency Medicine, UT Health San Antonio, February 22, 2017.]

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.

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. Importantly, there is little data on the safety of suction units used in this setting. We will review the available literature and guidelines on suction requirements with an emphasis on inferring a set of technical specifications that can be used to test existing devices and design and develop future devices.

Summary of the Background Section

- The required specifications for suction devices is not well studied and there are no guidelines specific to the prehospital combat use.

Recommendations of Background Section

- None specified.

Textbook Review

The technique of oropharyngeal suctioning is generally described in textbooks of prehospital, respiratory, and basic nursing care. A review of a representative sample reveals little direct information on minimum or desired specifications. Inferred from the textbook sample are general specifications such as portability, leak-proof effluent container, easy to clean and decontaminate, and variable vacuum pressure control.

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.

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 relevant information on the specifications for suctioning in tactical combat casualty care.

Summary of the Textbook Review Section

- Textbooks generally do not inform the discussion of prehospital combat casualty care suction requirements.

Recommendations of the Textbook Review Section

- None specified.

Peer-Reviewed Journals

There is limited peer-reviewed literature on suction specifications and characteristics. 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.¹ 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.^{1,2} 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, the experimental setup used in Vandenberg, et al's used the wall suction available in hospital emergency departments, so their 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 but are also likely to reduce clogging. Kozak, et al described in 1997 that 62% of Los Angeles County paramedics surveyed reported clogging as a significant problem.³ Recently, Kei and Mebuser described an improvised setup including an 8 mm endotracheal tube and infant meconium aspirator and showed in the laboratory that it reduced clogging when compared to the Yankauer suction tip.⁴ 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.⁵ 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 an order of magnitude. Simon, et al conducted a similar evaluation in 1993.⁶ 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.⁷ 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.⁸ 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 substantial 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 significant 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.^{1,2,6} Other fluids include charcoal suspended in sorbitol, salad oil, motor oil, and porcine blood.^{1,2,5,4}

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.⁴ 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.⁵ Others report a range of capacity from 140-1000 mL, suggesting a lack of consensus on the appropriate capacity.^{6,8} 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.⁹ 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
 - Minimum performance especially flowrates of validated simulated emesis
 - Effluent container capacity
 - Reliability, ruggedness, and ease of use, and ergonomics
 - Noise and light abatement

Manufacturing Standards for Suction Devices

A review of the available manufacturer and regulatory 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).^{10,11,12} Compliance with ISO, *per se*, is voluntary but generally it is followed since 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 x 300 mm (23.6 x 11.8")
 - Weight < 6kg (13.2 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
 - Pharyngeal suctioning: 200 mL simulated vomitus in 10s (nominal 1200 mL/min)

The test standard for pharyngeal suctioning for electrically powered devices is described in the ISO appendix A:¹⁰

Prepare the simulated vomitus by dissolving 10 g of food grade xanthan gum in 1 l of distilled water and adding 100 g of 1 mm diameter glass beads having a specific gravity of approximately 2,55. Benzoic acid 0,1 % (mass fraction) can be added as a preservative. Use a graduated cylinder having a capacity of at least 300 ml with graduations no more than 50 ml apart. Agitate the simulated vomitus to disperse the glass beads immediately before testing. Pour 250 ml at ambient temperature into the graduated cylinder. Attach the suction tubing to the suction equipment and operate the equipment with the level of the simulated vomitus at the same horizontal level as the top of the collection container. Place the suction tubing into the graduated cylinder and record the time taken to evacuate 200 ml of the simulated vomitus.

Thick mucus secretions can be 100-150 times as thick as the thickest blood. Yet the ISO standard is for water and small glass beads. There is no evidence to support the relationship of the test mixture to actual human vomitus. There is a risk the standard is inadequate to test devices intended for prehospital oropharyngeal suctioning.

Interestingly, there is also no mention in the ISO standards or in other documents for a standard reflecting particulate matter. The use of 1 mm diameter glass beads in the test solution is the only nod (and a weak one at that) to the reality that oropharyngeal fluids often contain large chunks of material. 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.¹³

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.

On a historical note, a previous standard from the American Society for Testing and Materials (ASTM) provides the following consensus recommendation for oral-nasal-tracheal suctioning of 0-160 mm Hg static vacuum pressure and 40 L/min air flow rate.¹⁴ Since this recommendation covers both oropharyngeal and tracheal (and presumably, bronchial) suctioning, and the two techniques have very different needs and safety parameters, it can no longer be considered state-of-the-art. In any event, ISO has superseded ASTM in many applications including suction devices.

