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Improving Prehospital Traumatic Shock Care – Implementation and Clinical Effectiveness of a Pragmatic, Quasi-Experimental Trial in a Resource-Constrained South African Setting.

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ABSTRACT

Introduction

Improving prehospital (i.e. ambulance-based) care in low-and-middle income countries is one strategy to reducing the global post-injury morbidity and mortality. Yet, knowledge gaps exist regarding effective implementation strategies and clinical intervention to improve prehospital trauma care.

Methods

We conduct a two-arm, controlled, mixed-methods, hybrid type-II trial in the Western Cape of South Africa to assess the implementation effectiveness and clinical effectiveness resulting from the pragmatic implementation of a simplified prehospital bundle of care (called, "EMS-TruShoC") using a novel high-efficiency EMS training ("HEET") format in a resource-constrained setting. Implementation effectiveness was assessed among EMS providers and stakeholders, using the RE-AIM framework. We assigned the intervention site. Clinical effectiveness was assessed at the patient level, using changes in shock index-age. We performed a difference-in-differences (D-I-D) analysis with a mixed effects model.

Results

198 of 240 (82.5%) EMS providers participated, 93 (47%) intervention and 105 (53%) control, with similar baseline characteristics. The overall implementation effectiveness was excellent (80.6%), broken down as follows: Reach was good (65%), Effectiveness was excellent (87%), Implementation Fidelity was good (72%), and Adoption was excellent (87%). Participants and stakeholders generally reported very high satisfaction with the implementation strategy citing that it was a strong operational fit and effective educational model for their organization. A total of 770 patients were included: 329 (42.7%) intervention and 441 (57.3%) controls, with no baseline differences. Intervention arm patients had more improved shock index*age compared to control at 4 months, which not statistically significant (-1.4 D-I-D; P=0.35). There was no significant difference in change of shock index*age over time between the groups for any of the other time intervals (P=0.99).

Conclusion

In this hybrid type II quasi-experimental trial of EMS-TruShoC (bundled care) using the novel HEET training approach, we found overall excellent implementation effectiveness but no overall statistically significant clinical effectiveness.

KEY WORDS:

Accident and Emergency Medicine; Trauma Management; International Health Services.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- We used a hybrid type II implementation science design to jointly assess implementation outcomes and clinical effectiveness which accelerates translation of knowledge into practice.
- Our pragmatic research approach promoted organizational embeddedness and the inclusion of 'usual' patients, both of which enhance the 'real-world' relevance of our findings.
- We used an educational approach to introduce a simplified bundle of care, and we uniquely assessed a full-spectrum of outcomes i.e., at the educational, implementation, and patient levels.
- Our patient-level outcome – change of shock index age – while a practical measure, may have had limited sensitivity to detect a meaningful change in prehospital shock.

BACKGROUND

Injured persons in low- and middle-income countries (LMICs) experience a disproportionately large burden of global post-injury death and disability, in large part because of inadequate trauma care.[1-4] New care delivery strategies tailored for limited resource settings are therefore needed, especially considering that the global burden of trauma is rising.[3]

Improving the quality of prehospital (i.e. ambulance-based) care in LMICs is one such strategy. High quality prehospital care could avert 54% of all mortality from emergency conditions, including trauma.[5] While the efficacy of individual interventions, such as on-scene hemorrhage control and maintaining short scene times have been demonstrated, strategies to implement a package of these interventions in LMIC prehospital settings remain underdeveloped.[6-8] Less than 2% of Emergency Medicine guidelines are developed for LMICs.[9] [10] Understanding how best to implement prehospital trauma care in LMICs is a critical gap in the literature.[11]

To address this scientific gap, we previously created and pilot tested a simplified bundle of prehospital trauma care termed, 'Emergency Medical Services Traumatic Shock Care (EMS-TruShoC)'. EMS-TruShoC is both evidence-based and expert-ratified, and it is tailored for resource-limited settings.[12-14] The EMS-TruShoC bundle is designed to support EMS providers in identifying and managing shock, a major cause of preventable death after trauma, which requires immediate resuscitation to reduce morbidity and mortality.[15] EMS-TruShoC was designed and packaged to promote rapid clinical uptake and sustained use by prehospital providers. In a 2017 single-site pilot and feasibility study, we implemented EMS-TruShoC using a novel educational strategy termed, "High-Efficiency EMS Training (HEET)."[12] HEET – the implementation strategy – is a low-dose, high-frequency, training and sensitization program, based on contemporary principles in adult-learning. In the pilot study, we demonstrated that it was feasible to implement EMS-TruShoC via the HEET program at a single site.[12]

The purpose of this study is to gain more robust implementation and clinical effectiveness data by using a larger participant sample size and by introducing a comparator arm of both providers and patients. The specific objective is to conduct a two-group controlled trial to assess the implementation effectiveness and clinical effectiveness resulting from a pragmatic implementation

of EMS-TruShoC using HEET in a resource-constrained EMS system of the Western Cape of South Africa.

