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Gaining Consensus on a Protocol for General Surgery Physician Assistants in the Management of Non-Compressible Abdominal Hemorrhage in military austere Environments: a Delphi Study

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Background: Non-compressible abdominal hemorrhage (NCAH) is a potentially preventable cause of death due to injury. Limited-exploratory laparotomy by a non-surgeon is a temporary intervention to sustain life until definitive surgical intervention by Trauma Surgeons can be obtained. This study aims to establish consensus on a protocol for non-surgeons performing exploratory laparotomy to manage NCAH in an austere environment.

Method: This study included anonymized Trauma Surgeons and General Surgery Physician Assistants from military and civilian backgrounds. Participants were recruited from various professional surgical organizations, including direct interaction with Trauma Surgeons and Surgical Physician Assistants. Participants used a modified Delphi survey with a 9-point Likert scale in two rounds. The two surveys were categorized into four Parts: Protocol for NCAH (Part A), the potential role of General Surgery Physician Assistants (Part B), and measures of success (Part C). A total of 24 statements were voted on and assessed. Votes were divided into three zones: Agreement (median 7-9), Uncertain (median 4-6), and Disagreement (median 1-3). To reach a consensus, 70% agreement was required within a zone. If more than 30% of the votes fell outside of a specific zone, consensus was not achieved. After consensus, the original protocol was revised in an online meeting with experts.

Results: The initial analysis involved 29 participants. After two survey rounds, 19 out of 24 statements reached a consensus. Part A: 10 statements gained consensus. In austere environments, controlling non-compressible abdominal hemorrhage can be challenging. A qualified General Surgery Physician Assistant should intervene. A FAST exam can be used for screening. Bleeding can be managed with packing and pressure. After managing the hemorrhage, the abdominal wall should be left open with a temporary closure technique. Part B: 9 statements gained consensus. In austere locations, a licensed General Surgery Physician Assistant with a minimum of three years of experience working under the supervision of a Trauma/General Surgeon can perform interventions for limited-exploratory laparotomy for patients with non-compressible abdominal hemorrhage. Part C: General Surgery Physician Assistants will be required to have the same success rates as any qualified Surgeon.

Conclusion: Implementing a revised protocol for managing NCAH by General Surgery Physician Assistants is feasible. General Surgery Physician Assistants will need formal training to manage NCAH. With the support of Trauma Surgeons who provide direct and indirect supervision, General Surgery Physician Assistants/Associates can develop a comprehensive understanding of the necessary skills and make sound decisions when treating patients with this condition. This teamwork can also increase surgical capacity and potentially decrease mortality rates for patients with NCAH in austere environments.

Background:

Despite the development of innovative interventions such as resuscitative endovascular balloon occlusion of the aorta (REBOA) and whole blood resuscitation over the past 26 years, the trauma surgical community has not yet found a way to sustain the life of a patient experiencing noncompressible abdominal hemorrhage (NCAH) long enough to reach definitive surgical care within an hour.^{1,2} Individuals who sustain survivable injuries associated with NCAH will, on average, hemorrhage within 30 minutes of sustaining injury ²⁰.

Future near-peer conflicts raise concerns about the availability of qualified surgical providers who can control bleeding and resuscitate. Despite more surgeon training, supply is expected to remain unchanged for 15 years, leading to a shortage of 10,100 to 19,900 surgeons by 2036 (GlobalData Plc., 2024). Military trauma surgeons are in short supply, and the military's surgical capacity is dwindling (Sternberg, 2019). Previous task shifting/sharing in the United States Military has not been successful, and non-trauma surgeons, such as OB/GYNs, are ill-equipped to manage trauma patients on the battlefield (Sternberg, 2019). Training and working alongside Trauma and General Surgeons, General Surgery Physician Assistants acquire skill acquisition, skill sustainment and develop a comprehensive understanding, which leads to better discipline-specific decision-making abilities in trauma surgery and critical care (Adams, 2022). General Surgery Physician Assistants can potentially help increase surgical capacity for the military and civilian surgical communities.

The current literature focuses on using surgical adjuncts to stop bleeding for up to two hours to sustain life until definitive surgical care can be delivered³. Although discussions of General Surgical Physician Assistants' assignments to military forward surgical teams to either assist in the operating room or to perform damage control resuscitation in the trauma bay while

surgeons are operating during combat operations, no scientific research has been conducted to evaluate such interventions^{4,5} (Baker et al., 2021). General Surgical Physician Assistants performing emergency surgical interventions closer to the point of injury using currently developed interventions may potentially sustain life for up to 1 hour⁵⁻⁷.

This article proposes a protocol for trained non-surgeons managing patients with NCAH in austere environments, focusing on General Surgery Physician Assistants performing limited exploratory laparotomy. Limited-exploratory laparotomy performed by a non-surgeon is not a definitive hemorrhage control intervention; it is a temporizing intervention to sustain life until definitive surgical intervention by Trauma Surgeons can be obtained⁸. General Surgery Physician Assistants performing limited-exploratory laparotomy in the austere environment may be the key to decreasing the mortality of service members and government personnel during combat operations. This study presents the findings of a modified Delphi study to explore the degree of consensus of a protocol for non-surgeons performing limited-exploratory laparotomy to manage NCAH in the austere environment using a revised protocol⁸.

Method:

Purpose of the Study and rationale for using the Delphi Technique

To establish consensus on a developed protocol, we developed two research questions:

- What is the consensus on a protocol for managing NCAH using limited-exploratory laparotomy in austere environments?
- What is the consensus for a General Surgery Physician Assistant to perform limited-exploratory laparotomy using a protocol on a patient with NCAH in austere environments?

A modified Delphi study was conducted to address both Research Questions. The Delphi technique was utilized to reach a consensus amongst a panel of experts to explore a concept beyond the existing comprehension of the Trauma Surgical community in austere environments⁹. To ensure appropriate reporting of this modified Delphi Study, the Conducting and Reporting of Delphi Studies (CREDES) reporting requirements were followed¹⁰.

Definition of Consensus

Establishing consensus through the Delphi method does not have set guidelines regarding percentage or technique^{10,12,13}. The definition of consensus was determined using the RAND/UCLA Appropriateness method¹³. A 9-point Likert scale was used to rate survey items. Votes were divided into three zones: Agreement (median 7-9), Uncertain (median 4-6), and Disagreement (median 1-3). To reach a consensus, 70% agreement was required within a zone. If more than 30% of the votes fell outside of a specific zone, consensus was not achieved. See Appendix A for a detailed definition of Consensus.

Selection of Delphi panel

For this study, the Delphi panel comprised anonymized military and civilian Trauma Surgeons and General Surgery Physician Assistants/Associates from across the United States. This research study recruited participants from the Eastern Association for the Surgery of Trauma member's site. Participants were also queried by direct interaction with Trauma Surgeons at the San Antonio Military Medical Center and the American Association for Surgical Physician Assistants. Prospective participants were invited to participate in the Delphi rounds through email and letter via the United States Postal Service. Those interested in participating

responded using either of the two methods. A second email or letter was sent if no response was received within one to two weeks. All participants who acknowledged receipt of the invitation letter and agreed to participate in the Delphi Study were sent a participant consent form approved by the George Washington University Institutional Review Board (IRB). Those prospective participants who signed and returned the consent form were enrolled in the modified Delphi Survey.

Expert committee

An expert committee was installed to advise on developing the protocol and revising it based on the consensus data from the Delphi rounds. The expert committee comprised five Trauma Surgeons (BS, SAS, MVB, DJ, TN) and two General Surgery Physician Assistants (SH, AM). Two expert researchers (PLM, PVW) were commissioned to ensure the validity and reliability of the Delphi process.

The protocol (the initial protocol is available upon request) encompasses evidence-based practices that maximize medical practitioners' decision-making skills. It integrates diverse literature from all medical/surgical research types to provide the best solutions to the healthcare research question¹¹.

The survey contained three parts (Parts A through C). Parts A and B aimed to reach a consensus about what is known about the study of NCAH and its incorporation into a protocol (Part A) and on the potential role of General Surgery Physician Assistants in limited-exploratory laparotomy (Part B). In addition, Part C of the Delphi round 1 survey inquired about measures of success.

The survey items aimed to gather consensus on several areas of interest, including demographics, understanding of the problem, familiarity with current interventions, acceptance of General Surgery Physician Assistants performing limited-exploratory laparotomy, technical competencies required for such procedures, acceptance of the protocol, and support for efficacy trials. Foundational tasks/skills/concepts were based on graduating from an approved General Surgery Physician Assistant program and completing post-graduation fellowship training such as Trauma intensive care residency, as well as obtaining certifications in Advanced Trauma Life Support (ATLS), Fundamental of Critical Care Support (FCCS), Advance Surgical Skills for Exposure in Trauma (ASSET), Advanced Trauma Operative Management (ATOM), and Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA). Additional training skills were also identified through the survey process.

The study gathered anonymous data from Trauma Surgeons and General Surgery Physician Assistants/Associates through two rounds of surveys⁹. The limitation of conducting only two rounds was due to panelist fatigue^{12,13}. The first-round survey was developed based on the outcomes of a previously published scoping review and through discussions of protocols/recommendations with one experienced Trauma Surgeon and one experienced General Surgery Physician Assistant¹⁹. The survey was then pilot-tested by two Trauma Surgeon opinion leaders and two senior General Surgery Physician Assistants/Associates. After the initial pilot testing, the survey was distributed to eight Emergency Medicine Physicians for review and comment on its appropriateness. No changes were made to the surveys following the pilot testing, and all participants expressed that the survey was clear and appropriate.

The complete surveys from the first and second rounds are available on request⁸. The initial survey was developed in Microsoft Word and distributed via email. The manually drafted

survey was constructed to allow participants to write notes and answer openly and freely using a comment box and drafting on the survey sheet. The second survey was an electronic survey developed and distributed by REDCap. Both surveys aimed to assess the acceptability of a knowledge tool of a protocol for non-surgeons to perform limited-exploratory laparotomy on patients with NCAH hemorrhage. The survey was designed with a 9-point Likert Scale to gather ratings and responses, and each item was accompanied by a comment box for additional input by each Trauma Surgeon and General Surgery Physician Assistant.

The survey's second round was sent out to the panelists after analyzing the data from the first round. The summary of the first round was distributed to all panelists to keep them informed about the results of the previous round. By providing a feedback summary of the previous round, panelists could provide more relevant responses for the current round. The feedback summary included the mean, median, standard deviation, interquartile range, percent of agreement and disagreement, and degree of consensus from the 29 Delphi panelists, along with comments and arguments provided by the panelists. Descriptive statistics were used to compare the surveyed panelists using interquartile ranges, and the coefficient of variation was used to evaluate the significance of other covariables that may have affected the outcome¹⁴.

The protocol underwent an iterative review by the expert panel. The protocol was revised after a thorough review of the original protocol and consensus data.

Results

Figure 1, flow chart illustrates the stages of this modified Delphi Study. The flow chart has five stages: the development stage, survey stage #1, the revision stage, survey stage #2, and

the agreement stage⁹. The flow chart provides a brief but comprehensive view of the modified Delphi process.

Participants

Seventy-one potential participants were invited to participate in this study. Forty expressed their interest in participating in the modified Delphi Study. Of the interested participants, 30 (75%) completed and returned a signed consent form and the initial survey. However, only 29 participants were included in the first-round analysis, as one person did not complete the survey. Of these 29 participants, 27 (93.1%) participated in the second round to gain consensus, which was used to revise the protocol.

Most participants were between 40 and 49 years of age: 17 (59.2%) participants in the first survey and 18 (66.7%) participants in the second survey. Physicians were the majority participant group in survey one, 16 (55.2%), and 15 (55.6%) in survey two. When considering how long each participant has worked in their respective occupational category (Physicians, PA), 27 (93.1%) indicated they had worked more than five years in the first survey. Eight (29.6%) participants worked for approximately 11 to 15 years in their professions, six (22.2%) of participants have worked in their professions for 16 to 20 years, and an additional 5 (18.5%) have worked for 21 to 25 years in their professions. Eleven (37.9%) participants in Survey One have deployed less than three times, and another 18 (62.1%) have deployed at least three to four times to support the Global War on Terror. Of the participants in survey two, 18 (66.7%) have indicated they have deployed at least three to four times to support the Global War on Terror, and another nine (33.3%) indicated that they had deployed less than three times during the Global War or Terror. In survey one, 23 (79.3%) participants, and in survey two, 23 (85.2%) participants indicated that they deployed in non-special operation units during their deployment

in the Global War on Terror. Table 1 presents survey participant demographics for the two survey rounds.

First-Round Consensus Data (Parts A and B)

In Part A about the evidence-based protocol, five out of thirteen statements gained consensus in incorporating the study results into the protocol. Statement 5 gained consensus, indicating that four units of whole blood are enough to determine if a patient is a transient or non-responder during damage control resuscitation. Statement 9 also gained consensus, noting that most abdominal bleeding can be controlled with tight four-quadrant packing and/or direct pressure of bleeding vessels. For statement 10, in patients with severe hemorrhage that cannot be controlled with tight four-quadrant packing and/or direct pressure, REBOA can be used as an alternative to gain proximal aortic control over a left-sided thoracotomy and/or Supraceliac aortic control. Statement 12 recommends that after all major bleeding is controlled, the abdominal cavity should be systematically explored for bleeding and intestinal leakage (from the ligament of Treitz to the rectum). Lastly, statement 13 suggests that in austere environments, the abdominal wall should be left open upon managing intraabdominal hemorrhage, with the use of a temporary abdominal wall closure technique such as a Bogota bag with a chest tube placed on low suction to remove intraperitoneal fluid.

The remaining eight statements did not meet consensus, as noted in Appendix B. There was disagreement with these eight statements, indicating that thirty percent of the votes were outside the median region. Despite the median being within the “Agreement Zone,” greater than thirty percent of the votes were not within that region, contributing to the non-consensus (APPENDIX B).

In Part B, about the potential role of General Surgery Physician Assistants/Associates in controlling abdominal hemorrhage, 8 out of 11 statements gained consensus. A licensed General Surgery Physician Assistant with at least three years of experience working in an operative General/Trauma Surgery environment can be an asset to the General/Trauma Surgery disciplines in managing patients with NCAH in austere environments. General Surgery Physician Assistants can assess and identify indications for exploratory laparotomy, place an ultrasound-guided REBOA to assist in the management of Zone I and III hemorrhage, perform a full midline laparotomy incision (from the xiphoid to the pubic symphysis), perform a tight four-quadrant abdominal packing, systematically explore the abdominal cavity for bleeding and intestinal leakage (from the ligament of Treitz to the rectum), effectively use REBOA during intra-abdominal hemorrhage to control proximal aortic hemorrhage and perform a temporary abdominal closure.

The remaining three statements did not meet consensus, as noted in Appendix C. There was disagreement with statements one, three, and ten as noted in Appendix C.

Second-Round Consensus Data (Parts A and B)

Table 2 indicates that eight statements that did not gain consensus in round one were revised, with Statement # 3 being split into four subsections. Statement #7 was revised to ensure consistent consensus that invasive interventions are necessary to sustain life in patients with NCAH despite DCR. This resulted in the production of eleven new statements, which underwent consensus in Part A. Out of the eleven revised statements, five gained consensus during the second round of surveys.

In Part A, Statement #1 establishes that NCAH is the leading cause of potentially preventable death in prehospital/battlefield settings. Statement #2 established that in austere environments with limited resources and no licensed surgical provider or team, there is insufficient evidence to guide medical/surgical intervention for patients with NCAH; furthermore, how to sustain their lives for more than six hours is unclear. Statement # 6 establishes that in an austere environment without a Trauma/General Surgeon present, a patient with NCAH may undergo surgical intervention (limited-exploratory laparotomy) if a trained and qualified General Surgery Physician Assistant is available. However, this should only be done if adequate teams (anesthesia providers, nurses, and surgical technicians) and supplies to sustain the patient's physiology during the operation are present. According to Statement #7, it has been concluded that DCR alone may not be enough to sustain the life of patients with NCAH in austere environments for a prolonged evacuation lasting four hours. In order to ensure the potential survival of a patient with NCAH in such conditions, it may be necessary to perform an invasive intervention. Statement #8 established consensus for the use of a focused assessment with sonography for trauma (FAST) exam or diagnostic peritoneal lavage use as a screening tool to assess the presence of significant intra-abdominal hemorrhage in patients with NCAH in austere environments. Statement #11 established consensus noting that all expanding and leaking hematomas, including retro-hepatic hematoma, should only be managed with packing by appropriately trained and qualified General Surgery Physician Assistants/Associates in austere/remote environments where a Trauma/General Surgeon is not immediately available. Statement #10 established that during the first and second surveys, there was no consensus that an appropriately trained and qualified General Surgery Physician Assistant with a qualified and trained anesthesiology and surgical support team could successfully perform a limited-

laparotomy with hemorrhage control in hemodynamically unstable trauma patients that meet the indication for abdominal hemorrhage control in austere/remote environments, as listed in the attached protocol.

Statements #3, 4, and 5 were revised from previous Round #1, Statement #3; in Round #2, one of the four statements from this revised question gained consensus (Statement #6), and the remaining three statements (Statements #3,4,5) did not maintain consensus. Statement #9 did not gain consensus for placement of an ultrasound-guided REBOA catheter with the balloon up as a potential first step before surgically opening the abdomen in patients with NCAH in austere environments.

Part B (Table 3) contained three additional statements that did not gain consensus in Round #1. After revision, Statement #1 and Statement # 10 in Round 2, Part B did not gain consensus. Statement #3 gained consensus indicating a fellowship-trained licensed General Surgery Physician Assistant or a General Surgery Physician Assistant who is currently working in a Trauma Surgery Department with at least three to four years of experience operating next to a Trauma Surgeon or General Surgeon has the ability to perform limited-exploratory laparotomy interventions in austere environments to control bleeding only with a team of qualified medical providers.

Final Consensus Results

Table 4 summarizes the statements that received consensus during Rounds 1 and 2 of the modified Delphi Study. The study presents the results of a survey conducted in two rounds, where participants agreed on a set of statements. Table 4 summarizes the findings, indicating that

Part A had a consensus on 10 out of 13 statements, while Part B had a consensus on nine out of 11 statements. Overall, 19 out of the 24 statements reached consensus across both parts.

Measures of Success (Part C)

Three measures of success were solicited from the participants in part C, who completed the first survey for the modified Delphi Study. Success was defined as survival if the intervention was performed in an austere environment by a General Surgery Physician Assistant performing hemorrhage control on a patient with NCAH. The first measure of success was to assess what participants perceived as a successful outcome of a General Surgery Physician Assistant performing a four-quadrant abdominal packing ONLY in a patient with NCAH in austere environments. Nineteen (65.5%) indicated an expectation that greater than fifty percent survival would be acceptable (Appendix D). The second question queried what participants believed would be an acceptable level of success for General Surgery Physician Assistants performing a four-quadrant abdominal packing AND vascular shunting in a patient with NCAH in austere environments. Sixteen (57.1%) participants indicated that greater than 50% is a measure of success for a General Surgery Physician Assistant to perform a four-quadrant abdominal packing AND vascular shunting in a patient with NCAH in austere environments (Appendix D). The final measure of success queried what participants believed would be an acceptable measure of success for a General Surgery Physician Assistant performing abdominal hemorrhage on a patient with NCAH in austere environments. Fourteen (50%) participants indicated that greater than 50% would be a measure of success (Appendix D).

Revision of the Protocol

The Expert Committee edited the protocol after an iterative review of the modified Delphi Study final results and the original protocol. Major revisions were made in the initial indications to initiate limited-exploratory laparotomy in patients with NCAH in Austere/Remote environments. The revised changes included attempting teleconsultation, if possible (Trauma Surgeon), Patients with suspected abdominal or pelvic hemorrhage that cannot be stabilized before surgical team arrival, and having a high index of suspicion that continuous hemorrhage is coming from a source in the abdomen based on positive FAST or penetrating wound location (spleen, liver, retroperitoneum, complex vascular). The next minor revisions concerned the placement of REBOA during DCR with the balloon down versus the previous discussion of having the balloon up. The next minor revision comprised anesthetizing the patient with General Anesthesia (etomidate, propofol, ketamine). The addition of hemostatic agents in the temporary control of abdominal packing was also included in the final version. The revised protocol is presented in Appendix C.