Manufacturer Guidance

A major manufacturer of in-hospital and portable suction units published a monograph that provides some general guidance on desired suction characteristics.¹⁵ It provides the following general guidance:

Portable pumps can also be used to produce vacuum, particularly for hospital areas not served by the wall system. Negative pressure generated by this equipment may be comparable to wall vacuum when the portable pump is new or well maintained. However, flow rates on some pumps may be lower (assuming equal service life and maintenance) than central systems. Users should identify pressures and flow specifications when evaluating portable units.

The monograph is also informative on the issue of clogging. In part it states:¹⁵

Clogging results from four major causes:

1. *The normal passage of lint-laden room air through the mechanism when regulators remain attached to the outlet and are left on when not in use.*
2. *The accumulation of aerosols during normal suction procedures.*
3. *Flooding which follows accidental overflow of aspirated fluids due to shut-off failures or connection errors.*
4. *Aspiration of smoke and debris during surgical procedures.*

All of these risks can be reduced or eliminated by proper use of effective shut-off valves in collection canisters, properly installed over-flow safety traps on vacuum regulators and disposable particulate filters. Filters, however, become more restrictive to air flow as they clean the air that passes through them and accumulate particulate matter.

Of note, this description regards in-hospital wall suction systems and not portable devices. Nevertheless, the concern of clogging is relevant and can be translated as a specification calling for a device that is clog-resistant or easy to clear.

Food and Drug Administration Regulations

The Food and Drug Administration (FDA) classifies medical devices according to their hazard risk.¹⁶ 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 than 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.

<u>Device Nomenclature</u>	<u>Regulation Number</u>	<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.

The FDA does require all producers of medical device to follow Good Manufacturing Practices and Requirements. There are no specific FDA guidelines or regulations regarding emergency suction devices.

Summary of the Manufacturing Standards for Suction Devices Section

- Suction devices are FDA class II
- ISO 10079 provides detailed minimal standards for suction devices intended for use in emergency and prehospital care. They do not address combat casualty care.
- The evidence supporting minimum performance standards for suction devices is not strong. No standard has been validated clinically or operationally, and may be inadequate for emergency and prehospital care.
- The standards are not specific to battlefield medicine and are unlikely to be applicable to combat casualty care environments

Recommendations of the Manufacturing Standards for Suction Devices Section

- Establish clinically-relevant standards for suction use in prehospital and far-forward combat casualty care environments.
 - Validate key performance characteristics such as suction flow rates and vacuum pressure.
 - Use test procedures reflecting real-world conditions in key areas such as the use of simulated vomit in volumes and consistencies that have been validated.

Proposed Specifications

This section proposes specifications for a suction device specifically intended for use in prehospital combat casualty care. This information is derived from proprietary work conducted by the institution and its collaborative partners.

Methodology

Survey of Users and Experts

A survey of experts and users was conducted to establish priorities in portable suction characteristics relevant to prehospital care. A team of two engineers and a business professional conducted 102 interviews with relevant medical personnel in the Texas and National Capitol regions of the U.S. Included in those interviews were paramedics, EMT's, supply chain personnel, manufacturing representatives, FDA consultants, emergency medicine doctors, military special forces, and police officers. Additionally, informal interviews with subject matter experts in military prehospital care were obtained and incorporated into the results. From the user interviews, it was possible to determine that the customer segment that has the highest need was in the paramedic segment. Paramedics working field calls are typically encumbered with over 80 lbs of equipment that is separated into three cumbersome packages. As such, the development of a lightweight and portable technology is key in reducing the amount of weight and space that their equipment takes up. By reducing the size and weight, it then makes it possible for paramedics to be better equipped for more situations without adding to the already heavy load they carry.

Qualitative results of the user survey demonstrate the following four areas as high priority (mentioned most frequently by participants), in order:

1. Portability
2. Strong suction
3. Ease of use
4. Training support for using device optimally

Other items that are important but mentioned less frequently are, in order:

5. Include a light for visibility
6. Indicator to show remaining battery life
7. Shape of catheter to get into mouth easier
8. Larger diameter tubing to prevent clogging
9. Longer tube for reaching patient
10. Small and less bulky effluent container
11. Use specific (design by setting)
12. Able to perform oronasogastric suctioning
13. Controls and device visible in the dark

14. Different size tips like a drill bit kit

15. Backup to battery power

Specification Development

Taking the user feedback and expert opinion, combined with a synthesis of available literature, a set of specifications is proposed. As a baseline, off-the-shelf manufacturer's specifications list categories were utilized. Specifications are divided into physical characteristics, performance characteristics, and selected engineering and functional specifications. Where appropriate, ranges of values are provided to imply that different uses and designs may benefit from different specification values.