METHODS

Design

The study was designed as a pragmatic, hybrid type II, quasi-experimental trial to assess the implementation of EMS-TruShoC bundled care using the HEET strategy compared to traditional (classroom-based) training of equivalent content. Implementation and clinical effectiveness outcomes were assessed using a sequential explanatory, mixed-methods approach.[16 17] A mixed-methods evaluation allowed collecting experiences and perspectives that were important to better understand and explain the quantitative findings.[17] The sequential approach allowed the qualitative data to help explain quantitative trends identified.[16] The RE-AIM framework, a well-reported implementation science planning and evaluation framework, guided the project implementation and evaluation of outcomes.[18 19] A hybrid type II design allowed equal emphasis to be placed on assessing implementation outcomes as well as clinical effectiveness.[20] A quasi-experimental approach was used because it was not possible to randomize the intervention at the level of the provider because of concerns about crossover, and there were not enough sites available to randomize at the level of the site. Ambulance base matching was based on the number of numbers of EMS providers, ambulance fleet size, the annual trauma patient volume, and jurisdictional population-type (i.e., dense-urban) at each base.

Setting

The 2017 pilot study was conducted in the Western Cape of South Africa, a middle-income country with high income inequality, twice the global mortality rate from injury, and loss of 1-million disability adjusted life years (DALYs) per annum.[2 21] The Western Cape, approximately 130,000-Km^2 with approximately 7-million people in 2019, has over 1-million persons estimated to live in dense, informal settlements, where interpersonal violence, and road traffic collisions are major contributors to the trauma burden.[22 23]

Organization and Participants

The organizational setting was a government-operated EMS system – the Western Cape Government (WCG) Department of Health EMS.[24 25] Study-eligible providers were approximately 120 clinically-active EMS providers at each of the intervention and control ambulance bases with national qualifications of basic-, intermediate-, and advanced-life support (BLS, ILS, and ALS, respectively). At the time of this study, foundational education for WCG EMS providers from across the Western Cape Province included a 6-week certificate courses for BLS, a 12-week course for ILS, and a 4-year (degree-earning) training for ALS providers [26].

Inclusion and Exclusion Criteria

EMS providers eligible for participation were duty rostered at either the intervention or control site during the implementation period – no additional selection criteria were imposed to keep the approach pragmatic and to increase the external validity of the results.[27] New hires and temporary EMS staff who joined either site after the start date of implementation were excluded. Patients eligible for inclusion were ≥18 years of age, with a traumatic injury, who received care from an EMS provider at either the intervention or control site. Patients were excluded if they were prisoners, pregnant, or had injuries classified as burns, hangings, drownings, or electrocutions.

Study Sites

The Khayelitsha and Mitchells Plain WCG EMS bases were identified as suitable research sites, and although either site was suitable to host the implementation activities, Khayelitsha was selected as the intervention site because it was more immediately administratively available. Each base had similar numbers and tiers of providers, trauma populations and caseloads, ambulance response times, and the same tertiary care trauma center. The intervention site (Khayelitsha) received the educational intervention from September to November, 2018. There were no implementation activities at the control site (Mitchell Plain) except usual classroom-based trauma training with similar learning objectives as EMS-TruShoC.

Intervention

The intervention was EMS-TruShoC bundled care which was designed to promote both the recognition and early management of traumatic shock.[12 14] Components of the EMS-TruShoC bundle were not new interventions or novel concepts to Western Cape EMS providers; they were

simply presented in a repackaged (bundled) format to improve recall and clinical application. Implementation at Khayelitsha occurred from August to November, 2018. Management of shock included five core (priority) interventions designed to be delivered in all cases of traumatic shock, and several non-core (optional) clinical interventions relevant to special circumstances (e.g., cervical spinal cord injury) (Supplementary Material 1). The five items, each evidence-based, that comprised the bundle include: (1) scene times <10 minutes, (2) early hemorrhage control, (3) insertion of a large bore intravenous catheter, (4) oxygen delivery, and (5) direct transport to a trauma center.[12] The control site received usual trauma training, which had similar learning objectives as EMS-TruShoC, except there was no emphasis nor focus on the bundled approach to care.