Discussion

This study gained consensus on 19 of 24 statements for General Surgery Physician Assistants performing limited-exploratory laparotomy to manage noncompressible torso trauma in an austere environment. The consensus was used to develop a revised protocol, which includes indications for hemorrhage control and temporary control of abdominal bleeding and addresses severe bleeding of the liver and spleen, abdominal aorta and visceral branches, and the supramesocolic region.

The revised protocol proposes a new concept for managing NCAH by general surgery physician assistants in austere environments. This protocol can be used by surgeons and trained

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3 general surgery physician assistants, who are credentialed and supported by a team to manage
4 the patient's physiology. Experts have determined that a properly trained physician assistant can
5 manage operative hemorrhage control in an austere environment with direct or indirect physician
6 oversight, but they should not perform vascular shunting. Only those general surgery physician
7 assistants credentialed by a certified credentialing body and operating under direct or indirect
8 supervision should consider performing the interventions outlined in the revised protocol.
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12 The use of REBOAs to support hemorrhage control during DCR and potentially during
13 the truncal control intervention is an essential component of supporting the intervention of non-
14 surgeons performing limited-exploratory laparotomy. Early implementation of REBOAs for
15 proximal hemorrhage control limits blood loss, while Trauma Surgeons and General Surgery
16 Physician Assistants intervene to temporize intraabdominal hemorrhage.
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19 Task shifting/sharing is a strategic method of assigning healthcare duties among teams
20 within your medical discipline. The need for task shifting/sharing results from the “large and
21 unmet burden of surgical disease” and the declining number of surgical professionals to meet this
22 progressive challenge¹⁵. It involves delegating specific responsibilities from highly skilled
23 professionals to those with less training and qualifications who work under the direct or indirect
24 supervision of the delegating provider. The delegation occurs only after a comprehensive
25 understanding of the specific medical discipline has been established to allow the healthcare
26 professional to make appropriate decisions¹⁶. The task-shifting/sharing approach helps make the
27 most of available human resources in healthcare. The World Health Organization has discussed
28 task shifting/sharing, currently used in 23 African countries¹⁷.
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31 Moreover, task shifting/sharing has been implemented in 27 countries outside Africa,
32 including Europe, America, Canada, New Zealand, and Australia¹⁸. Healthcare providers who
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engage in task shifting/sharing have outcomes equivalent to those of their more educated mentors¹⁶. This Delphi study concludes that General Surgery Physician Assistants/Associates are capable healthcare providers who, if given appropriate training and supervision, can manage a patient with NCAH in austere environments with direct and indirect supervision using a protocol.

Limitations

It is essential to acknowledge the limitations of this modified Delphi Study. One significant limitation is the lack of registries for General Surgery Physician Assistant participants. Additionally, it is assumed that all General Surgery Physician Assistants/Associates have received similar training and worked in academic institutions with direct and indirect supervision. However, this assumption is only partially accurate as most General Surgery Physician Assistants in the United States are trained on the job in non-academic institutions rather than completing a fellowship program after their core Physician Assistant program studies have been completed. This difference between the two categories of General Surgery Physician Assistants/Associates is a limitation and a gap that needs to be addressed in future research.

Conclusion

The results of this Delphi study indicate that managing NCAH in austere environments by General Surgery Physician Assistants using limited-exploratory laparotomy is a feasible option after intense and focused training and mentorship. Using a revised protocol to manage NCAH is a feasible option and goal for General Surgery Physician Assistants to achieve under direct and potentially indirect supervision in the distant future.

Contributors

DA, PLM, and PVW designed the study with input from all authors. DA and SH performed data collection and analysis. MM provided statistical data consultation and analysis. PLM, TCN, and PVW reviewed all data for writing, acceptability, and critical revisions.

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Figure 1: Modified Delphi Study Flow Chart

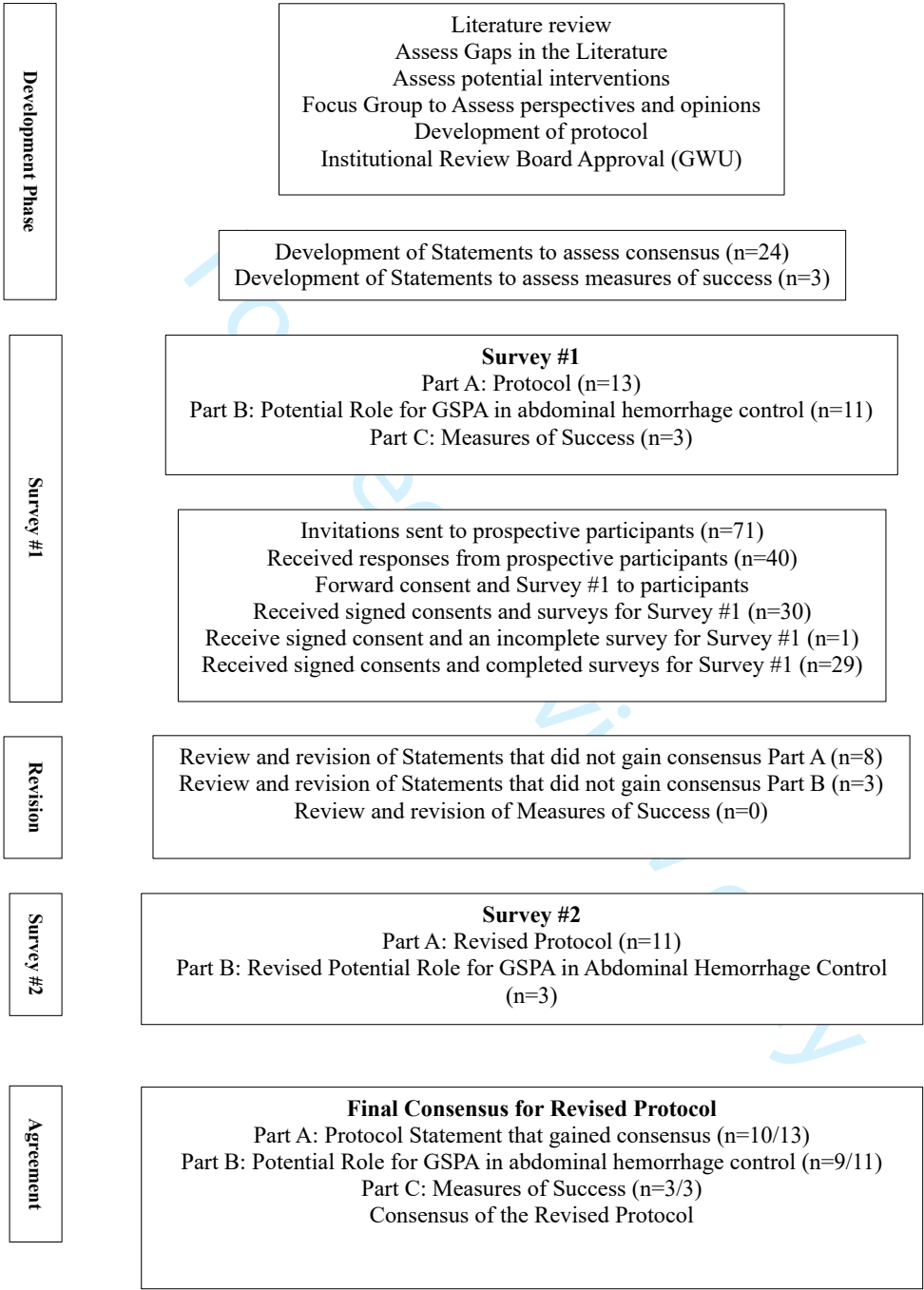


Table 1: Demographics of Participants

Characteristics	Number (%) Survey # 1	Number (%) Survey # 2
N: (number of Respondents)	29	27
Gender:		
Male	26 (89.7%)	24 (88.9%)
Female	3 (10.3%)	2 (7.4%)
Other	0 (0.0%)	1 (3.7%)
Age Group (years):		
20-29	1 (3.4%)	0 (0.0%)
30-39	3 (10.3%)	1 (3.7%)
40-49	17 (59.2%)	18 (66.7%)
50-59	7 (24.1%)	7 (25.9%)
60 and up	1 (3.4%)	1 (3.7%)
Medical License:		
MD	16 (55.2%)	15 (55.6%)
DO	3 (10.3%)	2 (7.4%)
PA	10 (34.5%)	10 (37.0%)
How many years have you been practicing as a Licensed MD, DO, PA?		
Up to 5	2 (6.9%)	
More than 5	27 (93.1%)	
How many years have you been practicing as a Licensed MD, DO, PA?		
5 years or less		1 (3.7%)
6 – 10 years		3 (11.1%)
11 – 15 years		8 (29.6%)
16 – 20 years		6 (22.2%)
21 – 25 years		5 (18.5%)
26 – 30 years		3 (11.1%)
31 – 35 years		1 (3.7%)
Greater than 36 years		0 (0.0%)
Number of Deployments providing medical support for War on Terror:		
<3 deployments	11 (37.9%)	
3-4 deployments	11 (37.9%)	
5-6 deployments	6 (20.7%)	
>6 deployments	1 (3.5%)	
Missing	0 (0.0%)	
Number of Deployments providing medical support for War on Terror:		
<3 deployments		9 (33.3%)
3-4 deployments		12 (44.4%)
5-6 deployments		5 (18.5%)
7-8 deployments		0 (0.0%)
>8 deployments		1 (3.7%)
Missing		0 (0.0%)
Type of Unit Supported (may select more than one):		
Special Ops	13 (44.8%)	11 (40.7%)
Non-Special Ops	23 (79.3%)	23 (85.2%)
Federal Government	6 (20.7%)	5 (18.5%)
Neither Military nor Fed Govt	4 (13.8%)	3 (11.1%)

Table 2: Comparison of First and Second-Round Surveys for Part A: Protocol

Recommendations Statements: Survey One	Number of Panelist First Survey	Media First Survey	IQR First Survey	Consensus	Recommendations Statements: Survey Two	Number of Panelist Second Survey	Median Second Survey	IQR Second Survey	Consensus	Joint Consensus from First and Second Survey
1: Non-compressible torso hemorrhage is the last of 5 potentially preventable causes of death due to injury.	29	7	3 - 8	No	1.Noncompressible torso hemorrhage (NCTH) is the leading cause of potentially preventable death in the prehospital/battlefield environment.	27	9	8 - 9	Very Good	Very Good
2: In austere/remote environments that are resource-limited and there is no licensed surgical providers or team; there is no current published literature to support medical or surgical intervention or adjunctive therapy to sustain life for greater than 6 hours in patients with non-compressible torso hemorrhage of the abdomen.	29	8	5 - 8	No	2.In austere/remote environments that are resource limited and there is no licensed surgical provider or team; evidence is scarce to guide medical or surgical intervention to sustain life for greater than 6 hours in patients with non-compressible torso hemorrhage of the abdomen.	27	8	8 - 9	Very Good	Very Good
3: A patient who is suspected of having non-compressible torso hemorrhage of the abdomen who meets the following criteria should have an intervention performed to control bleeding by a qualified licensed <u>medical</u> provider to sustain life until a more qualified licensed <u>surgical</u> provider is available, if each of the following indications are met: -Inability to discuss and obtain guidance with a Trauma Surgeon -Evacuation to temporary versus definitive surgical site is greater than 3 hours -Hemodynamically unstable (MAP of <65, transient or non-responder to volume resuscitation) -Patient is a transient or non-responder after 4 units of whole blood - High index of suspicion that continuous hemorrhage is coming from a source in the abdomen based on positive FAST or penetrating wound location (spleen,	29	7	5 - 8	No	In an austere environment lacking a Trauma/General Surgeon at the bedside, a patient who is suspected of having non-compressible torso hemorrhage of the abdomen who meets the following criteria should have a surgical intervention (truncal hemorrhage control) performed to control bleeding by a qualified General Surgery Physician Assistant: 3.Evacuation to Damage Control Surgery Site is greater than 1(one) hour 4.Hemodynamically unstable (MAP of < 65mmhg, transient or non-responder to blood products) 5.High index of suspicion that continuous hemorrhage is	27 27	7 7	2 - 8 4 - 8	No No	No No

<p>liver, retroperitoneum, complex vascular)</p> <p>-In suboptimal environments (Austere/Remote Environments, battlefield setting with severely delayed evacuation)</p> <p>-Adequate resources to sustain life during the Truncal hemorrhage control.</p>					<p>coming from a source in the abdomen based on positive FAST with or without use of a Diagnostic Peritoneal Lavage or a penetrating wound of the abdomen (spleen, liver, retroperitoneum, complex vascular)</p> <p>6.Adequate resources to sustain life during the operation to obtain truncal hemorrhage control</p>	27	7	4.5 - 8	No	No
						27	7	6 - 8	Good	Good
4: Damage control resuscitation on patients with non-compressible torso hemorrhage of the abdomen in an austere/remote environment with a MAP of <65mmhg and is either a non-responder or a transient responder to whole blood resuscitation, can sustain life for 6 hours or longer with limited resources.	29	4	3 - 6	No	7.In a remote/austere environment without a dedicated operating theater, damage control resuscitation using whole blood in non-responders or transient responders' patients with non-compressible torso hemorrhage in the abdomen and a MAP < 65mmhg can sustain life for 4 hours or longer.	27	5	4 - 7	No	No
5: 4 units of whole blood is sufficient to assess if a patient is a transient or non-responder during damage control resuscitation.	29	8	7 - 8	Very Good						Very Good
6: In austere/remote environments where no formal imaging is available, a FAST exam is a reliable indicator of intra-abdominal hemorrhage.	29	7	6 - 8	No	8.In austere/remote environments where CT scan is not available, a FAST exam or diagnostic peritoneal lavage can be used as screening tools to assess for the presence of significant intra-abdominal hemorrhage in the hands of a qualified provider.	27	8	8 - 9	Very Good	Very Good
7: An appropriately placed ultrasound guided REBOA with the balloon down is potentially an essential first step prior to surgically opening the abdomen in patients with non-compressible torso hemorrhage of the abdomen in austere/remote environments.	29	7	5 - 8	No	9.An appropriately placed ultrasound guided REBOA catheter with the balloon up is potentially an essential first step prior to surgically opening the abdomen in patients with non-compressible torso hemorrhage in austere/remote environments.	27	7	5 - 8	No	No
8: An appropriately trained and licensed medical provider can perform a full	29	7	5 - 8	No	10.An appropriately trained and qualified General Surgerv	27	8	4 - 8	No	No

midline laparotomy incision in hemodynamically unstable trauma patients that meet the indications for truncal hemorrhage control in austere/remote, as listed in the attached protocol.					Physician Assistant with a qualified and trained anesthesiology and surgical support team can successfully perform a full laparotomy with hemorrhage control in hemodynamically unstable trauma patients that meet the indication for truncal hemorrhage control in austere/remote environments, as listed in the attached protocol						Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.
9: Most bleeding within the abdomen can be controlled with tight four quadrant packing and/or direct pressure of bleeding vessels.	29	7	6 - 8	Good							Good
10: In patients with severe hemorrhage that is not controlled with tight four quadrant packing and or direct pressure. REBOA would serve as alternative to gain proximal aortic control over a left sided thoracotomy and or Supraceliac aortic control.	29	7	6 - 8	Good							Good
11: All large, expanding and or leaking hematomas should be explored with the exception of a retro-hepatic hematoma.	29	7	5 - 8	No	11.All expanding and/or leaking hematomas, including retro-hepatic hematoma, should only be managed with packing by non-surgeons (appropriately trained and qualified General Surgery Physician Assistants) in austere/remote environments where a Trauma/General Surgeon is not immediately available.	27	7	6 - 8	Good	Good	
12: After all major bleeding is controlled, the abdominal cavity should be systematically explored for bleeding and intestinal leakage (from the ligament of Treitz to the rectum).	29	9	8 - 9	Very Good							Very Good
13: Upon managing intraabdominal hemorrhage in austere/remote environments, the abdominal wall should be left open with the use of a temporary abdominal wall closure technique such as the use of a Bogota bag with a chest tube placed on low suction to remove intraperitoneal fluid.	29	8	8 - 9	Very Good							Very Good

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Table 3: Comparison of First and Second-Round Surveys for the Potential Role of General Surgery Physician Assistants in abdominal hemorrhage control

Recommendations Statements: Survey One	Number of Panelist First Survey	Media First Survey	IQR First Survey	Consensus	Recommendations Statements: Survey Two	Number of Panelist Second Survey	Median Second Survey	IQR Second Survey	Consensus	Joint Consensus from First and Second Survey
1: In a patient who is hemodynamically unstable (MAP of <65, transient or non-responder to volume resuscitation) and is 3 hours or greater from definitive surgical care with a positive FAST exam and no means of medical evacuation, the compromised patient can sustain his/her life for up to 6 hours without intervention.	29	3	2 - 4	No	1: A hemodynamically unstable patient (MAP of <65mmhg, transient or non-responder to volume resuscitation) and is 3 hours or greater from a formal Damage Control Surgical Capability with a positive FAST exam and no means of medical evacuation, the compromised patient will NOT be able to sustain his/her life for up to 4 hours without intervention.	27	7	6 - 8.5	No	No
2: A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment is an asset to the General Surgery and or Trauma Surgery disciplines.	29	9	8 - 9	Very Good						Very Good
3: A Fellowship trained licensed General Surgery Physician Assistant with at least three years of experience working in an Operative General Surgery or Trauma Surgery, has the capacity to perform surgical procedures that he or she is credentialed to perform in the absence of an attending surgeon.	29	7	6 - 8	No	3: A Fellowship trained licensed General Surgery Physician Assistant or a General Surgery Physician Assistant who is currently working in a Trauma Surgery Department with at least three to four years of experience operating next to a Trauma Surgeon or General Surgeon, has the ability to perform truncal hemorrhage control interventions in austere/remote environments to control bleeding only with a team of qualified medical providers	27	7	6.5 - 8	Good	Good
4: A Fellowship trained licensed General Surgery Physician Assistant who has at least three years of experience working in an Operative General Surgery or Trauma Surgery	29	8	7 - 9	Very Good						Very Good

environment, can reference the Indications for the initiation for truncal hemorrhage control in patients with non-compressible torso hemorrhage of the abdomen in austere/remote environments to decide if truncal hemorrhage control is indicated.										
5: A Fellowship trained licensed General Surgery Physician Assistant who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment, can place an ultrasound guided REBOA in zone III to gain proximal aortic control.	29	8	7 - 8	Very Good						Very Good
6: A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment, may be trained to perform a full midline laparotomy incision (from the xiphoid to the pubic symphysis) on patients with non-compressible torso hemorrhage of the abdomen in austere/remote environments.	29	8	6 - 9	Good						Good
7: A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment may be trained to perform a tight four quadrant abdominal packing on patients with non-compressible torso hemorrhage of the abdomen in austere/remote environments.	29	8	7 - 9	Very Good						Very Good
8: A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment may be trained to systematically explore the abdominal cavity for bleeding and intestinal leakage (from the ligament of Treitz to the rectum).	29	8	7 - 9	Very Good						Very Good

9: A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment can be trained to effectively use REBOA during intra-abdominal hemorrhage to control proximal aortic hemorrhage.	29	8	6 - 9	Good						Good
10: A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment can be trained to perform temporary vascular stenting of a vascular injury that cannot be ligated in an unstable patient with non-compressible torso hemorrhage of the abdomen in austere/remote environments.	29	7	3 - 8	No	10: A General Surgery Physician Assistant with operative experience at a trauma center can be trained to perform intra-abdominal vascular shunting in hemodynamically unstable patients due to intra-abdominal hemorrhage in austere/remote environment where a Trauma /General Surgeon is not immediately available.	27	7	2.5 - 8	No	No
11. A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment can be trained to perform a temporary abdominal closure utilizing a Bogota bag and using a chest tube at low suction to remove intraperitoneal fluid in patient with non-compressible torso hemorrhage of the abdomen in austere/remote environments.	29	8	8 - 9	Very Good						Very Good

