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Defining a Research Agenda for Layperson Prehospital Hemorrhage Control
A Consensus Statement

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Abstract

IMPORTANCE Trauma is the leading cause of death for US individuals younger than 45 years, and uncontrolled hemorrhage is a major cause of trauma mortality. The US military's medical advancements in the field of prehospital hemorrhage control have reduced battlefield mortality by 44%. However, despite support from many national health care organizations, no integrated approach to research has been made regarding implementation, epidemiology, education, and logistics of prehospital hemorrhage control by layperson immediate responders in the civilian sector.

OBJECTIVE To create a national research agenda to help guide future work for prehospital hemorrhage control by laypersons.

EVIDENCE REVIEW The 2-day, in-person, National Stop the Bleed (STB) Research Consensus Conference was conducted on February 27 to 28, 2019, to identify and achieve consensus on research gaps. Participants included (1) subject matter experts, (2) professional society–designated leaders, (3) representatives from the federal government, and (4) representatives from private foundations. Before the conference, participants were provided a scoping review on layperson prehospital hemorrhage control. A 3-round modified Delphi consensus process was conducted to determine high-priority research questions. The top items, with median rating of 8 or more on a Likert scale of 1 to 9 points, were identified and became part of the national STB research agenda.

FINDINGS Forty-five participants attended the conference. In round 1, participants submitted 487 research questions. After deduplication and sorting, 162 questions remained across 5 a priori–defined themes. Two subsequent rounds of rating generated consensus on 113 high-priority, 27 uncertain-priority, and 22 low-priority questions. The final prioritized research agenda included the top 24 questions, including 8 for epidemiology and effectiveness, 4 for materials, 9 for education, 2 for global health, and 1 for health policy.

CONCLUSIONS AND RELEVANCE The National STB Research Consensus Conference identified and prioritized a national research agenda to support laypersons in reducing preventable deaths due to life-threatening hemorrhage. Investigators and funding agencies can use this agenda to guide their future work and funding priorities.

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Key Points

Question What are the key areas and questions on which future research of prehospital hemorrhage control by laypersons should be focused?

Findings In this consensus statement, a cohort of 45 subject matter experts, professional society leaders, and funding agency representatives conducted a 3-round modified Delphi consensus process to identify and prioritize key research gaps in prehospital hemorrhage control by laypersons. Participants identified 113 high-priority questions in the themes of epidemiology and effectiveness, materials, education, global health, and health policy, with the top 24 questions constituting the prioritized national research agenda.

Meaning The National Stop the Bleed Research Consensus Conference identified and prioritized a research agenda to support laypersons in reducing preventable deaths due to life-threatening hemorrhage.

+ **Invited Commentary**

+ **Supplemental content**

Author affiliations and article information are listed at the end of this article.

Introduction

Trauma is the second leading cause of death in the United States and the leading killer of people younger than 45 years.[1] Uncontrolled hemorrhage is the second most common cause of trauma mortality.[1,2] The US military's combat experience and improvements in trauma care during the past 18 years have resulted in a 44% mortality reduction for combat trauma.[2] Therefore, in its 2016 report, the National Academies of Sciences, Engineering, and Medicine recommended translating military health care experience to civilian care with an aim of zero preventable deaths.[3] In parallel, the Hartford Consensus focused on training public safety professionals and bystanders on performing bleeding control and providing immediate response.[4] In 2015 the White House launched the Stop the Bleed (STB) initiative to provide immediate responders with the tools and knowledge to stop life-threatening bleeding.[5,6]

After the Hartford Consensus[4] and the White House launch of STB, many key questions remain to advance this initiative. Despite support from many national health care organizations, to date, there has not been an integrated approach to research regarding implementation, epidemiology, education, and logistics of prehospital hemorrhage control by layperson immediate responders in the civilian sector. Funding has also been limited. In addition, notwithstanding the great strides in the battlefield, limited research on the effectiveness of military techniques within the civilian sector has been performed.