Implementation Strategy

EMS-TruShoC was implemented among EMS providers using the HEET program. HEET was designed as a low-dose (15 to 20-minute), high-frequency (once biweekly) training program built on principles of professional adult learning.[12 14] Training was delivered by self-nominated trained paramedics peers, called "facilitators" instead of usual training officers. Each EMS provider participating in the study (the "learners") at the intervention site received one training module every other week, for a total of 5-modules. Each module was structured around a clinical case scenario and incorporated knowledge acquisition, self-efficacy conditioning, and skills practice. Key learning objectives were emphasized using a facilitated discussion approach.

Measures

Implementation Outcomes: The RE-AIM framework was used to plan the implementation and to evaluate outcomes.[18 19 28] Quantitative and qualitative data were collected for 4 of the 5 RE-AIM dimensions, defined as follows:

- Reach is the extent to which the intervention reached the EMS providers and traumatic shock patients (example index: proportion of EMS providers participating in trainings);
- Effectiveness is the educational performance of the EMS providers who received the educational intervention (example index: proportion of learners with improved educational assessments);

- Adoption is the prospect of the program becoming institutionalized within the organization (example index: proportion of stakeholders who deem the program fit for their organization as-is); and
- Implementation fidelity is how well the program was actually executed compared to the originally intended implementation (example index: proportion of training sessions conducted within the allotted time).

Each RE-AIM dimension contained several indices. Maintenance, defined as the existence of an institutionalized program beyond 6 months, was non-applicable to this study, because trainings lasted 10 weeks and were deliberately intended to expire upon the conclusion of the study.

Clinical effectiveness: This was assessed by patient's physiologic responses to on-board ambulance care. Two relevant measures were considered: the shock index (SI, i.e., heart rate divided by systolic blood pressure) and the shock index age (SI*Age). Both SI and SI*Age perform similarly and are better than traditional vital signs in predicting trauma outcomes.[29-33] We previously published findings of our primary outcome using changes in patient's shock index which demonstrated no significant difference between the intervention and control groups.[34] In this paper, we conduct a pre-planned secondary analysis using the SI*Age outcome in the intervention group compared to the control group. A SI*Age ≥36 is the cutoff point for shock in younger trauma populations characteristic of the Western Cape.[12 32 33 35] In this study, a negative delta SI*Age represents improved shock upon facility arrival. The target effect of the study is the difference between the intervention and control groups in mean change of delta SI*Age from pre- to post-implementation (i.e., difference-in-differences).[36] A more negative difference-in-differences indicates that the intervention is performing better than the control.

Data collection

Providers' demographics: All EMS provider participants provided their age, sex, current rank, years of experience, and EMS base after informed consent. Each participant was assigned a unique study identifying number used for tracking participation in training and collecting feedback. Providers who crossed over between intervention and control sites were tracked.

Implementation Processes: At the implementation site (Khayelitsha), implementation data collected from training session participation and evaluation forms, post-program exit surveys, and post-program exit interviews. All implementation data were organized according to the RE-AIM framework domains and indices.

In particular, educational assessment data were used to evaluate the effectiveness domain of RE-AIM and were collected during assessments performed by the HEET Team. The HEET Team conducted all educational assessments, pre- and 13-months post-training. Each learner was assessed in three distinct areas: knowledge (maximum 13-points), skills (maximum 10-points), and self-efficacy (maximum 9-points). Assessors provided hand-written scored assessment sheets to a research assistant. All data was collected and tracked by the HEET Team on paper forms that were entered into a Microsoft Excel (Redmond, WA) tracking sheet by a research assistant. Interviews were conducted by two trained research assistants, who conducted exit interviews (of a 20% random sample of learners and all facilitators) and relevant stakeholders (shift managers, station managers, and HEET Team members).