Table 4: Summary of Statements that Have Gained Consensus

Combined Statement from Survey One and Two that made consensus	Degree of Consensus	Strength of Recommendation
Part A: Protocol		
Noncompressible torso hemorrhage (NCTH) is the leading cause of potentially preventable death in the prehospital/battlefield environment.	Very Good	Strong
In austere/remote environments that are resource limited and there is no licensed surgical provider or team; evidence is scarce to guide medical or surgical intervention to sustain life for greater than 6 hours in patients with non-compressible torso hemorrhage of the abdomen.	Very Good	Strong
In an austere environment lacking a Trauma/General Surgeon at the bedside, a patient who is suspected of having non-compressible torso hemorrhage of the abdomen who meets the following criteria should have a surgical intervention (truncal hemorrhage control) performed to control bleeding by a qualified General Surgery Physician Assistant: <ul style="list-style-type: none"> Adequate resources to sustain life during the operation to obtain truncal hemorrhage control 	Good	Weak
4 units of whole blood is sufficient to assess if a patient is a transient or non-responder during damage control resuscitation.	Very Good	Strong
In austere/remote environments where CT scan is not available, a FAST exam or diagnostic peritoneal lavage can be used as screening tools to assess for the presence of significant intra-abdominal hemorrhage in the hands of a qualified provider.	Very Good	Strong
Most bleeding within the abdomen can be controlled with tight four quadrant packing and/or direct pressure of bleeding vessels.	Good	Weak
In patients with severe hemorrhage that is not controlled with tight four quadrant packing and or direct pressure. REBOA would serve as alternative to gain proximal aortic control over a left sided thoracotomy and or Supraceliac aortic control.	Good	Weak
All expanding and/or leaking hematomas, including retro-hepatic hematoma, should only be managed with packing by non-surgeons (appropriately trained and qualified General Surgery Physician Assistants) in austere/remote environments where a Trauma/General Surgeon is not immediately available.	Good	Weak
After all major bleeding is controlled, the abdominal cavity should be systematically explored for bleeding and intestinal leakage (from the ligament of Treitz to the rectum).	Very Good	Strong
Upon managing intraabdominal hemorrhage in austere/remote environments, the abdominal wall should be left open with the use of a temporary abdominal wall closure technique such as the use of a Bogota bag with a chest tube placed on low suction to remove intraperitoneal fluid.	Very Good	Strong

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Part B: Potential role of General Surgery Physician Assistants in truncal hemorrhage control		
A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment is an asset to the General Surgery and or Trauma Surgery disciplines.	Very Good	Strong
A Fellowship trained licensed General Surgery Physician Assistant or a General Surgery Physician Assistant that is currently working in a Trauma Surgery Department with at least three to four years of experience operating next to a Trauma Surgeon or General Surgeon, has the ability to perform truncal hemorrhage control interventions in austere/remote environments to control bleeding only with a team of qualified medical providers	Good	Weak
A Fellowship trained licensed General Surgery Physician Assistant who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment, can reference the Indications for the initiation for truncal hemorrhage control in patients with non-compressible torso hemorrhage of the abdomen in austere/remote environments to decide if truncal hemorrhage control is indicated.	Very Good	Strong
A Fellowship trained licensed General Surgery Physician Assistant who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment, can place an ultrasound guided REBOA in zone III to gain proximal aortic control.	Good	Weak
A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment, may be trained to perform a full midline laparotomy incision (from the xiphoid to the pubic symphysis) on patients with non-compressible torso hemorrhage of the abdomen in austere/remote environments.	Good	Weak
A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment may be trained to perform a tight four quadrant abdominal packing on patients with non-compressible torso hemorrhage of the abdomen in austere/remote environments.	Very Good	Strong
A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment may be trained to systematically explore the abdominal cavity for bleeding and intestinal leakage (from the ligament of Treitz to the rectum).	Very Good	Strong

A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment can be trained to effectively use REBOA during intra-abdominal hemorrhage to control proximal aortic hemorrhage.	Good	Weak
A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment can be trained to perform a temporary abdominal closure utilizing a Bogota bag and using a chest tube at low suction to remove intraperitoneal fluid in patient with non-compressible torso hemorrhage of the abdomen in austere/remote environments.	Very Good	Strong

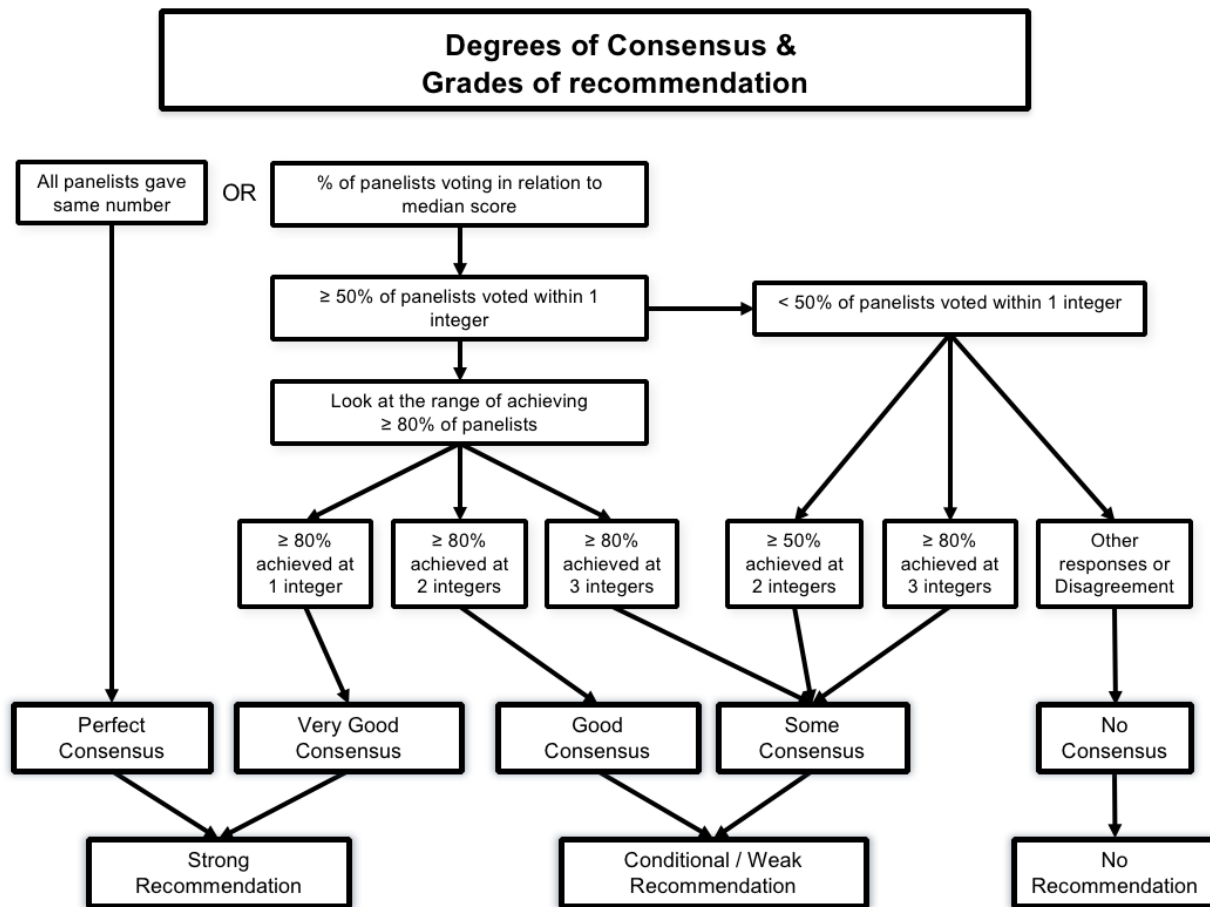
APPENDIX A

Definition of Consensus

Survey data sent to Delphi panelists were evaluated using a 9-point Likert scale. The consensus definition was based on the RAND/UCLA Appropriateness method (Fitch et al., 2001). The scale was ranked with one, meaning "totally disagree" or "harm outweighed the expected benefit," and nine, meaning "totally agree" or "benefit outweighs the expected harm" (Jones & Hunter, 1995, p.311; Fitch et al., 2001, p. 4). The consensus was defined as a score of 7 to 9 as "Agreement," scores of 4 to 6 were considered "Uncertain," and scores of 1 to 3 were considered "Disagreement." If no consensus was established, it was considered "uncertain" (Cho et al., 2019; Fitch et al., 2001; Jones & Hunter, 1995; Lee et al., 2020).

Defining the level of consensus was based on the RAND algorithm (Figure 2) (Cho et al., 2019; Franco-Sadud et al., 2019; Scheeren et al., 2019; Soni et al., 2019). Cho et al. (2019), Franco-Sadud et al. (2019), Scheeren et al. (2019), and Soni et al. (2019) describe the terms "Perfect consensus," "Very good consensus," "Good consensus," "Some consensus," and "No consensus" to provide an in-depth understanding of the level of consensus as described during the RAND algorithm. The term "Perfect consensus" describes 100 percent of participants rating the statement 7, 8, or 9. "Very good consensus" describes "median and middle 50% of respondents are found at one integer, or 80% of respondents are within one integer of the median" (Cho et al., 2019, p. E8; Franco-Sadud et al., 2019, p. E4; Soni et al., 2019, p. E3). "Good consensus" is described as "50% of respondents are within one integer of the median or 80% of the respondents are within two integers of the median" (Cho et al., 2019, p. E8; Franco-Sadud et al., 2019, p. E4; Soni et al., 2019, p. E3). "Some consensus" is described as "50% of respondents are within two integers of the median or 80% of respondents are within three integers of the median" (Cho et al., 2019, p. E8; Franco-Sadud et al., 2019, p. E4; Soni et al., 2019, p. E3). "No consensus" indicates "all other responses" or "any median with disagreement" (Cho et al., 2019, p. E8; Franco-Sadud et al., 2019, p. E4; Soni et al., 2019, p. E3).

APPENDIX B: RAND Algorithm



(Cho et al., 2019; Franco-Sadud et al., 2019; Scheeren et al., 2019; Soni et al., 2019)

Cho et al. (2019), Franco-Sadud et al. (2019), Scheeren et al. (2019), and Soni et al. (2019) further describe the degree of consensus and the strength of recommendation. The description elaborates on the previous definitions of the level of consensus and aligns them with the strength of recommendation. The strength of the recommendation was based on a modification of the Grade guidelines (Guyatt et al., 2011). Cho et al. (2019), Franco-Sadud et al. (2019), Scheeren et al. (2019), and Soni et al. (2019) used a modification of the Grade guidelines by using the terms as noted in the RAND Algorithm such as “Strong Recommendation,” “Conditional/Weak Recommendation,” and “No Recommendation” in place of the terms “High, Moderate, Low and Very Low” (Guyatt et al., 2011).

The modified Grade Method, as discussed by Cho et al. (2019), Franco-Sadud et al. (2019), Scheeren et al. (2019), and Soni et al. (2019), is based on the appropriateness and degree of consensus. Strong recommendations are based on the degree of consensus is at least good, and the median score is not in the undermined middle zone (the median is not in the four to six-zone; therefore, it is either in the seven to nine-zone or the one to three-zone) (Cho et al., 2019; Franco-Sadud et al., 2019; Scheeren et al., 2019; Soni et al., 2019). Therefore, a strong recommendation can have either two categories: “Strong With” or “Strong Against.” The “Strong

With” category is categorized as a median of seven to nine, and the “Strong Against” category is categorized as one to three.

Weak recommendations are based on the degree of consensus is “some consensus” with any median score or median score of four to six with any degree of consensus (Cho et al., 2019; Franco-Sadud et al., 2019; Scheeren et al., 2019; Soni et al., 2019). Therefore, a “Weak Recommendation” has two categories: “Weak With” and “Weak Against.” The “Weak With” category is defined as the middle 50% of the interquartile range is equal to four to nine. The “Weak Against” is defined as the middle 50% of the interquartile range is equal to one or less than four (Cho et al., 2019; Franco-Sadud et al., 2019; Scheeren et al., 2019; Soni et al., 2019).

“Conditional Recommendations,” which are categorized alongside “Weak Recommendations,” were categorized as 70 to 80% of the participants agreeing on a recommendation/statement (Cho et al., 2019; Franco-Sadud et al., 2019; Scheeren et al., 2019; Soni et al., 2019).

Completing the first round was the first phase to determine consensus. Due to a lack of consensus on specific questions, those questions were carried over into the second round. During the second round, survey questions from the first round that did not meet consensus were modified based on feedback from panelist-free discussion boxes. Those questions that did not meet consensus during the second round based on the RAND/UCLA Appropriateness method (Fitch et al., 2001) were explored during the qualitative interview phase of this study.

Analysis

Assessing the degree of agreement and disagreement amongst Delphi panelists, the surveyed results underwent analysis using central tendencies (means, medians) and levels of dispersion (standard deviations and interquartile ranges) to assess the degree of variability between the surveyed responses (Hasson et al., 2000; Lee et al., 2020). Additionally, means, medians, standard deviations, and interquartile ranges were used to compare proportion data between rounds to assess the overall acceptance rate of the surveyed data (Jones & Hunter, 1995; Lee et al., 2020).

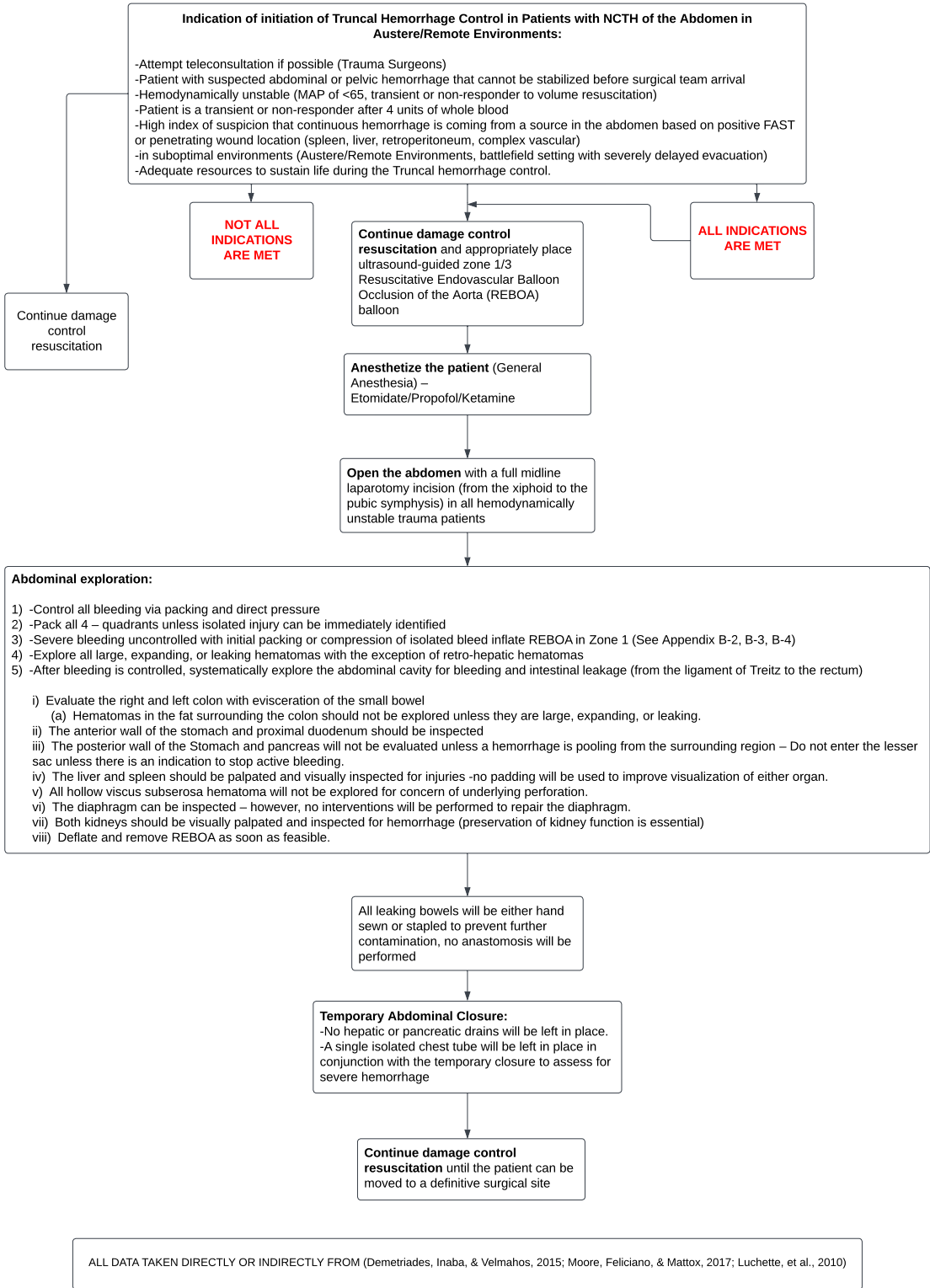
The study data were collected by the author of this article and entered into a Microsoft Office Excel for Mac version 16.41 (Microsoft et al.) Spreadsheet for data analysis (Cho et al., 2019; Fitch et al., 2001; Jones & Hunter, 1995; Lee et al., 2020). Once analyzed, the study data provided central tendencies and levels of dispersion to assess the level and degree of consensus for participant responses. The central tendencies expressed in this analysis are expressed as medians, and the dispersions are expressed as interquartile ranges. The consensus was based on the medians, and the level of dispersion was expressed using interquartile ranges. A participants’ response sheet was provided for each round, with the final data displayed after the second round.

Analysis of the data used three zones/regions: an Agreement zone/region (median 7 through 9), an Uncertain zone/region (median 4 through 6), and a Disagreement zone/region (median 1 through 3). The median establishes where 50 percent of the votes were cased. Establishing a consensus requires a minimum of 70 percent scoring of a statement within a specific zone/region. Therefore, if 30 percent of the votes are outside a particular “zone/region,” there is no consensus. A statement with a median score of seven or higher would be classified within the Agreement zone/region because 50 percent of the votes were categorized between

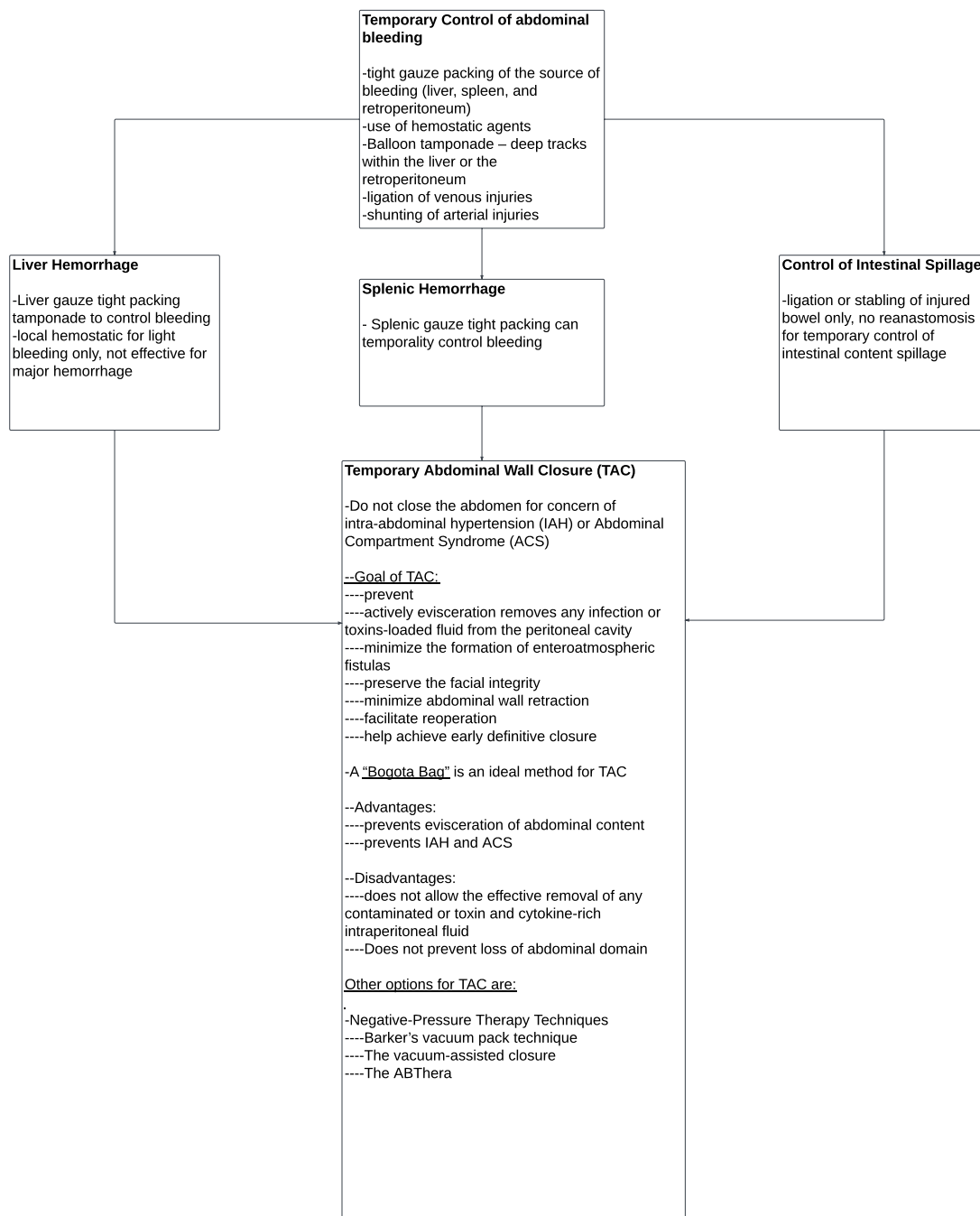
seven and nine. Despite being classified in the Agreement zone, there would be disagreement about the statement if 30 percent or more participants did not score “7, 8, or 9”.