In this context, the National STB Research Consensus Conference (a gathering of national and international subject matter experts, cosponsored by multiple national organizations and institutes) was convened. The aims of this conference were to identify critical gaps within current literature on prehospital hemorrhage control by laypersons, develop a consensus on research priorities, and create a national research agenda for future work on layperson prehospital hemorrhage control.

Methods

This study consisted of a 3-round modified in-person Delphi process and follows the Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) guidelines.[7] The modified Delphi approach is an iterative process of multiple rounds of voting to achieve consensus among experts in situations where evidence is scarce or expert opinion is important.[8,9] The Partners institutional review board approved the study, and verbal consent was obtained from all participants. The consensus conference took place on February 27 to 28, 2019.

Participants were selected by a planning committee and included subject matter experts, professional society representatives, government and private funding agency representatives, and a Delphi expert advisor (**Box**). Some subject matter experts from other public health fields were also invited to provide context from prior successful public health initiatives.

Before the conference, a scoping review on layperson prehospital hemorrhage control encompassing both peer-reviewed and non–peer-reviewed literature was conducted.[10] The results of the review were categorized into 5 themes based on available literature and investigator discussion: (1) epidemiology and effectiveness, (2) materials, (3) education, (4) global health, and (5) health policy. The scoping review was distributed to participants before the conference, and each participant was assigned 2 of the 5 themes for rating. Assignments were based on participants' stated preferences balanced against the need to have an even number of raters across themes.[8] This process resulted in 16 participants per theme.

All 3 rounds of the modified Delphi process were conducted during the 2-day conference (**Figure 1**). On the first day of the conference, participants were provided a folder that included an agenda and index cards color-coded for themes (**Table 1**). For each theme, there was a presentation by a research fellow (C.E., M.A.C., J.M., J.P.H.-E., T.A., E.de J., and D.O.-D.) providing the overview of current literature. A faculty discussant (C.G., R.H., J.S.W., L.J., S.K., and R.R.) followed with reflections on the summary and potential research gaps. This was followed by a facilitated open discussion

among participants aimed at soliciting perspectives on research questions within that theme. Additional presentations included presentations on (1) the history of STB, (2) implementation science, (3) psychological perspective, and (4) public agency perspectives.
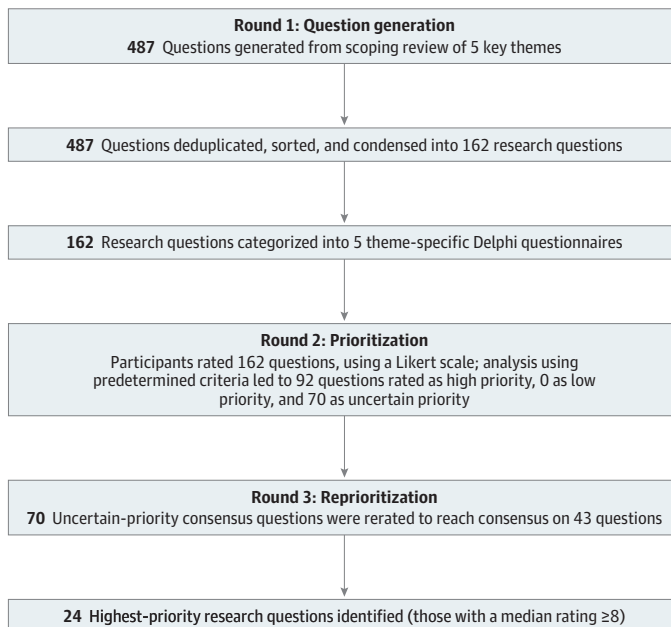

Box. Representation of Disciplines, Professional Societies, and Government Agencies[a]

Disciplines

Biomedicine

Emergency medicine

Engineering

General surgery

Health care policy/Delphi processes

Human factors studies

Implementation sciences

Industry

Military medicine

Ophthalmology

Plastics/reconstructive surgery

Psychiatry

Trauma and acute and critical care surgery

Professional societies

American Academy of Family Medicine

American Academy of Optometry

American Academy of Pediatrics

American College of Emergency Physicians

American College of Physicians

American College of Surgeons

American Red Cross

National Association of EMS Physicians

Society of Academic Emergency Medicine

Government agencies

Committee on Tactical Combat Casualty Care

National Institutes of Health

National Center for Disaster Medicine and Public Health

US Department of Defense: Joint Trauma System

US Department of Health and Human Services

US Department of Homeland Security

US Department of Transportation

Uniformed Services University of the Health Sciences

Abbreviation: EMS, emergency medical services.