Clinical Outcomes: Clinical data was collected by reviewing and abstracting EMS medical records from trauma patients at both study sites. Pre- and post-implementation data were collected for the 13 consecutive months preceding (i.e., August, 2017 to August, 2018) and following (i.e., January, 2019 to January, 2020) implementation, respectively. We used a previously validated, standardized chart review and abstraction methodology.[37] The primary treating provider (documented in the EMS patient care report form) was given attribution for the care consistent with EMS field care. Data collected for each patient included demographics (age, sex), mechanism of injury, vital signs, time from scene to hospital, and prehospital interventions. We also collected ambulance base and treating provider name to attribute the case to the intervention or control site. Clinical data were entered directly into a Research and Electronic Data Capture (REDCap) online research database.[38]

Analysis

Demographics: Baseline comparisons between EMS provider and patient characteristics in both groups, pre- and post-implementation, were performed using Wilcoxon, chi-squared, and two-tailed t-tests, based on the type and distribution of the variable.

Implementation Outcomes: Within each of the 4 RE-AIM domains, data for each index was calculated as a percentage. Indices were averaged to generate a mean effectiveness score for each domain. The overall implementation effectiveness score was calculated as the average of the mean effectiveness score for all domains. Cutoffs for implementation effectiveness were defined *a-priori* via consensus among the investigators, and defined similarly to the 2017 pilot study as: 80–100% is excellent; 60–79.9% is good; 40–59.9% is fair; and, <40% is poor.[12]

Qualitative data, designed to help explain any quantitative trends, were converged with the quantitative data.[16] Two experienced research assistants, who conducted the interviews, coded all their interview notes. Interview notes were reviewed to identify emerging themes using a consensus discussion between the lead author and the two research assistants. Themes were summarized (with supporting quotes) and arranged according to the 4 RE-AIM domains assessed in this study. The researchers adopted a post-positivist stance in the qualitative analysis (i.e., the quantitative data were believed to be real, but it was acknowledge that environmental, social, and individual differences influenced the quantitative reality).

Clinical Outcomes: The primary analysis was a difference-in-differences analysis to examine the difference between the control and intervention groups in changes in delta SI*Age over time.[36] This analysis was performed using a mixed effects model with a random effect for provider to account for clustering of outcomes for patients cared for by the same provider. Due to lack of variability between providers, as suggested by an estimated random intercept variance closer to zero, a regression model assuming independence within providers was used. To estimate the difference-in-differences, an interaction between study period and group (Intervention/Control) was of primary interest. Study period for trauma cases was classified as pre-implementation, 0-4 months post-implementation, 5-8 months post-implementation, or 9-13 months post-implementation. We divided the study period into intervals to study the change in intervention effect over time. All models also adjusted for the following predictors: Qualification of provider (BLS, ILS, ALS), patient sex, injury mechanism (blunt or penetrating), initial SI*Age, and pre-arrival minutes (time from injury to ambulance arrival). Subgroup analysis was conducted by

provider qualification. All statistical analyses were conducted using SAS version 9.4 (SAS Institute Inc., Cary, N.C.).

Ethics

Ethics approval was provided by the University of Cape Town Human Research Ethics Committee (HREC# 077/2018), the primary oversight ethics board, with a single-IRB reliance agreement with the Colorado Multiple Institutional Review Board (Protocol # 18-0607), and concurrence from the U.S. Department of Defense Human Research Protection Office. A waiver of informed consent for patients was granted; written informed consent was obtained for participating EMS providers.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

RESULTS

Provider characteristics

198 of 240 (82.5%) eligible EMS providers provided informed consent and participated. Of the 198, 93 (47%) were at the intervention site and 105 (53%) were at the control site (Table 1). There was no provider crossover. Each provider delivered care to a median of 3 (interquartile range [IQR]: 1-4) traumatic shock patients during the study, and 150 (76%) of providers cared for fewer than 5 traumatic shock patients during the study. EMS providers in both cohorts had similar age, sex, and years of experience in the pre-implementation (baseline) period. The intervention group had a significantly lower proportion of BLS providers compared to the control group.

Table 1. Providers' demographics and characteristics.