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APPENDIX C: Evidence-informed Protocol - Revised

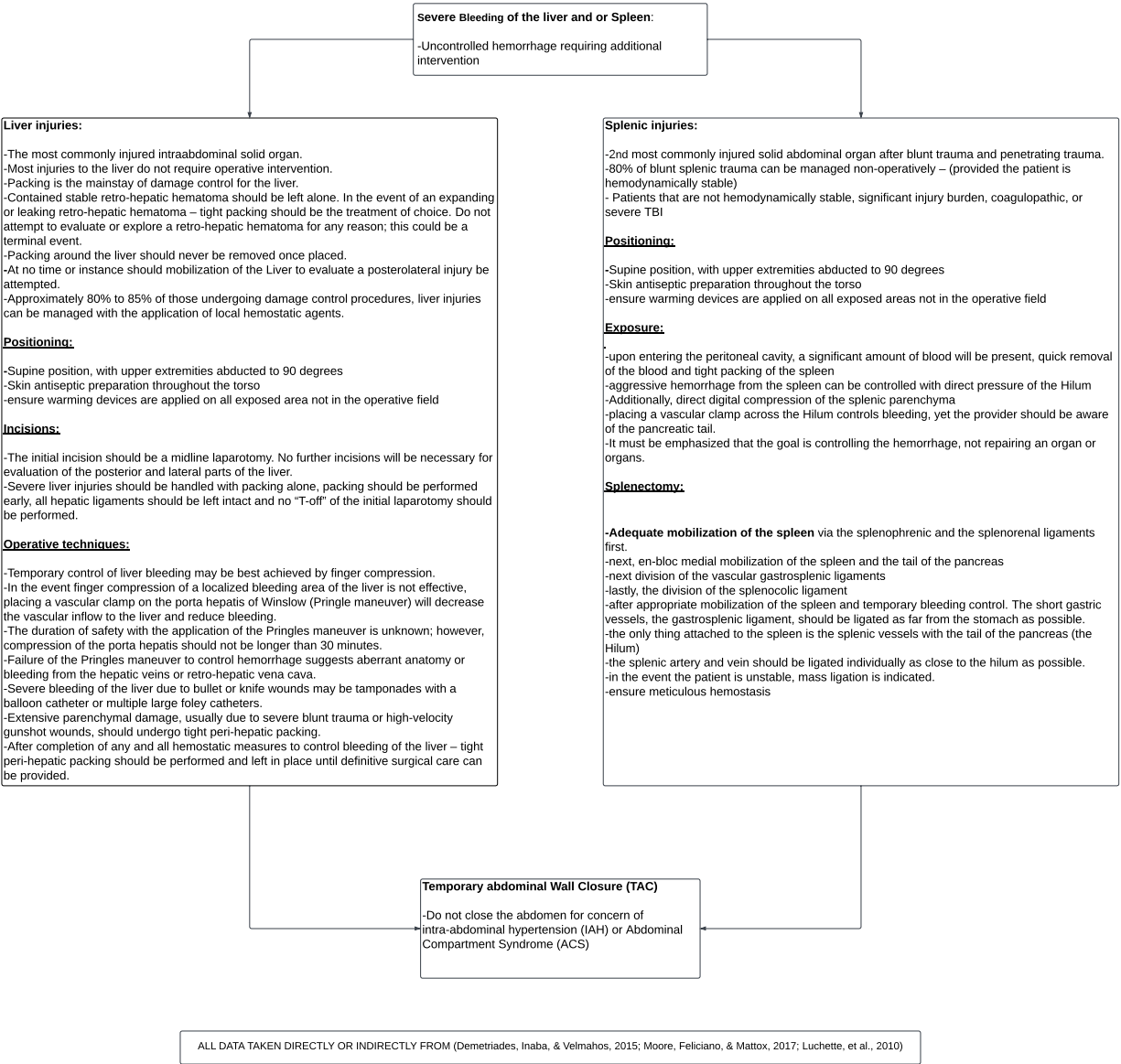


APPENDIX C2: Evidence-informed Protocol - Revised

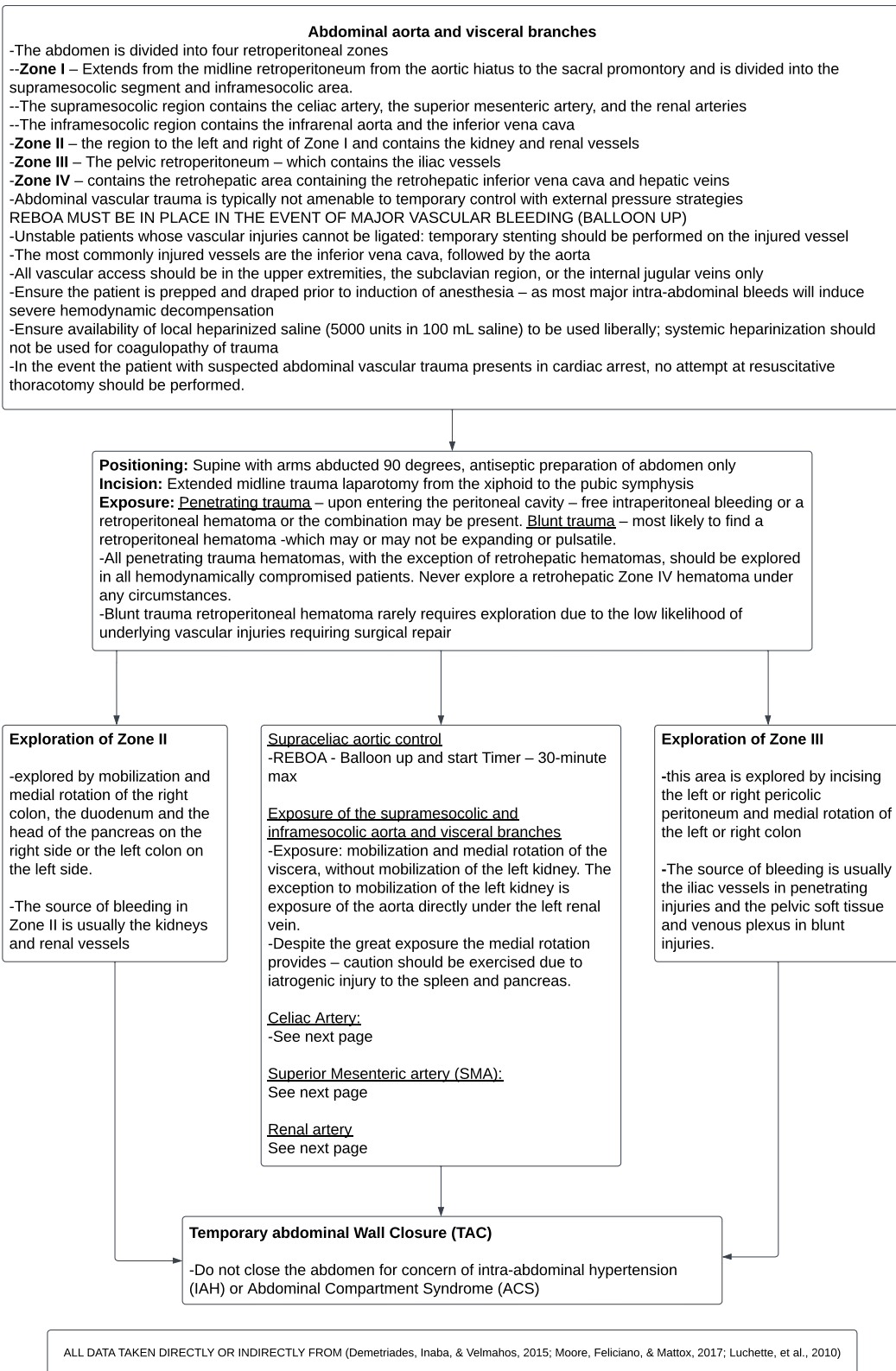


ALL DATA TAKEN DIRECTLY OR INDIRECTLY FROM (Demetriades, Inaba, & Velmahos, 2015; Moore, Feliciano, & Mattox, 2017; Luchette, et al., 2010)

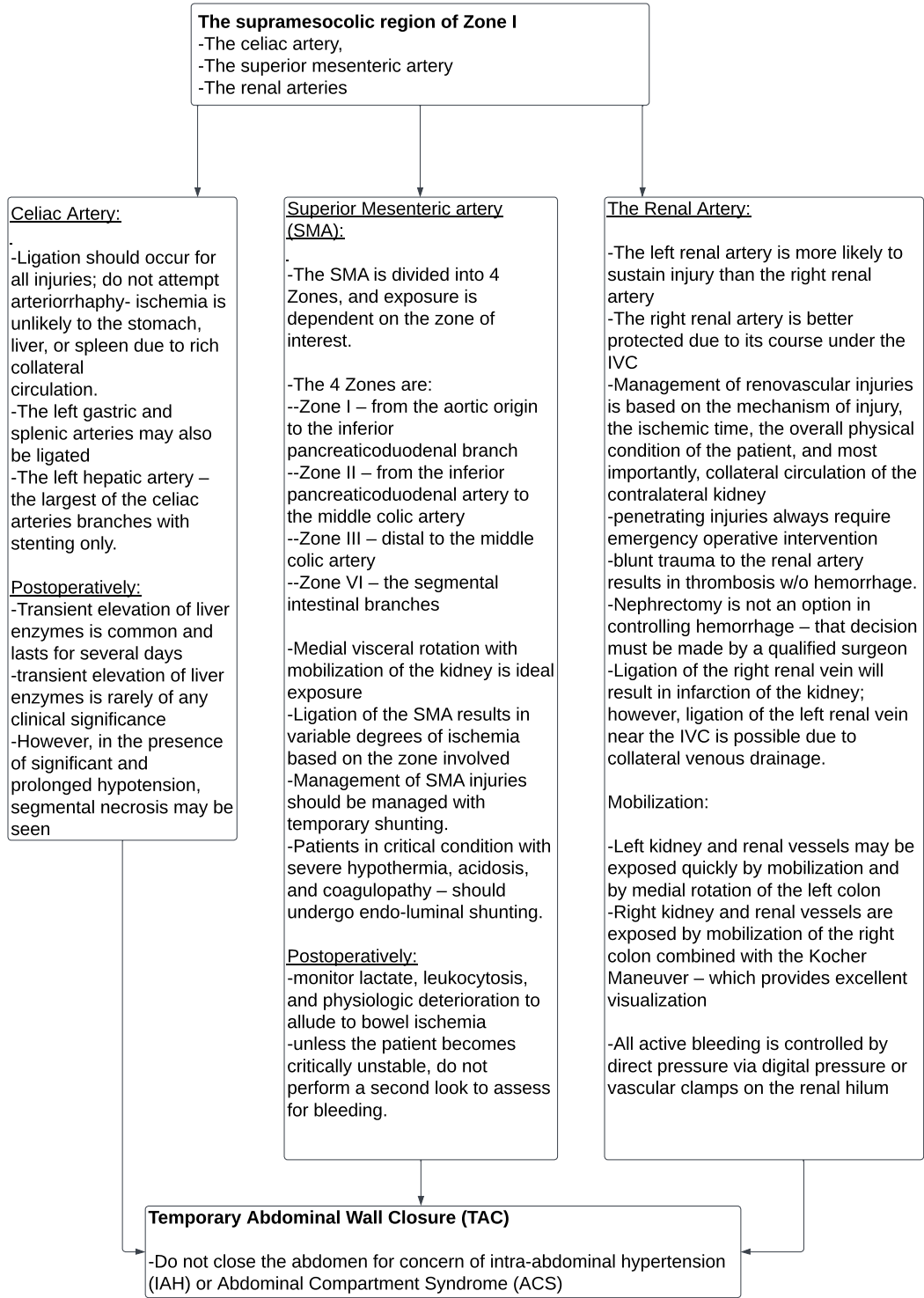
APPENDIX C3: Evidence-informed Protocol - Revised



APPENDIX C4: Evidence-informed Protocol - Revised



APPENDIX C5: Evidence-Informed Protocol - Revised



ALL DATA TAKEN DIRECTLY OR INDIRECTLY FROM (Demetriades, Inaba, & Velmahos, 2015; Moore, Feliciano, & Mattox, 2017; Luchette, et al., 2010)

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APPENDIX D: Measure of Success

First Measure of Success

What would be an acceptable percentage of success for a Fellowship trained licensed General Surgery Physician Assistant with at least three years of experience working in an Operative General Surgery or Trauma Surgery environment, to performing a four-quadrant abdominal packing ONLY in a patient with non-compressible abdominal hemorrhage of the abdomen in austere environments?							
	<10%	10%-20%	20%-30%	30%-40%	40%-50%	>50%	Missing Data
Survival							
Number of Participants that Selected Percent of Success	2	0	2	1	3	19	2
Percent of Participants	7%	0	7%	3%	10%	66%	7%

Second Measure of Success

What would be an acceptable percentage of success that would be acceptable to you to have a Fellowship-trained licensed General Surgery Physician Assistant, who has as least three years of experience working in an Operative General Surgery or Trauma Surgery environment to perform a four-quadrant abdominal packing, and vascular shunting in a patient with non-compressible abdominal hemorrhage in austere environments?							
	<10%	10%-20%	20%-30%	30%-40%	40%-50%	>50%	Missing Data
Survival							
Number of Participants that Selected Percent of Success	2	1	3	1	2	16	4
Percent of Participants	7%	3%	10%	3%	7%	55%	14%

Third Measure of Success

What would be an acceptable percentage of success that would be acceptable to you in order to have a Fellowship-trained licensed General Surgery Physician Assistant, who has as least three years of experience working in an Operative General Surgery or Trauma Surgery environment to perform a truncal hemorrhage in a patient with non-compressible abdominal hemorrhage in austere environments?							
	<10%	10%-20%	20%-30%	30%-40%	40%-50%	>50%	Missing Data
Survival							
Number of Participants that Selected Percent of Success	3	2	1	1	1	14	7
Percent of Participants	10%	7%	3%	3%	3%	48%	24%

BMJ Open

Gaining Consensus on a Protocol for General Surgery Physician Assistants in the Management of Non-Compressible Abdominal Hemorrhage in military austere Environments: a Delphi Study

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Background: Non-compressible abdominal hemorrhage (NCAH) is a potentially preventable cause of death due to injury. Limited-exploratory laparotomy by a non-surgeon is a temporary intervention to sustain life until definitive surgical intervention by Trauma Surgeons can be obtained. This study aims to establish consensus on a protocol for General Surgery Physician Assistants performing limited exploratory laparotomy to manage NCAH in an austere environment.

Method: This study included anonymized Trauma Surgeons and General Surgery Physician Assistants from military and civilian backgrounds. Participants were recruited from various professional surgical organizations, including direct interaction with Trauma Surgeons and Surgical Physician Assistants. Participants used a modified Delphi survey with a 9-point Likert scale in two rounds. The two surveys were categorized into three Parts: Protocol for NCAH (Part A), the potential role of General Surgery Physician Assistants (Part B), and measures of success (Part C). A total of 24 statements were voted on and assessed. Votes were divided into three zones: Agreement (median 7-9), Uncertain (median 4-6), and Disagreement (median 1-3). To reach a consensus, 70% agreement was required within a zone. If more than 30% of the votes fell outside of a specific zone, consensus was not achieved. After consensus, the original protocol was revised in an online meeting with experts.

Results: The initial analysis involved 29 participants. After two survey rounds, 19 out of 24 statements reached a consensus. Part A: 10 statements gained consensus, including in austere environments, controlling non-compressible abdominal hemorrhage can be challenging. A qualified General Surgery Physician Assistant should intervene. A FAST exam can be used for screening. Bleeding can be managed with packing and pressure. After managing the hemorrhage, the abdominal wall should be left open with a temporary closure technique. Part B: 9 statements gained consensus, including in austere locations, a licensed General Surgery Physician Assistant with a minimum of three years of experience working under the supervision of a Trauma/General Surgeon can perform interventions for limited-exploratory laparotomy for patients with non-compressible abdominal hemorrhage. Part C: General Surgery Physician Assistants will be required to have the same success rates as any qualified Surgeon.

Conclusion: Gaining consensus and implementing a revised protocol for managing NCAH by General Surgery Physician Assistants is attainable. General Surgery Physician Assistants will need formal training to manage NCAH. With the support of Trauma Surgeons who provide direct and indirect supervision, General Surgery Physician Assistants can develop a comprehensive understanding of the necessary skills and make sound decisions when treating patients with this condition. This teamwork can also increase surgical capacity and potentially decrease mortality rates for patients with NCAH in austere environments.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- We used a modified Delphi study with a 9-point Likert scale to assess the consensus on a protocol and the potential role of General Surgery Physician Assistants in performing limited exploratory laparotomy on patients with noncompressible abdominal hemorrhage in austere environments.

Background:

Despite the development of innovative interventions such as resuscitative endovascular balloon occlusion of the aorta (REBOA) and whole blood resuscitation over the past 26 years, the trauma surgical community has not yet found a way to sustain the life of a patient experiencing noncompressible abdominal hemorrhage (NCAH) long enough to reach definitive surgical care within an hour^{1,2}. Individuals who sustain survivable injuries associated with NCAH will, on average, hemorrhage within 30 minutes of sustaining injury³.

Future near-peer conflicts raise concerns about the availability of qualified surgical providers who can control bleeding and resuscitate. Despite more surgeon training, supply is expected to remain unchanged for 15 years, leading to a shortage of 10,100 to 19,900 surgeons by 2036⁴. Military trauma surgeons are in short supply, and the military's surgical capacity is dwindling⁵. Previous task shifting/sharing in the United States Military has not been successful, and non-trauma surgeons, such as OB/GYNs, are ill-equipped to manage trauma patients on the battlefield⁵. Training and working alongside Trauma and General Surgeons, General Surgery Physician Assistants acquire skill acquisition, skill sustainment and develop a comprehensive understanding, which leads to better discipline-specific decision-making abilities in trauma surgery and critical care⁶. General Surgery Physician Assistants can potentially help increase surgical capacity for the military and civilian surgical communities.

The current literature focuses on using surgical adjuncts to stop bleeding for up to two hours to sustain life until definitive surgical care can be delivered⁷. Although there have been discussions of assigning General Surgical Physician Assistants assignments to military forward surgical teams to either first assist in the operating room or to perform damage control resuscitation in the trauma bay while surgeons are operating during combat operations, no

A modified Delphi study was conducted to address both Research Questions. The Delphi technique was utilized to reach a consensus amongst a panel of experts to explore a concept outside the current standard of practice of the Trauma Surgical community in austere environments¹³.