[a] Attendees represent 1 or more of each of these categories.

Figure 1. Flowchart for the 3 Rounds of Modified Delphi Process

Round 1: Question generation
487 Questions generated from scoping review of 5 key themes

487 Questions deduplicated, sorted, and condensed into 162 research questions

162 Research questions categorized into 5 theme-specific Delphi questionnaires

Round 2: Prioritization
Participants rated 162 questions, using a Likert scale; analysis using predetermined criteria led to 92 questions rated as high priority, 0 as low priority, and 70 as uncertain priority

Round 3: Reprioritization
70 Uncertain-priority consensus questions were rerated to reach consensus on 43 questions

24 Highest-priority research questions identified (those with a median rating ≥8)

Round 1: Question Generation

Throughout day 1, participants wrote research questions on the color-coded index cards. There was no limit on how many research questions a participant could write. Study team members (E.G., C.E., M.A.C., J.M., J.P.H.-E., T.A., E.de J., D.O.-D., T.U.-L., M.P.J., and G.O.) collected the cards and grouped, deduplicated, and condensed them into candidate research questions that would populate the theme-specific questionnaires for round 2.

Round 2: Prioritization

On day 2, Delphi questionnaires were created. The questionnaires were modeled after the classic studies by the RAND Corporation and contained the research questions grouped by theme.[8] Conference participants were asked to prioritize each item using a Likert scale of 1 to 9 (1 indicates lowest priority; 9, highest priority). Team members then collected questionnaires before the morning panels and recorded the results. These results were sorted into high-, low-, and uncertain-priority groups based on previously defined strict criteria (eTable in the Supplement) to ensure high specificity in categorizing high- and low-priority questions.

Round 3: Reprioritization of Uncertain Category Questions

In round 3, participants were given their marked questionnaires back for context on how they voted in round 2. The results for consensus on each question, with its median rating and measure of dispersion, were presented to the participants. The entire audience then discussed these as summary results were displayed. This discussion allowed the voters to visualize how they prioritized research questions compared with the rest of their thematic group. High- and low-priority questions were recorded and not discussed. Discussion was limited to the uncertain-priority questions and was open to all participants. As noted by Mukherjee et al,[11] the Delphi technique is often reported to be time-consuming, which can lead to high dropout levels by experts between rounds. We addressed the possibility of excessive dropout by limiting the discussion for each question to 2 minutes. In this round, questions were reprioritized using a real-time digital audience polling system (Poll Everywhere) with the same 9-point Likert scale used in round 2. Revoting was restricted to the original members of each thematic group. The results from digital audience polling were analyzed and recategorized using the relaxed criteria (eTable in the Supplement) to maximize the number of questions that were sorted into high- or low-priority groups.

Finally, the highest-ranked questions in rounds 2 and 3 (with a median rating of 8 or more on a Likert scale ranging from 1-9) were identified and became part of the national STB research agenda. The results were shared with participants for any additional commentary or feedback. All conference proceedings were recorded and transcribed for qualitative analysis.

Table 1. Thematic Definitions and Corresponding Index Cards

Index card color	Theme	Definition
Yellow	Epidemiology and effectiveness	Understand the scope and nature of the problem and effectiveness of programmatic implementation in the civilian prehospital setting involving human study participants
Purple	Materials	Design and trial of various materials, including dressings, tourniquets, and their usability and equipment placement
Green	Education	Evaluate various educational design considerations, including modalities (examples include in-person training, phone or video applications, and social media) of assessments, content, and programmatic success
Red	Global health	Describe interventions and implementation across high-income, newly emerging, and low-income countries
Blue	Health policy	Describe and evaluate the roles played by governmental and nongovernmental entities and individuals in the policy process; studies of economic, technological, social, cultural, and other influences on policy development; and the effects of resulting policies, guidelines, standards and protocols