Variable	Category	Overall (N=198)	Study Group		P-value
			Control (N=105)	Intervention (N=93)	
Provider Sex	Male	107 (54%)	60 (57%)	47 (51%)	0.35
	Female	91 (46%)	45 (43%)	46 (49%)	
Provider Qualification	BLS[b]	83 (42%)	57 (54%)	26 (28%)	<0.001
	ILS	83 (42%)	36 (34%)	47 (51%)	
	ALS	32 (16%)	12 (11%)	20 (22%)	
Mean (SD) age in years		37.2 (7.3)	37.6 (7.9)	36.6 (6.5)	0.38
Median (IQR) years of experience		8.0 (5.0-11.0)	8.0 (5.0-12.0)	8.0 (5.0-11.0)	0.56[a]

[a] *Wilcoxon Test*

Implementation Outcomes

The overall implementation effectiveness was 80.6% and interpreted as 'excellent' (Table 2). The Reach (65%) and Implementation Fidelity (72%) domains were 'good', whereas the Effectiveness (87%) and Adoption (87%) domains were 'excellent'. Quantitative findings, along with the key explanatory qualitative themes, are presented below for each domain.

Reach

Reach was the poorest scoring (65%) domain (Table 2). The participation rate for eligible learners was 70%, with 30% non-participatory primarily due to workplace leave which limited their participation in training sessions but was unavoidable. Fully participating providers who were interviewed explained that the on-shift timing of the HEET trainings was highly favorable (compared to traditional EMS trainings which were inconveniently scheduled on their days off and resulted in poor participation). One learner explained that HEET is *"... accommodating to all staff, as some were not always able to attend the CME's on specific dates."* Additionally, providers mentioned that the short duration of sessions allowed the trainings to be feasibly incorporated into their work day without disrupting ambulance operations. Last, facilitators mentioned that support from the station managers and dispatch center was critical for protecting training time.

Table 2. Evaluation of Implementation Effectiveness using the RE-AIM Framework

Index	Quantitative Measure	Proportion	%	Qualitative Assessment (sample questions)	Summary of Key Qualitative Themes
Reach					
	Learners who participated/total eligible	93/113	69.9%	What factors helped learners participate in training sessions?	Timing during shifts. Operational team support. Short sessions.
	Patients receiving TruShoC bundle from EMS providers	115/195	59.0%	What prevented/enabled learners to deliver TruShoC to patients?	Bundled care allows easy recall. Approach is simple. BLS crews cannot place IVs.
		Mean (SD) =	**64.5% (7.7)**		
Effectiveness					
	Learners with improved knowledge in ≥1 core bundle area^	73/93	76.8%	What helped you improve your knowledge?	Using relevant cases. Discussion format. Peer led is non-intimidating.
	Learners with improved skills in ≥1 core bundle area^	77/93	82.8%	What helped you improve your skills?	Skills practice during each session. Using own ambulance equipment.
	Learners with improved self-efficacy in ≥1 core confidence area^	93/93	100.0%	What helped you improve your confidence?	Discussions. Better understanding. I know when to call for ALS assistance.
	Learners' composite evaluations of training sessions (mean)	4.49/5	89.8%	What did you like/dislike about this training program?	Need more time for Q&A. Was pressure to get back into service. A bit rushed.
		Mean (SD) =	**87.4% (10.0)**		
Adoption					
	Facilitators who participated/total eligible	18/20	90.0%	What organizational factors promoted your continued participation?	Managers and Dispatch Center support. HEET Team friendly. Learners eager.
	Facilitators who feel very positive about the program	9/9	100.0%	What are some reasons you feel positively about the program?	Learners improve knowledge, skills, attitudes. Promotes peer communication.
	Facilitators who want to maintain their teaching role in future	6/9	66.7%	Why do you want to remain in (or leave) your role as a facilitator?	Feels nice to teach. Content is relevant. Break from the 'usual'.
	Stakeholders who felt program should be part of EMS education	13/13	66.7%	Why should WCG EMS continue to use this program in the future?	Fills many EMS training needs. Time and cost-effective. Trauma is relevant.
	Facilitators' composite evaluation scores of training sessions (mean)	4.65/5	93.0%	What did you like/dislike about the training approach and your role?	Intimidating to initially teach. Then grew confident. I feel like a peer mentor.
	Learners' who recommend their colleagues participate in HEET	82/86	95.3%	Why would you recommend your colleagues participate as learners?	Effective to acquire new knowledge and skills. Fun. Promotes team dialogue.
	Station and shift managers had a good attitude towards the program	9/9	100.0%	What contributed (or hurt) your support of the program?	Improved communication/rapport. Gain knowledge/skills. HEET Team helped.
		Mean (SD) =	**87.3% (14.6)**		
Implementation Fidelity					
	Eligible providers participating in >=80% of trainings	72/98	73.5%	What factors allowed you to sustain participation in trainings?	Trainings at shift start. Facilitators organized us. In ambulance was convenient.