The Conducting and Reporting of Delphi Studies (CREDES) reporting requirements were followed to ensure appropriate reporting of this modified Delphi study¹⁴.

Definition of Consensus

Establishing consensus through the Delphi method does not have specific guidelines regarding percentage or technique¹⁴⁻¹⁶. The definition of consensus was determined using the RAND/UCLA Appropriateness method¹⁷. A 9-point Likert scale was used to rate survey items. Votes were divided into three zones: Agreement (median 7-9), Uncertain (median 4-6), and Disagreement (median 1-3). To reach a consensus, 70% agreement was required within a zone. If more than 30% of the votes fell outside of a specific zone, consensus was not achieved. See Appendix B and B-2 for a detailed definition of Consensus.

Focus Group To Assess Perspectives And Opinions

Three authors, DA, PM, and PVW participated in a focus group with Committee on Surgical Combat Casualty Care (CoSCCC) members. The focus group lasted approximately one hour and discussed several important perspectives and opinions crucial to this study. One significant perspective that stood out was how General Surgery Physician Assistants would develop the decision-making skills needed to potentially perform a limited exploratory laparotomy in an austere environment on a patient with NCAH.

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Selection of Delphi panel

For this study, the Delphi panel comprised anonymized military and civilian Trauma Surgeons and General Surgery Physician Assistants from across the United States. This research study recruited participants from the Eastern Association for the Surgery of Trauma member's site. Participants were also queried by direct interaction with Trauma Surgeons at the Defense Health Agency San Antonio Military Medical Center and the American Association for Surgical Physician Assistants. Prospective participants were invited to participate in the Delphi rounds through email and letter via the United States Postal Service. Those interested in participating responded using either of the two methods. A second email or letter was sent if no response was received within one to two weeks. All participants who acknowledged receipt of the invitation letter and agreed to participate in the Delphi Study were sent a participant consent form approved by the George Washington University Institutional Review Board (IRB). Those prospective participants who signed and returned the consent form were enrolled in the modified Delphi Survey.

Expert committee

An expert committee was installed to advise on developing the protocol and revising it based on the consensus data from the Delphi rounds. The expert committee comprised five Trauma Surgeons (BS, SAS, MVB, DJ, TN) and two General Surgery Physician Assistants (SH, AM). Two senior researchers (PLM, PVW) were commissioned to ensure the validity and reliability of the Delphi process.

The protocol integrates evidence-based practices to improve medical practitioners' decision-making skills, synthesizing diverse literature from various medical and surgical research to address research inquiries¹¹. The original protocol is available upon request.

The survey contained three parts (Parts A through C). Parts A and B aimed to reach a consensus about what is known about the study of NCAH and its incorporation into a protocol (Part A) and on the potential role of General Surgery Physician Assistants in limited-exploratory laparotomy (Part B). In addition, Part C of the Delphi round 1 survey inquired about measures of success.

The survey items aimed to gather consensus on several areas of interest, including demographics, understanding of the problem, familiarity with current interventions, acceptance of General Surgery Physician Assistants performing limited-exploratory laparotomy, technical competencies required for such procedures, acceptance of the protocol, and support for efficacy trials. Foundational tasks/skills/concepts were based on graduating from an approved General Surgery Physician Assistant program and completing post-graduation fellowship training such as Trauma intensive care residency, as well as obtaining certifications in Advanced Trauma Life Support (ATLS), Fundamental of Critical Care Support (FCCS), Advance Surgical Skills for Exposure in Trauma (ASSET), Advanced Trauma Operative Management (ATOM), and Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA). Additional training skills were also identified through the survey process.

The study gathered anonymous data from Trauma Surgeons and General Surgery Physician Assistants through two rounds of surveys¹³. The limitation of conducting only two rounds was due to panelist fatigue^{16,17}. The first-round survey was developed based on the outcomes of a previously published scoping review and through discussions of

1 protocols/recommendations with one experienced Trauma Surgeon and one experienced General
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3 Surgery Physician Assistant¹⁸. The survey was then pilot-tested by two Trauma Surgeon opinion
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8 leaders and two senior General Surgery Physician Assistants. After the initial pilot testing, the
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10 survey was distributed to eight Emergency Medicine Physicians for review and comment on its
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12 appropriateness. No changes were made to the surveys following the pilot testing, and all
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14 participants expressed that the survey was clear and appropriate.
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17 The complete surveys from the first and second rounds are available on request⁶. The
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19 initial survey was developed in Microsoft Word and distributed via email. The manually drafted
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21 survey was constructed to allow participants to write notes and answer openly and freely using a
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23 comment box and drafting on the survey sheet. The second survey was an electronic survey
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25 developed and distributed by REDCap. Both surveys aimed to assess the acceptability of a
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27 knowledge tool of a protocol for non-surgeons to perform limited-exploratory laparotomy on
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29 patients with NCAH hemorrhage. The survey was designed with a 9-point Likert Scale to gather
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31 ratings and responses, and each item was accompanied by a comment box for additional input by
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33 each Trauma Surgeon and General Surgery Physician Assistant.
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38 The survey's second round was sent out to the panelists after analyzing the data from the
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40 first round. The summary of the first round was distributed to all panelists to keep them informed
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42 about the results of the previous round. By providing a feedback summary of the previous round,
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44 panelists could provide more relevant responses for the current round. The feedback summary
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46 included the mean, median, standard deviation, interquartile range, percent of agreement and
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48 disagreement, and degree of consensus from the 29 Delphi panelists, along with comments and
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50 arguments provided by the panelists. Descriptive statistics were used to compare the surveyed
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panelists using interquartile ranges, and the coefficient of variation was used to evaluate the significance of other covariables that may have affected the outcome¹⁹.

The protocol underwent an iterative review by the knowledgeable panel. The protocol was revised after thoroughly reviewing the original protocol and consensus data.

Patient and public involvement

There is no involvement of any patients or members of the general public in this research.

Results

Figure 1's flow chart illustrates the stages of this modified Delphi Study. The flow chart has five stages: the development stage, survey stage #1, the revision stage, survey stage #2, and the agreement stage¹³. It provides a brief but comprehensive view of the modified Delphi process.

Participants

Seventy-one potential participants were invited to participate in this study. Forty expressed their interest in participating in the modified Delphi Study. Of the interested participants, 30 (75%) completed and returned a signed consent form and the initial survey. As shown in Table 1, the first-round analysis included only 29 participants due to one incomplete survey. Of the 29 participants, 27 (93.1%) took part in the second round to reach a consensus, which was then used to revise the protocol.

Most of the study participants were between 40 and 49 years old, comprising 18 individuals (62.1%). In this study, most participants were physicians (MD/DO), making up 17 individuals (58.6%). Furthermore, 9 participants (31.0%) reported working in their respective disciplines for 11-15 years, while 6 (20.7%) indicated 16-20 years of experience. Additionally,

11 participants (37.9%) indicated that they had deployed less than three times, while another 11 (37.9%) indicated that they had deployed 3-4 times. Finally, 16 participants (55.2%) deployed in non-special operation units during the global war on terror.

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Table 1: Demographics

Characteristics	Number (%)
N: (number of Respondents)	29
Gender:	
Male	27 (93.1%)
Female	2 (6.9%)
Other	0 (0.0%)
Age Group (years):	
20-29	0 (0.0%)
30-39	2 (6.9%)
40-49	18 (62.1%)
50-59	8 (27.6%)
60 and up	1 (3.5%)
Medical License:	
MD	14 (48.3%)
DO	3 (10.3%)
PA	12 (41.4%)
How many years have you been practicing as a Licensed MD, DO, PA?	
5 years or less	1 (3.4%)
6 – 10 years	3 (10.3%)
11 – 15 years	9 (31.0%)
16 – 20 years	6 (20.7%)
21 – 25 years	5 (17.2%)
26 – 30 years	3 (10.3%)
31 – 35 years	1 (3.4%)
36 - >36 year	1 (3.4%)
Number of Deployments providing medical support for War on Terror:	
<3 deployments	11 (37.9%)
3-4 deployments	11 (37.9%)
5-6 deployments	6 (20.7%)
>6 deployments	1 (3.5%)
Missing	0 (0.0%)
Type of Unit Supported	
-Non-Special operations	16 (55.2%)
-Special operation only	2 (6.9%)
-Special operation and non-special operations	5 (17.2%)
-Special operations and federal government	1 (3.5%)
-Special operation, non-special operations and non-special operations/non-federal government	1 (3.5%)
-Special Operation, non-special operations and federal government	3 (10.3%)

- Special operation, non-special operations, federal government and non-special operations/non-federal government	1 (3.5%)
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First-Round Consensus Data (Parts A and B)

In Part A of the revised protocol, five out of thirteen statements gained consensus in incorporating the study results into the protocol. Statement 5 gained consensus, indicating that four units of whole blood are enough to determine if a patient is a transient or non-responder during damage control resuscitation. Statement 9 also gained consensus, noting that most abdominal bleeding can be controlled with tight four-quadrant packing and/or direct pressure of bleeding vessels. For statement 10, in patients with severe hemorrhage that cannot be controlled with tight four-quadrant packing and/or direct pressure, REBOA can be used as an alternative to gain proximal aortic control over a left-sided thoracotomy and/or Supraceliac aortic control. Statement 12 recommends that after all major bleeding is controlled, the abdominal cavity should be systematically explored for bleeding and intestinal leakage (from the ligament of Treitz to the rectum). Lastly, statement 13 suggests that in austere environments, the abdominal wall should be left open upon managing intraabdominal hemorrhage, with the use of a temporary abdominal wall closure technique such as a Bogota bag with a chest tube placed on low suction to remove intraperitoneal fluid.

The remaining eight statements did not meet consensus, as noted in Appendix C. There was disagreement with these eight statements, indicating that thirty percent of the votes were outside the median region. Despite the median being within the “Agreement Zone,” greater than thirty percent of the votes were not within that region, contributing to the non-consensus.

In Part B, 8 out of 11 statements about the potential role of General Surgery Physician Assistants in controlling abdominal hemorrhage gained consensus. A licensed General Surgery

Physician Assistant with at least three years of experience working in an operative General/Trauma Surgery environment can be an asset to the General/Trauma Surgery disciplines in managing patients with NCAH in austere environments. General Surgery Physician Assistants can assess and identify indications for exploratory laparotomy, place an ultrasound-guided REBOA to assist in the management of Zone I and III hemorrhage, perform a full midline laparotomy incision (from the xiphoid to the pubic symphysis), perform a tight four-quadrant abdominal packing, systematically explore the abdominal cavity for bleeding and intestinal leakage (from the ligament of Treitz to the rectum), effectively use REBOA during intra-abdominal hemorrhage to control proximal aortic hemorrhage and perform a temporary abdominal closure.

The three remaining statements did not reach a consensus, as indicated in Appendix C. There was disagreement regarding statements one, three, and ten.

Second-Round Consensus Data (Parts A and B)

Appendix D indicates that eight statements that did not gain consensus in round one were revised, with Statement # 3 being split into four subsections. Statement #7 was revised to ensure consistent consensus that invasive interventions are necessary to sustain life in patients with NCAH despite DCR. This resulted in the production of eleven new statements, which underwent consensus in Part A. Out of the eleven revised statements, five gained consensus during the second round of surveys.

In Part A, Statement #1 establishes that NCAH is the leading cause of potentially preventable death in prehospital/battlefield settings. Statement #2 established that in austere environments with limited resources and no licensed surgical provider or team, there is insufficient evidence to guide medical/surgical intervention for patients with NCAH;

furthermore, how to sustain their lives for more than six hours is unclear. Statement # 6 establishes that in an austere environment without a Trauma/General Surgeon present, a patient with NCAH may undergo surgical intervention (limited-exploratory laparotomy) if a trained and qualified General Surgery Physician Assistant is available. However, this should only be done if adequate teams (anesthesia providers, nurses, and surgical technicians) and supplies to sustain the patient's physiology during the operation are present. According to Statement #7, it has been concluded that DCR alone may not be enough to sustain the life of patients with NCAH in austere environments for a prolonged evacuation lasting four hours. To ensure the potential survival of a patient with NCAH in such conditions, it may be necessary to perform an invasive intervention. Statement #8 established consensus for the use of a focused assessment with sonography for trauma (FAST) exam or diagnostic peritoneal lavage use as a screening tool to assess the presence of significant intra-abdominal hemorrhage in patients with NCAH in austere environments. Statement #11 established consensus, noting that all expanding and leaking hematomas, including retro-hepatic hematoma, should only be managed with packing by appropriately trained and qualified General Surgery Physician Assistants in austere/remote environments where a Trauma/General Surgeon is not immediately available. Statement #10 established that during the first and second surveys, there was no consensus that an appropriately trained and qualified General Surgery Physician Assistant with a qualified and trained anesthesiology and surgical support team could successfully perform a limited-laparotomy with abdominal hemorrhage control in hemodynamically unstable trauma patients that meet the indication for abdominal hemorrhage control in austere/remote environments, as listed in the attached protocol.

Statements #3, 4, and 5 were revised from previous Round #1, Statement #3; in Round #2, one of the four statements from this revised question gained consensus (Statement #6), and the remaining three statements (Statements #3,4,5) did not maintain consensus. Statement #9 did not gain consensus for placement of an ultrasound-guided REBOA catheter with the balloon up as a potential first step before surgically opening the abdomen in patients with NCAH in austere environments. Part B (Appendix E) contained three additional statements that did not gain consensus in Round #1. After revision, Statement #1 and Statement # 10 in Round 2, Part B did not gain consensus. Statement #3 gained consensus indicating a fellowship-trained licensed General Surgery Physician Assistant or a General Surgery Physician Assistant who is currently working in a Trauma Surgery Department with at least three to four years of experience operating next to a Trauma Surgeon or General Surgeon has the ability to perform limited-exploratory laparotomy interventions in austere environments to control bleeding only with a team of qualified medical providers.

Final Consensus Results

Table 2 summarizes the statements that received consensus during Rounds 1 and 2 of the modified Delphi Study. The study presents the results of a survey conducted in two rounds, where participants agreed on a set of statements. Table 2 summarizes the findings, indicating that Part A had a consensus on 10 out of 13 statements, while Part B had a consensus on nine out of 11 statements. Overall, 19 out of the 24 statements reached consensus across both parts.

Table 2: Summary of Statements that Have Gained Consensus

Combined Statement from Survey One and Two that made consensus	Degree of Consensus	Strength of Recommendation
Part A: Protocol		
Noncompressible torso hemorrhage (NCTH) is the leading cause of potentially preventable death in the prehospital/battlefield environment.	Very Good	Strong
In austere/remote environments that are resource limited and there is no licensed surgical provider or team; evidence is scarce to guide medical or surgical intervention to sustain life for greater than 6 hours in patients with non-compressible torso hemorrhage of the abdomen.	Very Good	Strong
In an austere environment lacking a Trauma/General Surgeon at the bedside, a patient who is suspected of having non-compressible torso hemorrhage of the abdomen who meets the following criteria should have a surgical intervention (truncal hemorrhage control) performed to control bleeding by a qualified General Surgery Physician Assistant: <ul style="list-style-type: none">Adequate resources to sustain life during the operation to obtain truncal hemorrhage control	Good	Weak
4 units of whole blood is sufficient to assess if a patient is a transient or non-responder during damage control resuscitation.	Very Good	Strong
In austere/remote environments where CT scan is not available, a FAST exam or diagnostic peritoneal lavage can be used as screening tools to assess for the presence of significant intra-abdominal hemorrhage in the hands of a qualified provider.	Very Good	Strong
Most bleeding within the abdomen can be controlled with tight four quadrant packing and/or direct pressure of bleeding vessels.	Good	Weak
In patients with severe hemorrhage that is not controlled with tight four quadrant packing and or direct pressure. REBOA would serve as alternative to gain proximal aortic control over a left sided thoracotomy and or Supraceliac aortic control.	Good	Weak
All expanding and/or leaking hematomas, including retro-hepatic hematoma, should only be managed with packing by non-surgeons (appropriately trained and qualified General Surgery Physician Assistants) in austere/remote environments where a Trauma/General Surgeon is not immediately available.	Good	Weak
After all major bleeding is controlled, the abdominal cavity should be systematically explored for bleeding and intestinal leakage (from the ligament of Treitz to the rectum).	Very Good	Strong
Upon managing intraabdominal hemorrhage in austere/remote environments, the abdominal wall should be left open with the use of a temporary abdominal wall closure technique such as the use of a Bogota bag with a chest tube placed on low suction to remove intraperitoneal fluid.	Very Good	Strong
Part B: Potential role of General Surgery Physician Assistants in truncal hemorrhage control		
A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment is an asset to the General Surgery and or Trauma Surgery disciplines.	Very Good	Strong
A Fellowship trained licensed General Surgery Physician Assistant or a General Surgery Physician Assistant that is currently working in a Trauma Surgery Department with at least three to four years of experience operating next to a Trauma Surgeon or General Surgeon, has the ability to perform truncal hemorrhage control interventions in austere/remote environments to control bleeding only with a team of qualified medical providers	Good	Weak
A Fellowship trained licensed General Surgery Physician Assistant who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment, can reference the Indications for the initiation for truncal hemorrhage control in patients with non-compressible torso hemorrhage of the abdomen in austere/remote environments to decide if truncal hemorrhage control is indicated.	Very Good	Strong
A Fellowship trained licensed General Surgery Physician Assistant who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment, can place an ultrasound guided REBOA in zone III to gain proximal aortic control.	Good	Weak

A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment, may be trained to perform a full midline laparotomy incision (from the xiphoid to the pubic symphysis) on patients with non-compressible torso hemorrhage of the abdomen in austere/remote environments.	Good	Weak
A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment may be trained to perform a tight four quadrant abdominal packing on patients with non-compressible torso hemorrhage of the abdomen in austere/remote environments.	Very Good	Strong
A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment may be trained to systematically explore the abdominal cavity for bleeding and intestinal leakage (from the ligament of Treitz to the rectum).	Very Good	Strong
A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment can be trained to effectively use REBOA during intra-abdominal hemorrhage to control proximal aortic hemorrhage.	Good	Weak
A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment can be trained to perform a temporary abdominal closure utilizing a Bogota bag and using a chest tube at low suction to remove intraperitoneal fluid in patient with non-compressible torso hemorrhage of the abdomen in austere/remote environments.	Very Good	Strong

Measures of Success (Part C)

Three measures of success were solicited from the participants in part C, who completed the first survey for the modified Delphi Study. Success was defined as the patient surviving after undergoing surgery performed by a General Surgery Physician Assistant for NCAH. The first measure of success was to assess what participants perceived as a successful outcome of a General Surgery Physician Assistant performing a four-quadrant abdominal packing ONLY in a patient with NCAH in austere environments. Nineteen (65.5%) indicated an expectation that greater than fifty percent survival would be acceptable (Appendix F). The second question queried what participants believed would be an acceptable level of success for General Surgery Physician Assistants performing a four-quadrant abdominal packing AND vascular shunting in a patient with NCAH in austere environments. Sixteen (57.1%) participants indicated that greater than 50% is a measure of success for a General Surgery Physician Assistant to perform a four-

quadrant abdominal packing AND vascular shunting in a patient with NCAH in austere environments (Appendix F). The final measure of success queried what participants believed would be an acceptable measure of success for a General Surgery Physician Assistant performing abdominal hemorrhage on a patient with NCAH in austere environments. Fourteen (50%) participants indicated that greater than 50% would be a measure of success (Appendix F).

Revision of the Protocol

The Expert Committee edited the protocol after an iterative review of the modified Delphi Study final results and the original protocol. Major revisions were made in the initial indications to initiate limited-exploratory laparotomy in patients with NCAH in Austere/Remote environments. The revised changes included attempting teleconsultation, if possible (Trauma Surgeon), Patients with suspected abdominal or pelvic hemorrhage that cannot be stabilized before surgical team arrival, and having a high index of suspicion that continuous hemorrhage is coming from a source in the abdomen based on positive FAST or penetrating wound location (spleen, liver, retroperitoneum, complex vascular). The next minor revisions concerned the placement of REBOA during DCR with the balloon down versus the previous discussion of having the balloon up. The next minor revision comprised anesthetizing the patient with General Anesthesia (etomidate, propofol, ketamine). The addition of hemostatic agents in the temporary control of abdominal packing was also included in the final version.