Results

A total of 45 attendees participated in conference proceedings; 44 were present on day 1 and 41 on day 2. Participants possessed a wide range of expertise, including individuals from various surgical subspecialties and national organizations, emergency and military medicine, and implementation experts (Box). The 3 best represented groups were emergency medicine (14 [31.1%]); acute, critical, and trauma care surgery (13 [28.9%]); and military medicine (4 [8.9%]) (**Figure 2**). The open discussion sessions at the conference highlighted the following issues in each predefined theme:

Theme 1: Epidemiology and effectiveness included the lack of prospective trials and prehospital data on layperson hemorrhage control in the civilian setting; differences in wounding patterns in the civilian setting compared with the military setting; geographic variations in wounding patterns; and cost-effectiveness of different interventions.

Theme 2: Materials included the efficacy of different tourniquet types and the need for standardization and the disproportionate emphasis on tourniquet use over direct pressure and wound packing.

Theme 3: Education included the efficacy and scalability of various training modalities, including in-person training, video-based lectures, and written instructions.

Theme 4: Global health included the economic effects of preventable trauma-associated deaths due to uncontrolled hemorrhage and the epidemiology of injury-related preventable deaths in lower- and middle-income countries.

Theme 5: Health policy included the true incidence of preventable deaths due to exsanguination to help advocacy groups highlight the potential effect of layperson hemorrhage control initiatives; policy implementation and enforcement issues in the civilian setting; and the need for understanding the true effects of large public implementation programs.

During round 1, a total of 487 research questions were generated. After categorization and deduplication, 162 research questions remained within the 5 themes: epidemiology and effectiveness (34 questions), materials (equipment and supplies) (33 questions), education (30 questions), global health (31 questions), and health policy (34 questions). These questions were then added to the theme-based Delphi questionnaires.

During round 2, attendees completed the Delphi questionnaires based on their assigned thematic groups. Of the 162 questions assessed, 92 were scored as high priority and 70 were scored as uncertain priority. No questions achieved consensus as low priority.

Figure 2. Attendees per Discipline
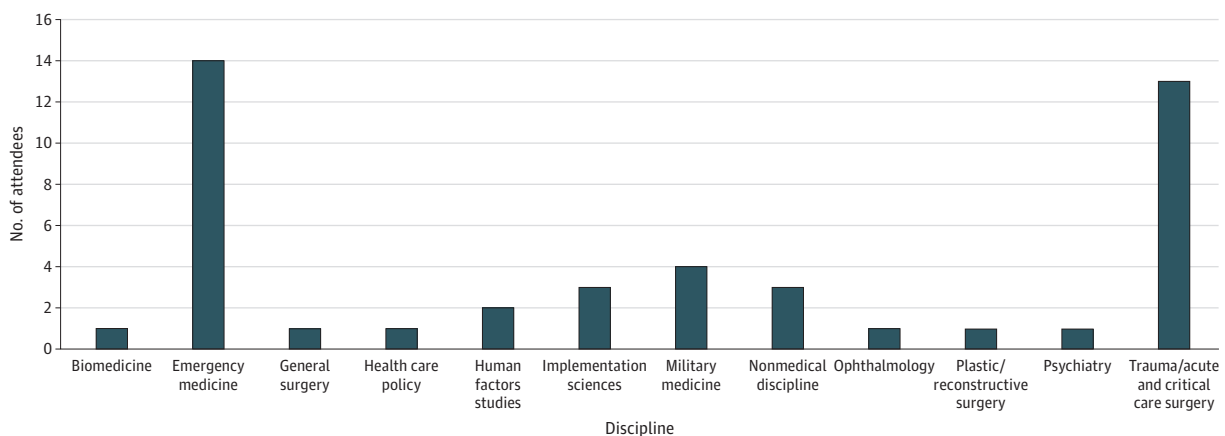
During round 3, the 70 uncertain-priority questions were rated. Using the relaxed criteria, 21 of these were reprioritized to high priority and 22 to low priority, and 27 remained in the uncertain-priority category.