Proposed Specification

Specifications (Proposed) for a portable suction device for use in prehospital combat casualty care.

Specification Criteria	Values or Statement
Physical Specifications	
Weight Range (overall device)	<1 Kg, <0.5kg for man-pack version.
Dimensions overall device (length, height, depth), including canister	30 x 10 x 10 cm
Canister Capacity (mL), Volume markings on canister?	1000 mL, 500 mL for man-pack version
Performance Specifications	
Directional performance	Functions in all orientations
Vomit Flowrate (removal)	3 L/min
Vacuum pressure range (measured at catheter tip)	0-550 Hg mm
Device Operation Time (under no load, under maximum load)	5 min, 3 min
Device operational temperature, humidity, moisture exposure range	Based on Mil Std pertinent for medical devices
Device operational atmospheric pressure range	Airworthy/safe to fly based on Mil Std
Device durability	Mil Std

Specification Criteria	Values or Statement
Device carry-ability	Handles or straps to allow easy carry by a person
Engineering Design Specifications	
External AC/DC input power range	120 VAC/12-24 VDC nominal
Battery Type (rechargeable or disposable)	Both
Battery Cell Chemistry	Per Design
Max noise level (dB), overall device	≤ 69 dBA
Suction Tube Diameter	0.5-0.75 in ID
Suction Tube Length	3 feet nominal
Suction Tube Material	Flexible in hot/cold environments, not collapsible under max vacuum, lightweight, and coilable/packable
Device Case	Resistant to scratches, dents, and protect internal parts from shock, vibration, moisture, and dust.
Infection control	Easily disinfected with disposable components that contact the patient
Functional Requirements	
Pressure display	Not necessary
Variable vacuum pressure controller	Yes
Low battery display	Yes

Summary of the Proposed Specifications Section

- Users prioritized portability, strong suction, and ease of use as the key characteristics of a prehospital suction device.
- Training is a gap area identified by users in using portable suction.
- Physical, performance, engineering and functional specifications can be described for a suction unit designed for the prehospital combat environment.

Recommendations of the Proposed Specifications Section

- A suction device for prehospital combat use should be portable, powerful, and easy to use.
- Training of users should be included in the fielding and employment of prehospital suction.
- Physical, performance, engineering and functional specifications specific to combat casualty care should be incorporated in military service requirements for device design of prehospital suction.

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 specifications based on user and expert input regarding specific aspects of suction device characteristics, performance, engineering, and function.

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Appendix A - Section Summaries and Recommendations

Summary of the Background Section

- The required specifications for suction devices is not well studied and there are no guidelines specific to the prehospital combat use.

Recommendations of Background Section

- None specified.

Summary of the Textbook Review Section

- Textbooks generally do not inform the discussion of prehospital combat casualty care suction requirements.

Recommendations of the Textbook Review Section

- None specified

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
- Minimum performance especially flowrates of validated simulated emesis
- Effluent container capacity
- Reliability, ruggedness, and ease of use, and ergonomics
- Noise and light abatement

Summary of the Manufacturing Standards for Suction Devices Section

- Suction devices are FDA class II
- ISO 10079 provides detailed minimal standards for suction devices intended for use in emergency and prehospital care. They do not address combat casualty care.
- The evidence supporting minimum performance standards for suction devices is not strong. No standard has been been validated clinically or operationally, and may be inadequate for emergency and prehospital care.
- The standards are not specific to battlefield medicine and are unlikely to be applicable to combat casualty care environments

Recommendations of the Manufacturing Standards for Suction Devices Section

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

Summary of the Proposed Specifications Section

- Users prioritized portability, strong suction, and ease of use as the key characteristics of a prehospital suction device.
- Training is a gap area identified by users in using portable suction.

- Physical, performance, engineering and functional specifications can be described for a suction unit designed for the prehospital combat environment.

Recommendations of the Proposed Specifications Section

- A suction device for prehospital combat use should be portable, powerful, and easy to use.
- Training of users should be included in the fielding and employment of prehospital suction.
- Physical, performance, engineering and functional specifications should be incorporated in requirements for device design of prehospital suction.

Appendix B - Key Task of the Report

Develop a specifications list for a portable, lightweight prehospital suction device. Using market research that includes key stakeholder input (e.g., military experts and field medics), develop a list of key operational and ergonomic specifications for the combat suction device including weight, size, power requirements, etc. Support each specification using relevant stakeholder data or standards derived from industry or medical literature sources. Deliverables will be: A report of specifications.

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
 - *Suction*
 - *Vacuum*
 - *Aspiration*
 - *Airway, airway management*
 - *Airway obstruction*
 - 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
- User surveys
- Informal feedback from subject matter experts

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 casualties.

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