Discussion

This study gained consensus on 19 of 24 statements for General Surgery Physician Assistants to perform limited-exploratory laparotomy to manage noncompressible torso trauma in an austere environment. The consensus was used to develop an untested revised protocol. This

protocol includes indications for controlling abdominal hemorrhage temporarily and addressing severe bleeding of the liver and spleen, abdominal aorta and visceral branches, and the supramesocolic region.

The proposed revised protocol is untested and introduces a new approach to managing NCAH by general surgery physician assistants in austere environments. This protocol is intended for use by surgeons and trained general surgery physician assistants who are credentialed and supported by a team to manage the patient's physiology. According to experts, a properly trained physician assistant can manage operative hemorrhage control in an austere environment with direct or indirect physician oversight, but they should not perform vascular shunting. Only general surgery physician assistants credentialed by a certified credentialing body and operating under direct or indirect supervision should consider performing the interventions outlined in the revised protocol.

The use of REBOAs to support abdominal hemorrhage control during DCR and potentially during the truncal control intervention is an essential component of supporting the intervention of non-surgeons performing limited-exploratory laparotomy. Early implementation of REBOAs for proximal abdominal hemorrhage control limits blood loss, while Trauma Surgeons and General Surgery Physician Assistants intervene to temporize intraabdominal hemorrhage.

Task shifting/sharing is a strategic method of assigning healthcare duties among teams within your medical discipline. The need for task shifting/sharing results from the “large and unmet burden of surgical disease” and the declining number of surgical professionals to meet this progressive challenge²⁰. It involves delegating specific responsibilities from highly skilled professionals to those with less training and qualifications who work under the direct or indirect

supervision of the delegating provider. The delegation occurs only after a comprehensive understanding of the specific medical discipline has been established to allow the healthcare professional to make appropriate decisions²¹. The task-shifting/sharing approach helps make the most of available human resources in healthcare. The World Health Organization has discussed task shifting/sharing, currently used in 23 African countries²².

Moreover, task shifting/sharing has been implemented in 27 countries outside Africa, including Europe, America, Canada, New Zealand, and Australia²³. Healthcare providers who engage in task shifting/sharing have outcomes equivalent to those of their more educated mentors²¹. This Delphi study concludes that General Surgery Physician Assistants are capable healthcare providers who, if given appropriate training and supervision, can manage a patient with NCAH in austere environments with direct and indirect supervision using a protocol.

Limitations

It is essential to acknowledge the limitations of this modified Delphi Study. One significant limitation is the lack of registries for General Surgery Physician Assistant participants. Additionally, it is assumed that all General Surgery Physician Assistants have received similar training and worked in academic institutions with direct and indirect supervision. However, this assumption is only partially accurate as most General Surgery Physician Assistants in the United States are trained on the job in non-academic institutions rather than completing a fellowship program after their core Physician Assistant program studies have been completed. This difference between the two categories of General Surgery Physician Assistants is a limitation and a gap that needs to be addressed in future research.

Conclusion

The results of this Delphi study suggest that managing NCAH in challenging environments by General Surgery Physician Assistants using limited exploratory laparotomy is a viable option following intensive and focused training and mentorship. The next important step is to test the revised protocol to evaluate its feasibility in clinical trials. Using the new protocol to treat NCAH is a reasonable goal for General Surgery Physician Assistants to achieve under direct or potentially indirect supervision in the future.

Figure Legend

- Figure 1: Modified Delphi Study Flow Chart

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Contributorship Statement

DA, PLM, and PVW designed the study with input from all authors. DA and SH performed data collection and analysis. MM provided statistical data consultation and analysis. PLM, TCN, and PVW reviewed all data for writing, acceptability, and critical revisions. The guarantor of the study is Dr. Donald Adams / DA; accepts full responsibility for the finished work and/or the conduct of the study, had access to the data, and controlled the decision to publish.'

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Competing Interests Statement

All the authors have no conflict of interest or competing interest.

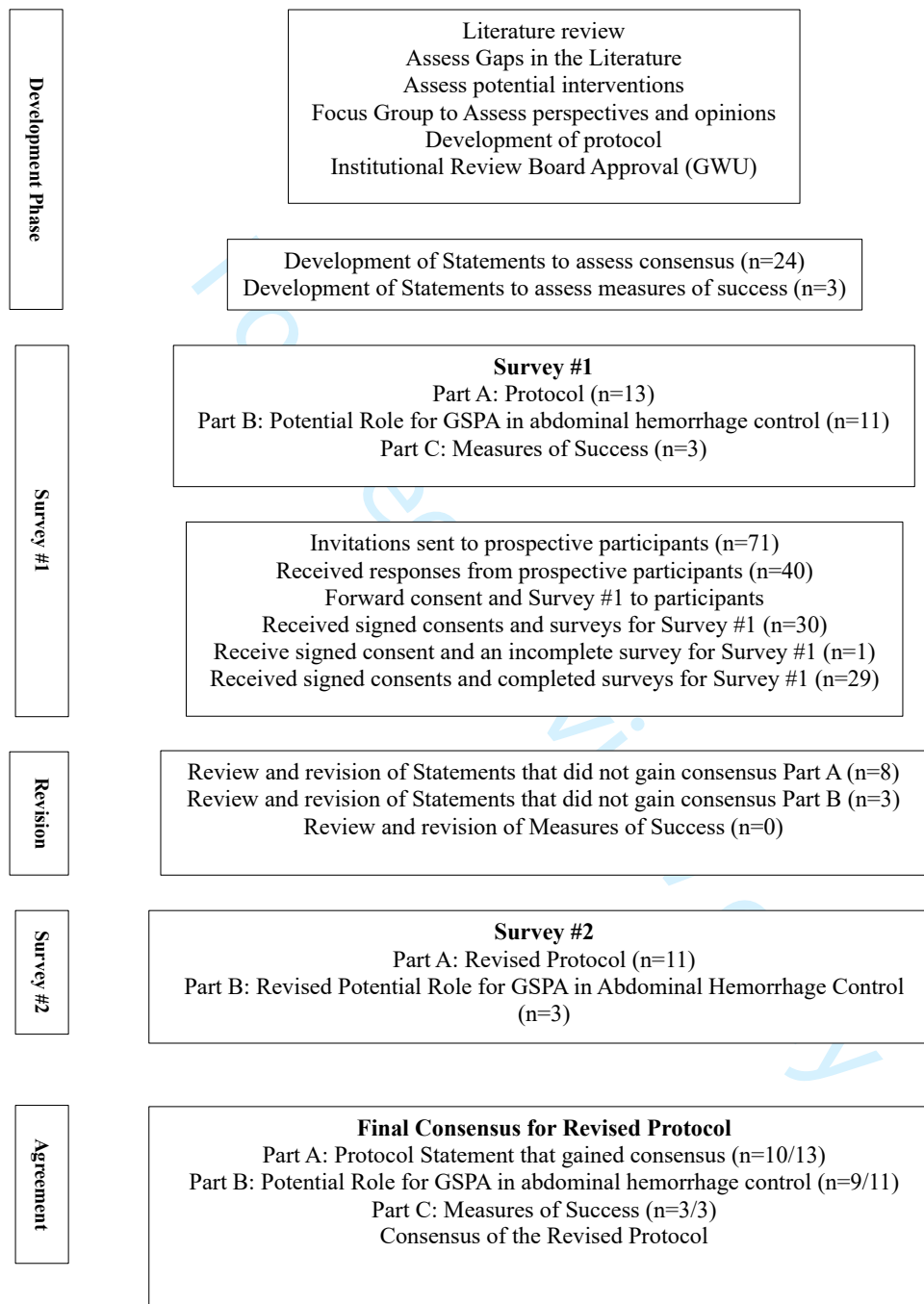
Data Sharing Statement

All data from this manuscript is available upon request after approval from the George Washington University Institutional Review Board.

Ethics Approval Statement

The George Washington University institutional review board approved this study (NCR203117). All participants gave informed consent before participating in this study.

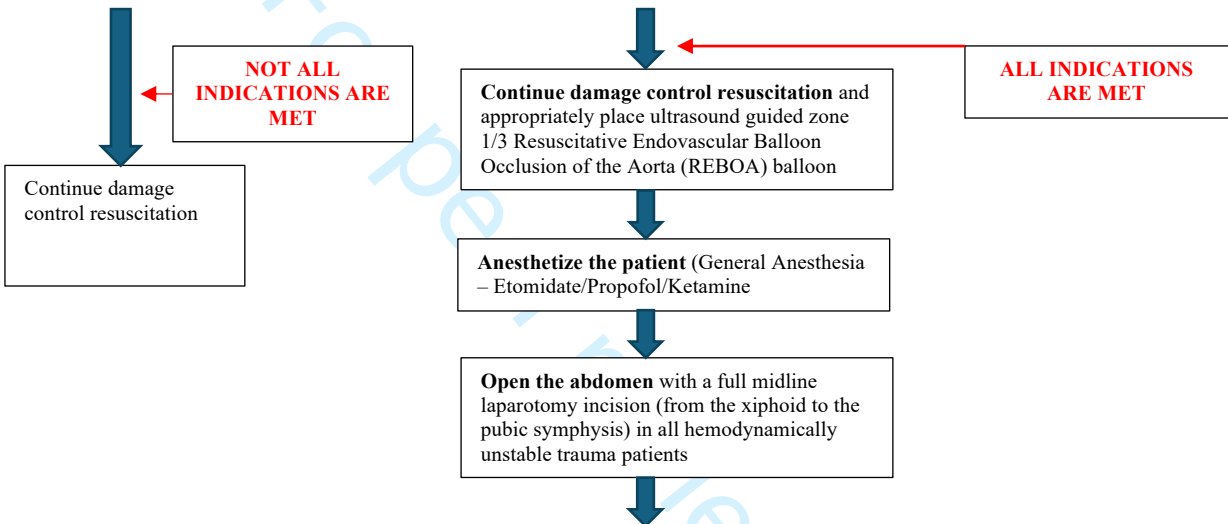
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Figure 1: Modified Delphi Study Flow Chart

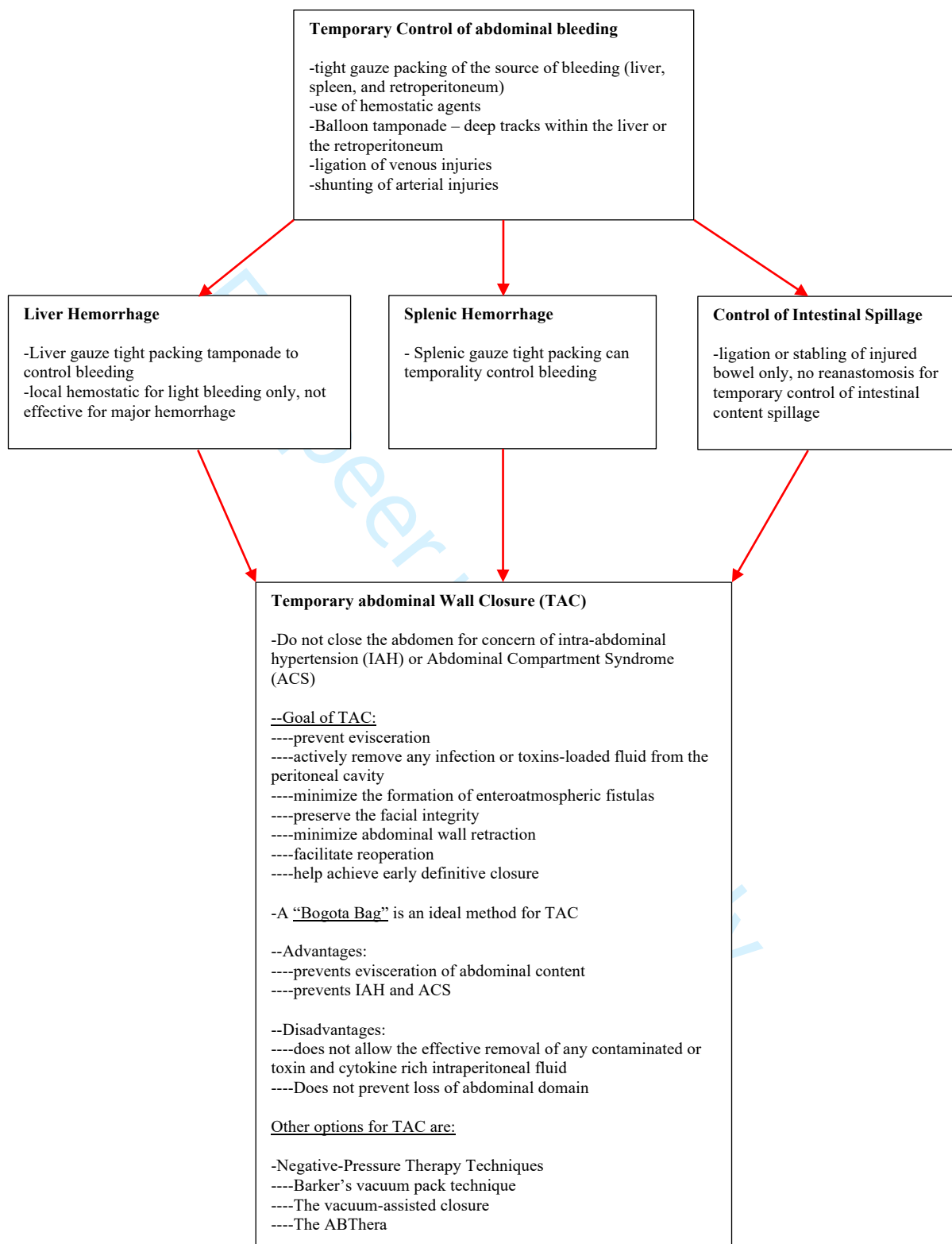
APPENDIX A. Protocol - Revised

Indication of initiation of Truncal Hemorrhage Control in Patients with NCTH of the Abdomen in Austere/Remote Environments:

- Attempt teleconsultation if possible (Trauma Surgeons)
- Patient with suspected abdominal or pelvic hemorrhage that cannot be stabilized before surgical team arrival
- Hemodynamically unstable (MAP of <65, transient or non-responder to volume resuscitation)
- Patient is a transient or non-responder after 6 units of whole blood
- High index of suspicion that continuous hemorrhage is coming from a source in the abdomen based on positive fast or penetrating wound location (spleen, liver, retroperitoneum, complex vascular)
- in suboptimal environments (Austere/Remote Environments, battlefield setting with severely delayed evacuation)
- Adequate resources to sustain life during the Truncal hemorrhage control.

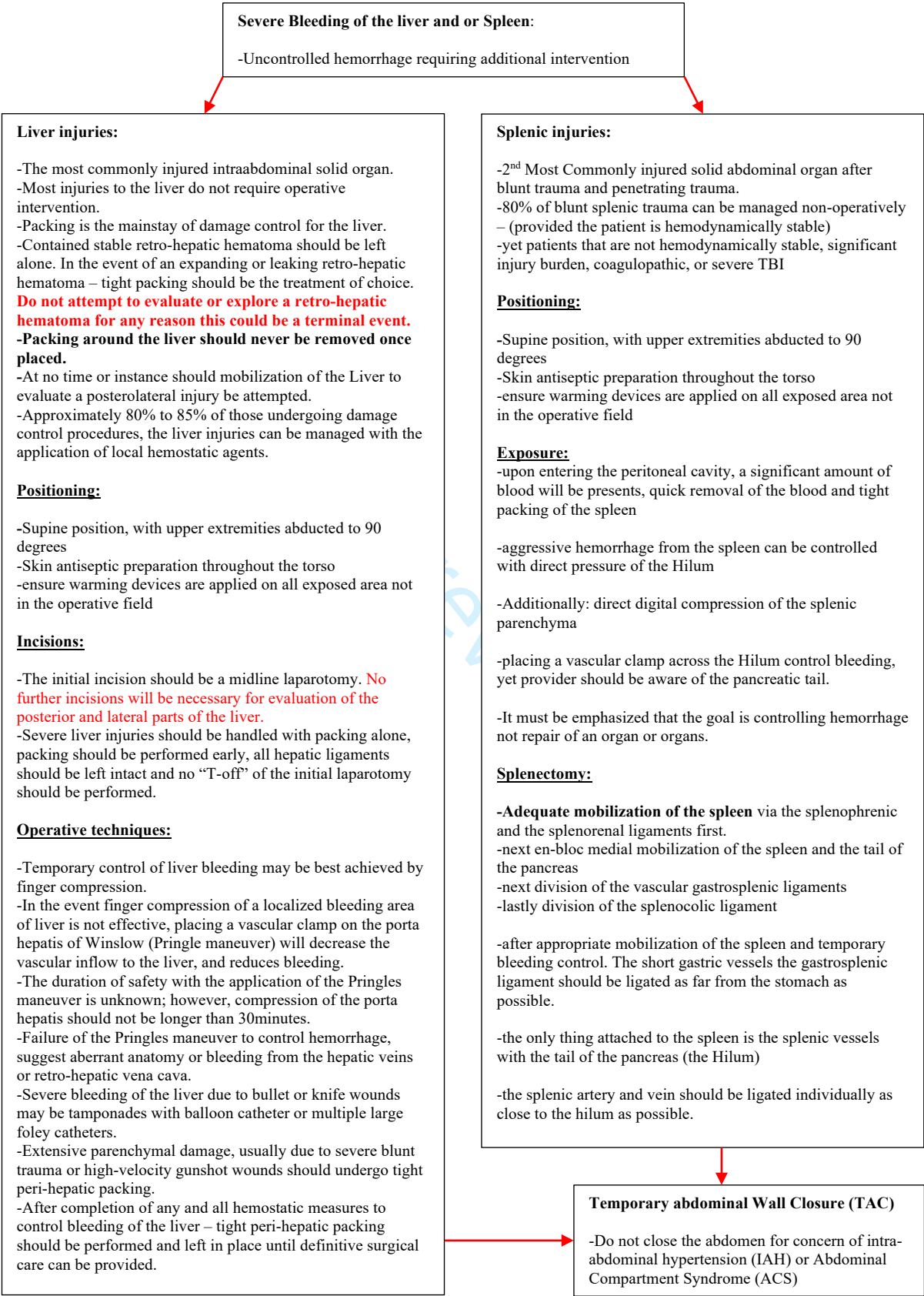


APPENDIX A-2



ALL DATA TAKEN DIRECTELY OR INDIRECTLY FROM (Demetriades, Inaba, & Velmahos, 2015) (Moore, Feliciano, & Mattox, 2017) (Luchette, et al., 2010)

APPENDIX A-3



ALL DATA TAKEN DIRECTELY OR INDIRECTLY FROM (Demetriades, Inaba, & Velmahos, 2015) (Moore, Feliciano, & Mattox, 2017) (Luchette, et al., 2010)

APPENDIX A-4

Abdominal aorta and visceral branches

- The abdomen is divided into four retroperitoneal zones
- Zone I** – Extends from the midline retroperitoneum from the aortic hiatus to the sacral promontory is divided in the supramesocolic segment and inframesocolic area.
- The supramesocolic region contains the celiac artery, the superior mesenteric artery, and the renal arteries
- The inframesocolic region contains the infrarenal aorta and the inferior vena cava
- Zone II** – the region to the left and right of Zone I and contain the kidney and renal vessels
- Zone III** – The pelvic retroperitoneum – which contains the iliac vessels
- Zone IV** – contains the retrohepatic area containing the retrohepatic inferior vena cava and hepatic veins
- Abdominal vascular trauma is typically not amenable to temporary control with external pressure strategies
- REBOA MUST BE IN PLACE IN THE EVENT OF MAJOR VASCULAR BLEEDING (BALLOON DOWN)**
- Unstable patients whose vascular injuries cannot be ligated temporary stenting should be performed to the injured vessel
- The most commonly injured vessels are the inferior vena cava followed by the aorta
- All vascular access should be in the upper extremities, the subclavian region or the internal jugular veins only
- Ensure patient is prepped and draped prior to induction of anesthesia – as most major intra-abdominal bleeds will induce severe hemodynamic decompensation
- Ensure availability of local heparinized saline (5000 units in 100 mL saline) to be used liberally, Systemic heparinization should not be used to coagulopathy of trauma
- In the event the patient with suspected abdominal vascular trauma presents in cardiac arrest, no attempt at resuscitative thoracotomy should be performed.