A total of 113 questions rated as high priority, 22 as low priority, and 27 as uncertain priority were included in the final consensus (eFigure in the Supplement) . Among the high-priority questions, 24 questions (8 for epidemiology and effectiveness, 4 for materials, 9 for education, 2 for global health, and 1 for health policy) had a median score of 8 or greater and formed the national research agenda for prehospital hemorrhage control by layperson immediate responders (**Table 2**).

Discussion

Using a modified Delphi approach, we engaged a diverse stakeholder group of subject matter experts, professional society leaders, and funders to reach consensus on research priorities for STB. Participants came to consensus on high-priority questions within 5 themes: (1) epidemiology and effectiveness, (2) materials, (3) education, (4) global health, and (5) health policy. The top 24 highest-ranked research questions, based on participant voting, constitute the National STB Research Agenda. To our knowledge, these findings constitute the first consensus-driven research agenda for civilian prehospital bleeding control techniques to date.

Table 2. Top Research Priorities and Questions by Theme

Theme (No. of questions)	Research question generated
Epidemiology and effectiveness (8)	What is the importance and effect of the "bystander effect" on prehospital bleeding control?
	How can we assess the effect or effectiveness of tourniquet use?
	How do we standardize prehospital trauma care data collection?
	What are the barriers to implementation of bleeding control modalities in the civilian sector?
	What is the rate of potentially survivable prehospital injury mortality due to hemorrhage?
	Which bleeding control interventions are most effective for bystanders?
	Does bleeding control affect morbidity?
	How many injuries per year could benefit from civilian bleeding control?
Materials (4)	How do we set and ensure standards for hemorrhage control devices?
	What is the comparative effectiveness of tourniquets vs hemostatic gauze vs direct pressure?
	What are the design elements associated with high effectiveness of tourniquets used by laypeople?
	How can smartphone applications or app-based innovations improve layperson tourniquet use?
Education (9)	What are the essential standardized elements of bleeding control curriculum?
	What is the effectiveness of teaching laypeople to use improvised tourniquets?
	How long do laypeople retain bleeding control knowledge and skills?
	Can/should bleeding control be added to existing first-aid training (eg, BLS, CPR)?
	What is the best mode of training for scalability (eg, in-person, 911 dispatch, just-in-time cards, online, etc.)?
	Should bleeding control training require hands on training?
	Are laypeople willing to apply bleeding control interventions after training?
	What are the psychosocial barriers for laypeople applying bleeding control principles in a real-life scenario?
	Can we develop standardized, valid, and reliable assessment tools for bleeding control knowledge/efficacy?
Global health (2)	What is the epidemiology of preventable hemorrhage deaths in low- and middle-income countries?
	What is the economic effect of bleeding deaths worldwide?
Health policy (1)	How should a framework for public program performance assessment of STB programs be developed?

Abbreviations: BLS, basic life support; CPR, cardiopulmonary resuscitation; STB, Stop the Bleed.

Theme 1: Epidemiology and Effectiveness

One of the most pressing gaps identified was the paucity of prospective trials and prehospital data on implementation of a program of layperson-initiated hemorrhage control among the civilian population. Although various estimates of prehospital preventable trauma deaths exist, we do not have a true understanding of the effect of a broad STB implementation on mortality.[12-14] Prehospital trauma registries are often inadequate and rarely integrated with hospital electronic health records in a way that can capture reliable, actionable data. To combat the challenges of scarce high-quality prehospital data, the Military Health System used the concept of focused empiricism. Focused empiricism is essentially "using the best data available in combination with experience to develop clinical practice guidelines that, through an iterative process, continue to be refined until high-quality data can be generated to further inform clinical practice and standards of care."[3(p165)]

A primary area of discussion was the controversy over the variation of wounding patterns in civilian vs battlefield trauma. Retrospective preventable death analyses in the civilian population have reached varied conclusions about the utility of prehospital hemorrhage control.[15,16] Although some studies highlight the younger age of patients and higher injury severity encountered in the military compared with civilian trauma centers, others relay an increased incidence of military-style mechanisms of injury among civilians owing to blast injuries and firearms.[17,18] Patterns of injury and which interventions are most effectively used by bystanders to treat these injuries are important questions still to be addressed in the civilian population.

Another topic of discussion was the geographic variation in injury patterns and trauma outcomes.[19] Finally, the limited understanding of cost-effectiveness of prehospital hemorrhage control interventions was highlighted. Comparisons were drawn to existing layperson public health interventions, including cardiopulmonary resuscitation and automated external defibrillators as implementation models.[20] Multiple studies that have demonstrated the cost-effectiveness of these interventions in different settings may serve as a roadmap.[21-24]

Theme 2: Materials

Materials, that is, the equipment and supplies used to control hemorrhage, yielded the third-most high-priority questions among all themes (n = 4). With many types and manufacturers of tourniquets now available to the public, an area of major concern was their ease of use, effectiveness, and lack of standardization. Correct tourniquet application is not intuitive, and skill training provided on one type of device may not translate well or at all to other types of tourniquets.[25,26] Since the STB's inception, an increased number of publicly available hemorrhage control products have not been evaluated for effectiveness. In this context, experts proposed the establishment of formal standards for tourniquet design that take into account effectiveness, ease of use, and cost.

Another area of discussion was the disproportionate attention to tourniquet use compared with direct pressure and wound packing. Leonard et al[27] conducted a retrospective analysis on military data to compare the success rate and complications associated with combat application tourniquets and hemostatic gauze. The success rate was 98% for the combat application tourniquets and 89% for the gauze. Another study by Lee et al[28] examined the use of tourniquet and direct pressure in conjunction with one another. The authors posit that for most civilian trauma settings, the hemorrhage can be controlled by a stepwise approach of direct pressure, hemostatic agents, and wound packing.[28] Tourniquets are rarely required in these settings, except when massive bleeding or situations such as entrapment occur. These findings, in concert with the discrepancies in wounding patterns highlighted in the epidemiology theme, suggest that STB materials beyond tourniquets are a topic for essential future investigation.

Theme 3: Education

The primary gaps identified within this theme were around the efficacy of various modalities: in-person training, virtual (eg, phone-based applications, video) training, or a mix of modalities. The foundation of STB rests on providing the general public at large with the knowledge and tools to

control life-threatening hemorrhage, but the most effective means of accomplishing such training at scale remain unresolved.

Multiple programs have been developed to train laypeople in hemorrhage control. Many programs use the Trauma Combat Casualty Care course, a 2-day course that trains military personnel in first aid in combat, as their template.[29] The adaptation of this approach to the lay population has primarily been via the Bleeding Control Basic course, a joint product of the American College of Surgeons Committee on Trauma and the National Association of Emergency Medical Technicians' Prehospital Trauma Life Support, that focuses on hemorrhage control. The Bleeding Control Basic course simplifies Trauma Combat Casualty Care to a 1-hour course with lecture and hands-on components.[6,30] The primary limitations with this educational modality are scalability and retention.

Educational modalities to address scalability include "just-in-time" instructions to accompany bleeding control kits to inform laypeople how to control bleeding, similar in concept to the automated instructions that accompany automated external defibrillators. The first randomized clinical trial of Bleeding Control Basic training vs these other modalities demonstrated that 88% of laypersons can perform tourniquet application successfully.[30] However, unlike automated external defibrillators, where the instructions are tethered to the device, bleeding control kits do not have instructions attached, negating the positive effects of the instructions.[30] Two other trials[31,32] found that without prior training, just-in-time instructions are effective in approximately 50% of cases in teaching laypeople with no prior training in tourniquet application. When those laypeople watched a brief web-based video, however, success rates increased to 75%.[31,33] A recent trial[30] found that skill degradation over time is significant and laypeople could correctly apply a tourniquet only 55% of the time 3 to 9 months after the Bleeding Control Basic course. Multiple entities have implemented either independent or modified versions of these programs, but limited evaluation beyond subjective participant or instructor feedback is available.[34-40]