Positioning: Supine with arms abducted 90 degrees, antiseptic preparation of abdomen only

Incision: Extended midline trauma laparotomy, from the xiphoid to the pubic symphysis

Exposure: Penetrating trauma – upon entering the peritoneal cavity – free intraperitoneal bleeding or a retroperitoneal hematoma or the combination may be present. Blunt trauma – most likely to find a retroperitoneal hematoma -which may or may not be expanding or pulsatile.

-All penetrating trauma hematoma with the exception of retrohepatic hematomas should be explored in all hemodynamically compromised patients. **Never explore a retrohepatic Zone IV hematoma under any circumstances.**

-Blunt trauma retroperitoneal hematoma rarely require exploration, due to low likelihood for underlying vascular injuries requiring surgical repair

Exploration of Zone II

-explored by mobilization and medial rotation of the right colon, the duodenum and the head of the pancreas on the right side or the left colon on the left side.

-The source of bleeding in Zone II is usually the kidneys and renal vessels

Exploration of Zone ISupraceliac aortic control

-REBOA - Balloon up and start Timer – 30-minute max

Exposure of the supramesocolic and inframesocolic aorta and visceral branches

-Exposure: mobilization and medial rotation of the viscera, without mobilization of the left kidney. The exception to mobilization of the left kidney is exposure of the aorta directly under the left renal vein.

-Despite the great exposure the medial rotation provides – caution should be exercised due to iatrogenic injury to the spleen and pancreas.

Celiac Artery:

-See next page

Superior Mesenteric artery (SMA):

See next page

Renal artery

See next page

Exploration of Zone III

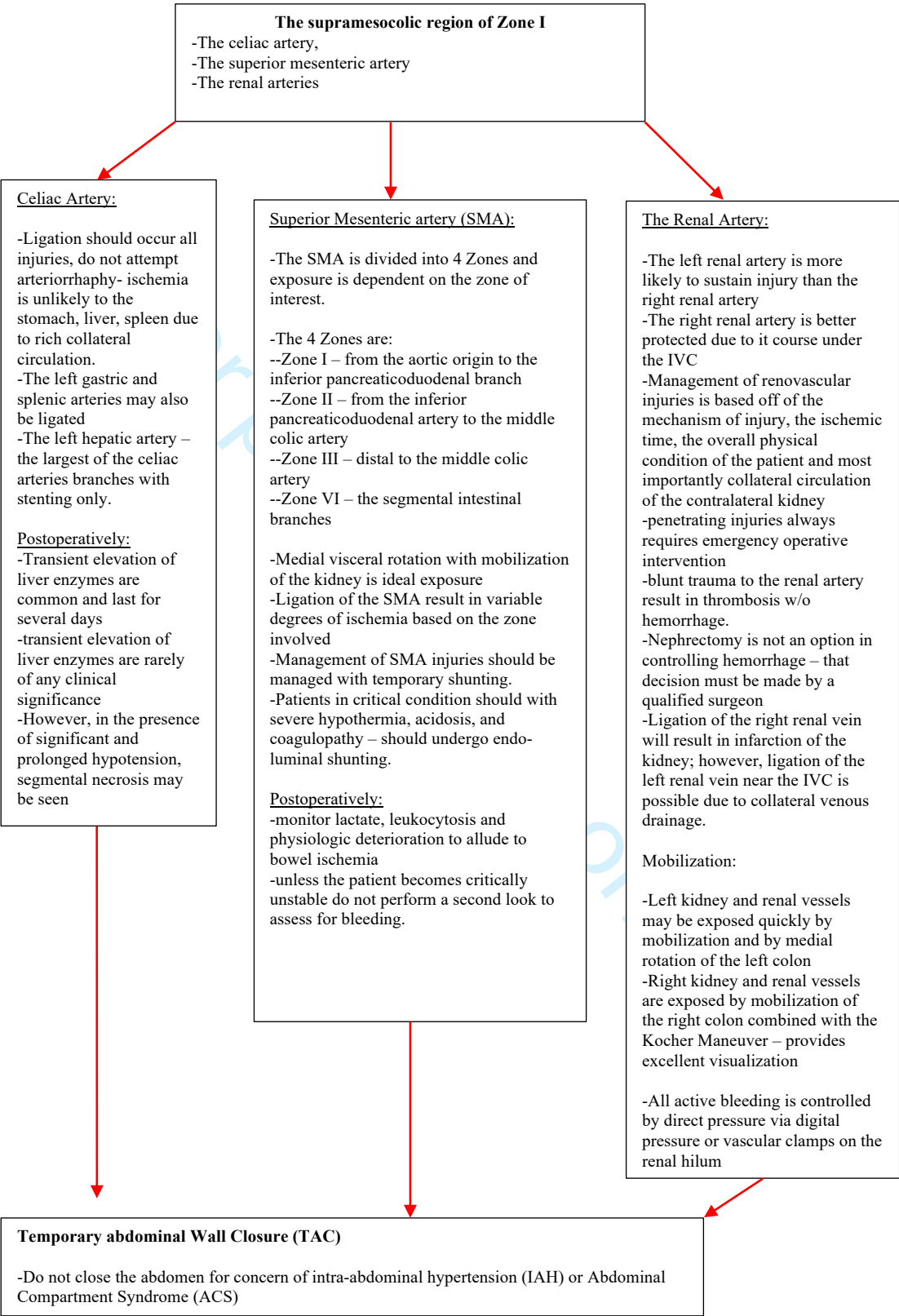
-this area is explored by incising the left or right pericolic peritoneum and medial rotation of the left or right colon

-The source of bleeding is usually the iliac vessels in penetrating injuries and the pelvic soft tissue and venous plexus in blunt injuries.

Temporary abdominal Wall Closure (TAC)

-Do not close the abdomen for concern of intra-abdominal hypertension (IAH) or Abdominal Compartment Syndrome (ACS)

APPENDIX A-5



ALL DATA TAKEN DIRECTELY OR INDIRECTLY FROM (Demetriades, Inaba, & Velmahos, 2015) (Moore, Feliciano, & Mattox, 2017) (Luchette, et al., 2010)

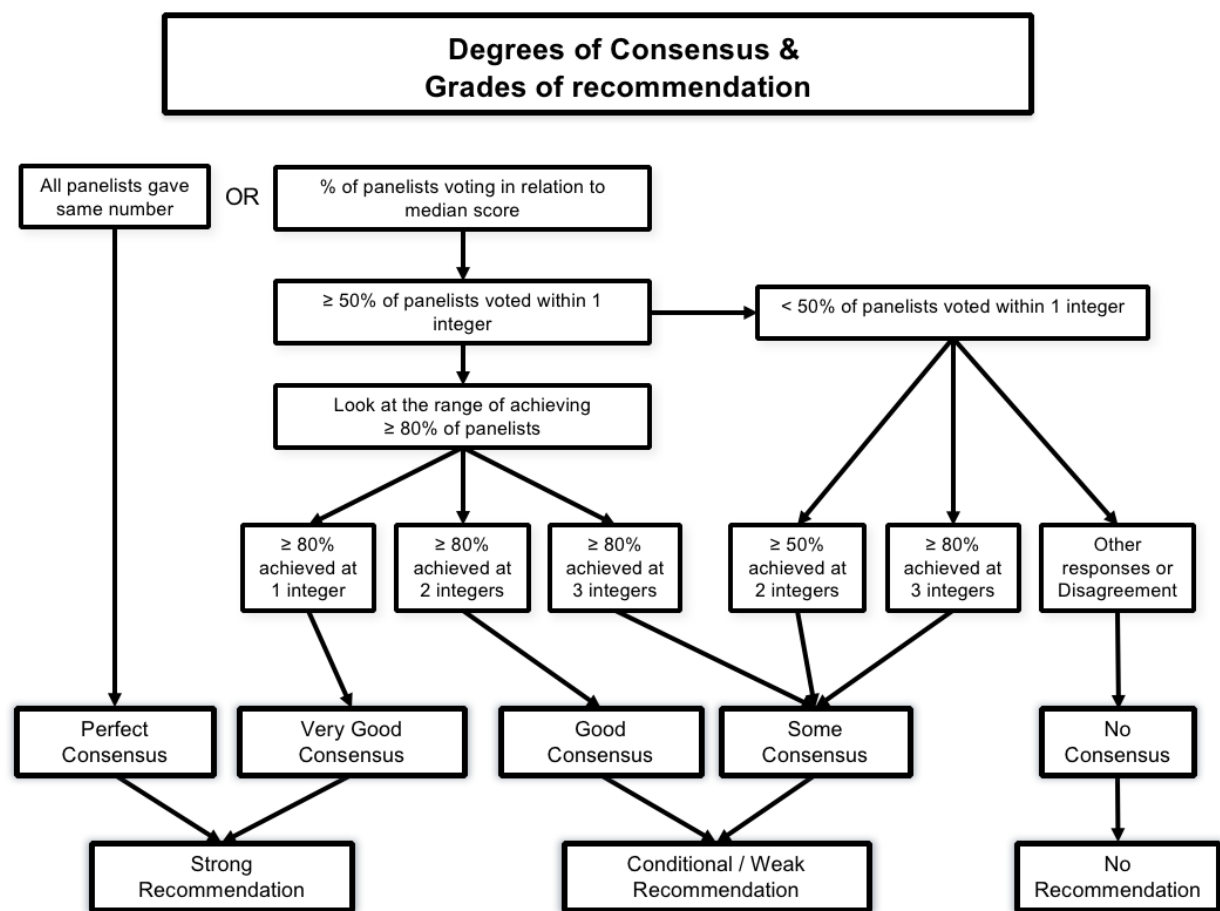
APPENDIX B

Definition of Consensus

Survey data sent to Delphi panelists were evaluated using a 9-point Likert scale. The consensus definition was based on the RAND/UCLA Appropriateness method (Fitch et al., 2001). The scale was ranked with one, meaning "totally disagree" or "harm outweighed the expected benefit," and nine, meaning "totally agree" or "benefit outweighs the expected harm" (Jones & Hunter, 1995, p.311; Fitch et al., 2001, p. 4). The consensus was defined as a score of 7 to 9 as "Agreement," scores of 4 to 6 were considered "Uncertain," and scores of 1 to 3 were considered "Disagreement." If no consensus was established, it was considered "uncertain" (Cho et al., 2019; Fitch et al., 2001; Jones & Hunter, 1995; Lee et al., 2020).

Defining the level of consensus was based on the RAND algorithm (Figure 2) (Cho et al., 2019; Franco-Sadud et al., 2019; Scheeren et al., 2019; Soni et al., 2019). Cho et al. (2019), Franco-Sadud et al. (2019), Scheeren et al. (2019), and Soni et al. (2019) describe the terms "Perfect consensus," "Very good consensus," "Good consensus," "Some consensus," and "No consensus" to provide an in-depth understanding of the level of consensus as described during the RAND algorithm. The term "Perfect consensus" describes 100 percent of participants rating the statement 7, 8, or 9. "Very good consensus" describes "median and middle 50% of respondents are found at one integer, or 80% of respondents are within one integer of the median" (Cho et al., 2019, p. E8; Franco-Sadud et al., 2019, p. E4; Soni et al., 2019, p. E3). "Good consensus" is described as "50% of respondents are within one integer of the median or 80% of the respondents are within two integers of the median" (Cho et al., 2019, p. E8; Franco-Sadud et al., 2019, p. E4; Soni et al., 2019, p. E3). "Some consensus" is described as "50% of respondents are within two integers of the median or 80% of respondents are within three integers of the median" (Cho et al., 2019, p. E8; Franco-Sadud et al., 2019, p. E4; Soni et al., 2019, p. E3). "No consensus" indicates "all other responses" or "any median with disagreement" (Cho et al., 2019, p. E8; Franco-Sadud et al., 2019, p. E4; Soni et al., 2019, p. E3).

APPENDIX B-2: RAND Algorithm



(Cho et al., 2019; Franco-Sadud et al., 2019; Scheeren et al., 2019; Soni et al., 2019)

Cho et al. (2019), Franco-Sadud et al. (2019), Scheeren et al. (2019), and Soni et al. (2019) further describe the degree of consensus and the strength of recommendation. The description elaborates on the previous definitions of the level of consensus and aligns them with the strength of recommendation. The strength of the recommendation was based on a modification of the Grade guidelines (Guyatt et al., 2011). Cho et al. (2019), Franco-Sadud et al. (2019), Scheeren et al. (2019), and Soni et al. (2019) used a modification of the Grade guidelines by using the terms as noted in the RAND Algorithm such as “Strong Recommendation,” “Conditional/Weak Recommendation,” and “No Recommendation” in place of the terms “High, Moderate, Low and Very Low” (Guyatt et al., 2011).

The modified Grade Method, as discussed by Cho et al. (2019), Franco-Sadud et al. (2019), Scheeren et al. (2019), and Soni et al. (2019), is based on the appropriateness and degree of consensus. Strong recommendations are based on the degree of consensus is at least good, and the median score is not in the undermined middle zone (the median is not in the four to six-zone; therefore, it is either in the seven to nine-zone or the one to three-zone) (Cho et al., 2019; Franco-Sadud et al., 2019; Scheeren et al., 2019; Soni et al., 2019). Therefore, a strong recommendation can have either two categories: “Strong With” or “Strong Against.” The “Strong

With” category is categorized as a median of seven to nine, and the “Strong Against” category is categorized as one to three.

Weak recommendations are based on the degree of consensus is “some consensus” with any median score or median score of four to six with any degree of consensus (Cho et al., 2019; Franco-Sadud et al., 2019; Scheeren et al., 2019; Soni et al., 2019). Therefore, a “Weak Recommendation” has two categories: “Weak With” and “Weak Against.” The “Weak With” category is defined as the middle 50% of the interquartile range is equal to four to nine. The “Weak Against” is defined as the middle 50% of the interquartile range is equal to one or less than four (Cho et al., 2019; Franco-Sadud et al., 2019; Scheeren et al., 2019; Soni et al., 2019).

“Conditional Recommendations,” which are categorized alongside “Weak Recommendations,” were categorized as 70 to 80% of the participants agreeing on a recommendation/statement (Cho et al., 2019; Franco-Sadud et al., 2019; Scheeren et al., 2019; Soni et al., 2019).

Completing the first round was the first phase to determine consensus. Due to a lack of consensus on specific questions, those questions were carried over into the second round. During the second round, survey questions from the first round that did not meet consensus were modified based on feedback from panelist-free discussion boxes. Those questions that did not meet consensus during the second round based on the RAND/UCLA Appropriateness method (Fitch et al., 2001) were explored during the qualitative interview phase of this study.

Analysis

Assessing the degree of agreement and disagreement amongst Delphi panelists, the surveyed results underwent analysis using central tendencies (means, medians) and levels of dispersion (standard deviations and interquartile ranges) to assess the degree of variability between the surveyed responses (Hasson et al., 2000; Lee et al., 2020). Additionally, means, medians, standard deviations, and interquartile ranges were used to compare proportion data between rounds to assess the overall acceptance rate of the surveyed data (Jones & Hunter, 1995; Lee et al., 2020).

The study data were collected by the author of this article and entered into a Microsoft Office Excel for Mac version 16.41 (Microsoft et al.) Spreadsheet for data analysis (Cho et al., 2019; Fitch et al., 2001; Jones & Hunter, 1995; Lee et al., 2020). Once analyzed, the study data provided central tendencies and levels of dispersion to assess the level and degree of consensus for participant responses. The central tendencies expressed in this analysis are expressed as medians, and the dispersions are expressed as interquartile ranges. The consensus was based on the medians, and the level of dispersion was expressed using interquartile ranges. A participants’ response sheet was provided for each round, with the final data displayed after the second round.

Analysis of the data used three zones/regions: an Agreement zone/region (median 7 through 9), an Uncertain zone/region (median 4 through 6), and a Disagreement zone/region (median 1 through 3). The median establishes where 50 percent of the votes were cased. Establishing a consensus requires a minimum of 70 percent scoring of a statement within a specific zone/region. Therefore, if 30 percent of the votes are outside a particular “zone/region,” there is no consensus. A statement with a median score of seven or higher would be classified within the Agreement zone/region because 50 percent of the votes were categorized between

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seven and nine. Despite being classified in the Agreement zone, there would be disagreement about the statement if 30 percent or more participants did not score “7, 8, or 9”.

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APPENDIX C: Final Voting Results for Round 1 Survey for Non-Surgeons Management of Non-Compressible Abdominal Hemorrhage (NCAH) using Truncal Hemorrhage Control in Austere Environment

Recommendation	# Of Panelists	Median (IQR)	Zone	# Of votes out of Zone	Consensus
Part A: Protocol					
1: Non-compressible torso hemorrhage is the last of 5 potentially preventable causes of death due to injury.	29	7(3-8)	Agreement	13 (45%)	Not Good
2: In austere/remote environments that are resource limited and there is no licensed surgical providers or team; there is no current published literature to support medical or surgical intervention or adjunctive therapy to sustain life for greater than 6 hours in patients with non-compressible torso hemorrhage of the abdomen.	29	8(5-8)	Agreement	10 (34.5%)	Not Good
3: A patient who is suspected of having non-compressible torso hemorrhage of the abdomen who meets the following criteria should have an intervention performed to control bleeding by a qualified licensed <u>medical</u> provider to sustain life until a more qualified licensed <u>surgical</u> provider is available, if each of the following indications are met:	29	7(5-8)	Agreement	13 (45%)	Not Good
<ul style="list-style-type: none"> -Inability to discuss and obtain guidance with a Trauma Surgeon -Evacuation to temporary versus definitive surgical site is greater than 3 hours -Hemodynamically unstable (MAP of <65, transient or non-responder to volume resuscitation) -Patient is a transient or non-responder after 4 units of whole blood -High index of suspicion that continuous hemorrhage is coming from a source in the abdomen based on positive FAST or penetrating wound location (spleen, liver, retroperitoneum, complex vascular) -In suboptimal environments (Austere/Remote Environments, battlefield setting with severely delayed evacuation) -Adequate resources to sustain life during the Truncal hemorrhage control. 					
4: Damage control resuscitation on patients with non-compressible torso hemorrhage of the abdomen in an austere/remote environment with a MAP of <65mmhg and is either a non-responder or a transient responder to whole blood resuscitation, can sustain life for 6 hours or longer with limited resources.	29	4 (3-6)	Uncertain	19 (66%)	Not Good
5: 4 units of whole blood is sufficient to assess if a patient is a transient or non-responder during damage control resuscitation.	29	8(7-8)	Agreement	4 (13.8%)	Very Good
6: In austere/remote environments where no formal imaging is available, a FAST exam is a reliable indicator of intra-abdominal hemorrhage.	29	7(6-8)	Agreement	10 (34.5%)	Not Good
7: An appropriately placed ultrasound guided REBOA with the balloon down is potentially an essential first step prior to surgically opening the abdomen in patients with non-compressible torso hemorrhage of the abdomen in austere/remote environments.	29	7(5-8)	Agreement	13 (45%)	Not Good
8: An appropriately trained and licensed medical provider can perform a full midline laparotomy incision in hemodynamically unstable trauma patients that meet the indications for truncal hemorrhage control in austere/remote, as listed in the attached protocol.	29	7(5-8)	Agreement	11 (38%)	Not Good
9: Most bleeding within the abdomen can be controlled with tight four quadrant packing and/or direct pressure of bleeding vessels.	29	7(6-8)	Agreement	8 (28%)	Good
10: In patients with severe hemorrhage that is not controlled with tight four quadrant packing and or direct pressure. REBOA would serve as alternative to gain proximal aortic control over a left sided thoracotomy and or Supraceliac aortic control.	29	7(6-8)	Agreement	8 (28%)	Good
11: All large, expanding and or leaking hematomas should be explored with the exception of a retro-hepatic hematoma.	29	7(5-8)	Agreement	11 (38%)	Not Good
12: After all major bleeding is controlled, the abdominal cavity should be systematically explored for bleeding and intestinal leakage (from the ligament of Treitz to the rectum).	29	9(8-9)	Agreement	3 (10.3%)	Very Good
13: Upon managing intraabdominal hemorrhage in austere/remote environments, the abdominal wall should be left open with the use of a temporary abdominal wall closure technique such as the use of a Bogota bag with a chest tube placed on low suction to remove intraperitoneal fluid.	29	8(8-9)	Agreement	4 (13.8%)	Very Good