Key gaps exist in measurement of efficacy of curriculum, modalities of training, and identification of barriers to skill application in real-life environments. Educational initiatives in hemorrhage control must look beyond the fields of surgery and emergency medicine to learn and understand how best to educate and train the greatest number of people in an effective, consistent, scalable, and cost-effective manner.[41]

Theme 4: Global Health

Hemorrhage is a major contributor to global trauma morbidity and mortality.[42] Thus, conference attendees stressed the possible need to measure the economic effect of deaths due to bleeding. Traumatic injuries not only cause an emotional burden on individuals, but can also result in significant financial costs.[43] According to the World Health Organization,[44] road traffic crashes cost governments a mean of 1% to 2% of their gross national product. Furthermore, in 2000, approximately 10% of medical expenditures in the US were estimated to be injury-related medical care.[43] How much of this expenditure is a result of preventable hemorrhage requires future evaluation.

Another important topic of discussion was the epidemiology of preventable hemorrhage-related deaths in lower- and middle-income countries. The reason for scarcity of literature on this topic is the lack of reliable prehospital data in these settings. Most of the studies in lower- and middle-income countries are limited to surveys and incident reports.[45,46] More robust evaluations of the burden of hemorrhage-related morbidity and mortality in these countries will help to inform education and intervention.

Theme 5: Health Policy

Identifying the true incidence of preventable trauma deaths owing to hemorrhage was highlighted as a policy priority. This knowledge would help policy makers, advocacy groups, and the public to understand the STB campaign's potential effect compared with other public health campaigns aimed at combating issues such as opioid abuse, smoking, or drunk driving. In contrast to the military, where

leaders have the ability to mandate, implement, and enforce an STB program, mandate and enforcement are limited in the civilian setting. A variety of gaps exist in Good Samaritan laws and helpers' liability associated with hemorrhage control, placement of bleeding control kits in public facilities, and mandated training in schools or by employers. Fear of complications or further harm has been cited as 1 of the top 3 reasons for bystanders to decline to intervene in an emergency, supporting a need for clarification of Good Samaritan legislation.[47] Several states have introduced legislation on public access kit placement in public facilities and/or schools to require training of students and/or staff, but cost-effectiveness, optimal kit location, and contents of kits are unspecified.[48-51]

Understanding the real effect of public programs in terms of the number of preventable deaths avoided was another gap highlighted. The Western Pennsylvania STB Campaign created a network of hospitals in a hub-and-spoke pattern for STB implementation in 72 counties across 4 states.[52] Although this campaign trained more than 27 000 individuals, including trainers, law-enforcement agents, and laypeople, markers of program success remain poorly defined. Future work must examine meaningful and reproducible benchmarks for program success, including assessment of program infrastructure, cost and funding mechanisms, and patient-centered outcomes. Furthermore, the effect of STB programs on the community must be evaluated to inform policy decisions.

Limitations

The findings of this study are not without limitations. First, the results and the resultant research agenda represent the consensus of 45 subject-area experts, government officials, and representatives of private organizations at a single 2-day meeting. Stakeholders from affiliated fields, including legislature, academia, public health, and philanthropy must be included in the ongoing dialogue on layperson prehospital hemorrhage control. In addition, representation of experts from a wider array of public and private sector entities would have been beneficial. For example, law-enforcement officials and medical product developers would have added to the diversity of perspectives. Second, the language of the questions generated could be interpreted differently, in the absence of context. Person-to-person dialogue played a critical role to clarify the language of the questions, but owing to the limited time frame, some ambiguity remained. This was addressed by sharing a draft of the prioritized questions with all conference participants for review and final approval.

Conclusions

The National STB Research Consensus Conference developed a national research agenda for civilian prehospital hemorrhage control. Investigators, clinicians, professional societies, and funding agencies should use this agenda to inform future research and funding priorities to achieve the goal of zero preventable deaths due to trauma.

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SUPPLEMENT.

eTable. Strict and Relaxed Criteria for Prioritization
eFigure. Categorized Research Priorities by Theme