APPENDIX C-2: Final Voting Results for Round 1 Survey for Non-Surgeons Management of Non-Compressible Abdominal Hemorrhage (NCAH) using Truncal Hemorrhage Control in Austere Environment

Recommendation	# Of Panelists	Median (IQR)	Zone	# Of votes out of Zone	Consensus
Part B: Potential role of General Surgery Physician Assistants in truncal hemorrhage control					
1: In a patient who is hemodynamically unstable (MAP of <65, transient or non-responder to volume resuscitation) and is 3 hours or greater from definitive surgical care with a positive FAST exam and no means of medical evacuation, the compromised patient can sustain his/her life for up to 6 hours without intervention.	29	3(2-4)	Disagreement	11 (38%)	No
2: A fellowship-trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment is an asset to the General Surgery and or Trauma Surgery disciplines.	29	9(8-9)	Agreement	1 (3.5%)	Very Good
3: A Fellowship trained licensed General Surgery Physician Assistant with at least three years of experience working in an Operative General Surgery or Trauma Surgery, has the capacity to perform surgical procedures that he or she is credentialed to perform in the absence of an attending surgeon.	29	7(6-8)	Agreement	11 (38%)	No
4: A Fellowship trained licensed General Surgery Physician Assistant who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment, can reference the Indications for the initiation for truncal hemorrhage control in patients with non-compressible torso hemorrhage of the abdomen in austere/remote environments to decide if truncal hemorrhage control is indicated.	29	8(7-9)	Agreement	4 (13.8%)	Very Good
5: A Fellowship trained licensed General Surgery Physician Assistant who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment, can place an ultrasound guided REBOA in zone III to gain proximal aortic control.	29	8(7-8)	Agreement	6 (21%)	Very Good
6: A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment, may be trained to perform a full midline laparotomy incision (from the xiphoid to the pubic symphysis) on patients with non-compressible torso hemorrhage of the abdomen in austere/remote environments.	29	8(6-9)	Agreement	8 (28%)	Good
7: A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment may be trained to perform a tight four quadrant abdominal packing on patients with non-compressible torso hemorrhage of the abdomen in austere/remote environments.	29	8(7-9)	Agreement	6 (21%)	Very Good
8: A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment may be trained to systematically explore the abdominal cavity for bleeding and intestinal leakage (from the ligament of Treitz to the rectum).	29	8(7-9)	Agreement	5 (17.3%)	Very Good
9: A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment can be trained to effectively use REBOA during intra-abdominal hemorrhage to control proximal aortic hemorrhage.	29	8(6-9)	Agreement	8 (28%)	Good
10: A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment can be trained to perform temporary vascular stenting of a vascular injury that cannot be ligated in an unstable patient with non-compressible torso hemorrhage of the abdomen in austere/remote environments.	29	7(3-8)	Agreement	13 (45%)	No
11. A Fellowship-trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment can be trained to perform a temporary abdominal closure utilizing a Bogota bag and using a chest tube at low suction to remove intraperitoneal fluid in patient with non-compressible torso hemorrhage of the abdomen in austere/remote environments.	29	8(8-9)	Agreement	4 (13.8%)	Very Good

Appendix D: Comparison of First and Second-Round Surveys for Part A: Protocol

Recommendations Statements: Survey One	Number of Panelist First Survey	Media First Survey	IQR First Survey	Consensus	Recommendations Statements: Survey Two	Number of Panelist Second Survey	Median Second Survey	IQR Second Survey	Consensus	Joint Consensus from First and Second Survey
1: Non-compressible torso hemorrhage is the last of 5 potentially preventable causes of death due to injury.	29	7	3 - 8	No	1.Noncompressible torso hemorrhage (NCTH) is the leading cause of potentially preventable death in the prehospital/battlefield environment.	27	9	8 - 9	Very Good	Very Good
2: In austere/remote environments that are resource-limited and there is no licensed surgical providers or team; there is no current published literature to support medical or surgical intervention or adjunctive therapy to sustain life for greater than 6 hours in patients with non-compressible torso hemorrhage of the abdomen.	29	8	5 - 8	No	2.In austere/remote environments that are resource limited and there is no licensed surgical provider or team; evidence is scarce to guide medical or surgical intervention to sustain life for greater than 6 hours in patients with non-compressible torso hemorrhage of the abdomen.	27	8	8 - 9	Very Good	Very Good
3: A patient who is suspected of having non-compressible torso hemorrhage of the abdomen who meets the following criteria should have an intervention performed to control bleeding by a qualified licensed <u>medical</u> provider to sustain life until a more qualified licensed <u>surgical</u> provider is available, if each of the following indications are met: -Inability to discuss and obtain guidance with a Trauma Surgeon -Evacuation to temporary versus definitive surgical site is greater than 3 hours -Hemodynamically unstable (MAP of <65, transient or non-responder to volume resuscitation) -Patient is a transient or non-responder after 4 units of whole blood - High index of suspicion that continuous hemorrhage is coming from a source in the abdomen based on positive FAST or penetrating wound location (spleen,	29	7	5 - 8	No	In an austere environment lacking a Trauma/General Surgeon at the bedside, a patient who is suspected of having non-compressible torso hemorrhage of the abdomen who meets the following criteria should have a surgical intervention (truncal hemorrhage control) performed to control bleeding by a qualified General Surgery Physician Assistant: 3.Evacuation to Damage Control Surgery Site is greater than 1(one) hour 4.Hemodynamically unstable (MAP of < 65mmhg, transient or non-responder to blood products) 5.High index of suspicion that continuous hemorrhage is	27 27	7 7	2 - 8 4 - 8	No No	No No

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<p>liver, retroperitoneum, complex vascular)</p> <p>-In suboptimal environments (Austere/Remote Environments, battlefield setting with severely delayed evacuation)</p> <p>-Adequate resources to sustain life during the Truncal hemorrhage control.</p>					<p>coming from a source in the abdomen based on positive FAST with or without use of a Diagnostic Peritoneal Lavage or a penetrating wound of the abdomen (spleen, liver, retroperitoneum, complex vascular)</p> <p>6.Adequate resources to sustain life during the operation to obtain truncal hemorrhage control</p>	27	7	4.5 - 8	No	No
						27	7	6 - 8	Good	Good
4: Damage control resuscitation on patients with non-compressible torso hemorrhage of the abdomen in an austere/remote environment with a MAP of <65mmhg and is either a non-responder or a transient responder to whole blood resuscitation, can sustain life for 6 hours or longer with limited resources.	29	4	3 - 6	No	7.In a remote/austere environment without a dedicated operating theater, damage control resuscitation using whole blood in non-responders or transient responders' patients with non-compressible torso hemorrhage in the abdomen and a MAP < 65mmhg can sustain life for 4 hours or longer.	27	5	4 - 7	No	No
5: 4 units of whole blood is sufficient to assess if a patient is a transient or non-responder during damage control resuscitation.	29	8	7 - 8	Very Good						Very Good
6: In austere/remote environments where no formal imaging is available, a FAST exam is a reliable indicator of intra-abdominal hemorrhage.	29	7	6 - 8	No	8.In austere/remote environments where CT scan is not available, a FAST exam or diagnostic peritoneal lavage can be used as screening tools to assess for the presence of significant intra-abdominal hemorrhage in the hands of a qualified provider.	27	8	8 - 9	Very Good	Very Good
7: An appropriately placed ultrasound guided REBOA with the balloon down is potentially an essential first step prior to surgically opening the abdomen in patients with non-compressible torso hemorrhage of the abdomen in austere/remote environments.	29	7	5 - 8	No	9.An appropriately placed ultrasound guided REBOA catheter with the balloon up is potentially an essential first step prior to surgically opening the abdomen in patients with non-compressible torso hemorrhage in austere/remote environments.	27	7	5 - 8	No	No
8: An appropriately trained and licensed medical provider can perform a full	29	7	5 - 8	No	10.An appropriately trained and qualified General Surgerv	27	8	4 - 8	No	No

midline laparotomy incision in hemodynamically unstable trauma patients that meet the indications for truncal hemorrhage control in austere/remote, as listed in the attached protocol.					Physician Assistant with a qualified and trained anesthesiology and surgical support team can successfully perform a full laparotomy with hemorrhage control in hemodynamically unstable trauma patients that meet the indication for truncal hemorrhage control in austere/remote environments, as listed in the attached protocol						Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.
9: Most bleeding within the abdomen can be controlled with tight four quadrant packing and/or direct pressure of bleeding vessels.	29	7	6 - 8	Good							Good
10: In patients with severe hemorrhage that is not controlled with tight four quadrant packing and or direct pressure. REBOA would serve as alternative to gain proximal aortic control over a left sided thoracotomy and or Supraceliac aortic control.	29	7	6 - 8	Good							Good
11: All large, expanding and or leaking hematomas should be explored with the exception of a retro-hepatic hematoma.	29	7	5 - 8	No	11.All expanding and/or leaking hematomas, including retro-hepatic hematoma, should only be managed with packing by non-surgeons (appropriately trained and qualified General Surgery Physician Assistants) in austere/remote environments where a Trauma/General Surgeon is not immediately available.	27	7	6 - 8	Good	Good	
12: After all major bleeding is controlled, the abdominal cavity should be systematically explored for bleeding and intestinal leakage (from the ligament of Treitz to the rectum).	29	9	8 - 9	Very Good							Very Good
13: Upon managing intraabdominal hemorrhage in austere/remote environments, the abdominal wall should be left open with the use of a temporary abdominal wall closure technique such as the use of a Bogota bag with a chest tube placed on low suction to remove intraperitoneal fluid.	29	8	8 - 9	Very Good							Very Good

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For peer review only

Appendix E: Comparison of First and Second-Round Surveys for the Potential role of General Surgery Physician Assistants in abdominal hemorrhage control

Recommendations Statements: Survey One	Number of Panelist First Survey	Media First Survey	IQR First Survey	Consensus	Recommendations Statements: Survey Two	Number of Panelist Second Survey	Median Second Survey	IQR Second Survey	Consensus	Joint Consensus from First and Second Survey
1: In a patient who is hemodynamically unstable (MAP of <65, transient or non-responder to volume resuscitation) and is 3 hours or greater from definitive surgical care with a positive FAST exam and no means of medical evacuation, the compromised patient can sustain his/her life for up to 6 hours without intervention.	29	3	2 - 4	No	1: A hemodynamically unstable patient (MAP of <65mmhg, transient or non-responder to volume resuscitation) and is 3 hours or greater from a formal Damage Control Surgical Capability with a positive FAST exam and no means of medical evacuation, the compromised patient will NOT be able to sustain his/her life for up to 4 hours without intervention.	27	7	6 - 8.5	No	No
2: A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment is an asset to the General Surgery and or Trauma Surgery disciplines.	29	9	8 - 9	Very Good						Very Good
3: A Fellowship trained licensed General Surgery Physician Assistant with at least three years of experience working in an Operative General Surgery or Trauma Surgery, has the capacity to perform surgical procedures that he or she is credentialed to perform in the absence of an attending surgeon.	29	7	6 - 8	No	3: A Fellowship trained licensed General Surgery Physician Assistant or a General Surgery Physician Assistant who is currently working in a Trauma Surgery Department with at least three to four years of experience operating next to a Trauma Surgeon or General Surgeon, has the ability to perform truncal hemorrhage control interventions in austere/remote environments to control bleeding only with a team of qualified medical providers	27	7	6.5 - 8	Good	Good
4: A Fellowship trained licensed General Surgery Physician Assistant who has at least three years of experience working in an Operative General Surgery or Trauma Surgery	29	8	7 - 9	Very Good						Very Good

environment, can reference the Indications for the initiation for truncal hemorrhage control in patients with non-compressible torso hemorrhage of the abdomen in austere/remote environments to decide if truncal hemorrhage control is indicated.										
5: A Fellowship trained licensed General Surgery Physician Assistant who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment, can place an ultrasound guided REBOA in zone III to gain proximal aortic control.	29	8	7 - 8	Very Good						Very Good
6: A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment, may be trained to perform a full midline laparotomy incision (from the xiphoid to the pubic symphysis) on patients with non-compressible torso hemorrhage of the abdomen in austere/remote environments.	29	8	6 - 9	Good						Good
7: A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment may be trained to perform a tight four quadrant abdominal packing on patients with non-compressible torso hemorrhage of the abdomen in austere/remote environments.	29	8	7 - 9	Very Good						Very Good
8: A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment may be trained to systematically explore the abdominal cavity for bleeding and intestinal leakage (from the ligament of Treitz to the rectum).	29	8	7 - 9	Very Good						Very Good

9: A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment can be trained to effectively use REBOA during intra-abdominal hemorrhage to control proximal aortic hemorrhage.	29	8	6 - 9	Good						Good
10: A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment can be trained to perform temporary vascular stenting of a vascular injury that cannot be ligated in an unstable patient with non-compressible torso hemorrhage of the abdomen in austere/remote environments.	29	7	3 - 8	No	10: A General Surgery Physician Assistant with operative experience at a trauma center can be trained to perform intra-abdominal vascular shunting in hemodynamically unstable patients due to intra-abdominal hemorrhage in austere/remote environment where a Trauma /General Surgeon is not immediately available.	27	7	2.5 - 8	No	No
11. A Fellowship trained licensed General Surgery Physician Assistant, who has at least three years of experience working in an Operative General Surgery or Trauma Surgery environment can be trained to perform a temporary abdominal closure utilizing a Bogota bag and using a chest tube at low suction to remove intraperitoneal fluid in patient with non-compressible torso hemorrhage of the abdomen in austere/remote environments.	29	8	8 - 9	Very Good						Very Good

APPENDIX F: Measure of Success

First Measure of Success

What would be an acceptable percentage of success for a Fellowship trained licensed General Surgery Physician Assistant with at least three years of experience working in an Operative General Surgery or Trauma Surgery environment, to performing a four-quadrant abdominal packing ONLY in a patient with non-compressible abdominal hemorrhage of the abdomen in austere environments?							
	<10%	10%-20%	20%-30%	30%-40%	40%-50%	>50%	Missing Data
Survival							
Number of Participants that Selected Percent of Success	2	0	2	1	3	19	2
Percent of Participants	7%	0	7%	3%	10%	66%	7%

Second Measure of Success

What would be an acceptable percentage of success that would be acceptable to you to have a Fellowship-trained licensed General Surgery Physician Assistant, who has as least three years of experience working in an Operative General Surgery or Trauma Surgery environment to perform a four-quadrant abdominal packing, and vascular shunting in a patient with non-compressible abdominal hemorrhage in austere environments?							
	<10%	10%-20%	20%-30%	30%-40%	40%-50%	>50%	Missing Data
Survival							
Number of Participants that Selected Percent of Success	2	1	3	1	2	16	4
Percent of Participants	7%	3%	10%	3%	7%	55%	14%

Third Measure of Success

What would be an acceptable percentage of success that would be acceptable to you in order to have a Fellowship-trained licensed General Surgery Physician Assistant, who has as least three years of experience working in an Operative General Surgery or Trauma Surgery environment to perform a truncal hemorrhage in a patient with non-compressible abdominal hemorrhage in austere environments?							
	<10%	10%-20%	20%-30%	30%-40%	40%-50%	>50%	Missing Data
Survival							
Number of Participants that Selected Percent of Success	3	2	1	1	1	14	7
Percent of Participants	10%	7%	3%	3%	3%	48%	24%

Supplementary File 1 – Recommendation for the Conducting and Reporting of Delphi Studies (CREDES)

Section/Topic	#	Checklist Item Description	Where reported
Rationale for the choice of the Delphi technique			
Justification	1	The choice of the Delphi technique as a method of systematically collating expert consultation and building consensus needs to be well justified. When selecting the method to answer a particular research question, it is important to keep in mind its constructivist nature	"Justification of Delphi Methodology"
Planning and design			
Planning and process	2	The Delphi technique is a flexible method and can be adjusted to the respective research aims and purposes. Any modifications should be justified by a rationale and be applied systematically and rigorously	"Design"
Definition of consensus	3	Unless not reasonable due to the explorative nature of the study, an a priori criterion for consensus should be defined. This includes a clear and transparent guide for action on (a) how to proceed with certain items or topics in the next survey round, (b) the required threshold to terminate the Delphi process and (c) procedures to be followed when consensus is (not) reached after one or more iterations	"Consensus, Agreement and Stability" and "Table 1"
Study conduct			
Informational input	4	All material provided to the expert panel at the outset of the project and throughout the Delphi process should be carefully reviewed and piloted in advance in order to examine the effect on experts' judgements and to prevent bias	"Procedure"
Prevention of bias	5	Researchers need to take measures to avoid directly or indirectly influencing the experts' judgements. If one or more members of the research team have a conflict of interest, entrusting an independent researcher with the main coordination of the Delphi study is advisable	"Procedure" and "Data Analysis"
Interpretation and processing of results	6	Consensus does not necessarily imply the 'correct' answer or judgement; (non)consensus and stable disagreement provide informative insights and highlight differences in perspectives concerning the topic in question	"Data Analysis" and "Consensus, Agreement and Stability"
External validation	7	It is recommended to have the final draft of the resulting guidance on best practice in palliative care reviewed and approved by an external board or authority before publication and dissemination	"Study Steering Group" and "Discussion"
Reporting			
Purpose and rationale	8	The purpose of the study should be clearly defined and demonstrate the appropriateness of the use of the Delphi technique as a method to achieve the research aim. A rationale for the choice of the Delphi technique as the most suitable method needs to be provided	"Aims" and "Justification of Delphi Methodology"

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Expert panel	9	Criteria for the selection of experts and transparent information on recruitment of the expert panel, sociodemographic details including information on expertise regarding the topic in question, (non)response and response rates over the ongoing iterations should be reported	"Expert Eligibility and Sample"
Description of the methods	10	The methods employed need to be comprehensible; this includes information on preparatory steps (How was available evidence on the topic in question synthesised?), piloting of material and survey instruments, design of the survey instrument(s), the number and design of survey rounds, methods of data analysis, processing and synthesis of experts' responses to inform the subsequent survey round and methodological decisions taken by the research team throughout the process	"Procedure" and "Data Analysis"
Procedure	11	Flow chart to illustrate the stages of the Delphi process, including a preparatory phase, the actual 'Delphi rounds', interim steps of data processing and analysis, and concluding steps	"Figure 1"
Definition and attainment of consensus	12	It needs to be comprehensible to the reader how consensus was achieved throughout the process, including strategies to deal with non-consensus	"Procedure" and "Data Analysis"
Results	13	Reporting of results for each round separately is highly advisable in order to make the evolving of consensus over the rounds transparent. This includes figures showing the average group response, changes between rounds, as well as any modifications of the survey instrument such as deletion, addition or modification of survey items based on previous rounds	A or protocol
Discusson of limitations	14	Reporting should include a critical reflection of potential limitations and their impact of the resulting guidance	"Discussion"
Adequacy of conclusions	15	The conclusions should adequately reflect the outcomes of the Delphi study with a view to the scope and applicability of the resulting practice guidance	A or protocol
Publication and dissemination	16	The resulting guidance on good practice in palliative care should be clearly identifiable from the publication, including recommendations for transfer into practice and implementation. If the publication does not allow for a detailed presentation of either the resulting practice guidance or the methodological features of the applied Delphi technique, or both, reference to a more detailed presentation elsewhere should be made (e.g. availability of the full guideline from the authors or online; publication of a separate paper reporting on methodological details and particularities of the process (e.g. persistent disagreement and controversy on certain issues)). A dissemination plan should include endorsement of the guidance by professional associations and health care authorities to facilitate implementation	"Study Steering Group" and "Patient and Public Involvement" and "Discussion"

From: Junger, S., S. A. Payne, J. Brine, L. Radbruch and S. G. Brearley (2017). "Guidance on Conducting and REporting Delphi Studies (CREDES) in palliative care: Recommendations based on a methodological systematic review." Palliat Med **31**(8): 684-706.