Training sessions with <=3 learners in a group	119/180	66.1%	What factors permitted small groups (2 learners) vs large groups?	Absences due to sickness or leave, and relatively few trainers, caused large groups.
Teaching quality of the facilitators scored by learners (mean)	4.3/5	86.0%	What factors made the training sessions effective or ineffective?	Facilitators are familiar peers. Spoke in terms we understood. Felt like a peer chat.
Learners correctly demonstrated the skills in sessions, scored by facilitators (mean)	4.47/5	89.4%	What factors helped you to gain proficiency in skills?	Facilitators demonstrated. Used ambulance equipment. Practiced in each session.
Training sessions that started >15-mins late	83/180	46.1%	What factors allowed you to start trainings on time (or not)?	Learners arrive late. Foot-dragging. Trainings conflicted with ambulance prep.
	Mean (SD) =	**72.2% (17.4)**		
Overall Mean Effectiveness (SD)		**80.6% (15.8)**		

^ *Compared pre-implementation to 13-months post-implementation*
EMS = Emergency Medical Services
HEET = High-Efficiency EMS Training
SD = Standard Deviation
WCG = Western Cape Government

Providers delivered all elements of bundle of care to only 59% of eligible patients, which contributed to the poor overall reach. When asked, providers explained that one of their major challenges was transport to the trauma center due to *"pushback from staff"* especially for patients who met shock criteria but appeared well. Additionally, EMS providers had variable access to tourniquets for external hemorrhage control. Last, providers did endorse performing many procedures but often failed to record them in the clinical forms, which consequently impeded the ability to measure delivery of bundled care. Conversely, providers who delivered the bundle explained that its simplicity enabled recall and delivery, as opposed to complicated algorithms and protocols. One paramedic noted, *"I could see massive difference in BLS/ILS patient management when they call for backup."*

Effectiveness

Effectiveness scored 'excellent' (87%) predominantly due to high improvements in pre- versus post-implementation assessments of knowledge, skills, and attitudes, and also due to learners' high ratings of the quality of training sessions (Table 2). Ninety-three intervention site providers completed pre- and post-training assessments and were included in the analysis. Learners and facilitators explained that HEET used EMS-relevant cases in a discussion-based format led by non-intimidating peers which facilitated knowledge transfer. A BLS learner stated that, *"I can ask the stupid questions and I know I won't be looked down to."* Additionally, the skills practice using providers' usual on-board equipment helped to facilitate good skills acquisition and retention. An ILS learner stated, *"Enjoyed that it was in the back of the ambulance where we also treat patients."* Learners' mentioned that their confidence was improved due to group discussion format, which helped identify deficiencies and allay any concerns, including when to call for ALS backup during challenging cases. A BLS learner noted, *"I felt empowered and like a paramedic…"* and that it was, *"Nice to have own ALS do training."*

Adoption

Adoption scored 'excellent' predominantly because all tiers of EMS stakeholders (facilitators, HEET Team, station managers, learners) appraised the HEET program and EMS-TruShoC content as excellent operational fit for the organization and helped to overcome barriers to traditional training, including low attendance rates and low efficacy training formats (Table 2). Facilitators

explained their personal satisfaction with the HEET program included: *"Interaction with peers", "learning how to present", "refresher of information", "safe environment to learn", "feels nice to teach", and "I gained confidence as a teacher."* Of note, 3 out of 9 facilitators were unsure about resuming their role in future trainings specifically because they were unsure if they would be provided additional paid time to prepare for training sessions. Shift and station managers felt positively about the program because they noted an improvement in team-wide communication and rapport, in addition to knowledge and skills acquisition. EMS leaders felt that although cost-effectiveness was not formally assessed, their observation was that HEET was incredibly cost-effective compared to their usual educational programs, and felt that it had a future role within the EMS organization, insofar as it was appropriately integrated.

Implementation Fidelity

Implementation Fidelity had a lower score of 'good' mainly because of logistic challenges associated with keeping the number of learners in small groups at three or less, and also due to delayed training start times (Table 2). The issue of >3 learners in a training session arose because when providers missed trainings (most often due to leave), they would jump into another crew's training session to *"catch up so we don't get left behind,"* even though make up training sessions were offered. The latter issue of delayed start times was attributable to providers having a sluggish start to their work day which was termed, *"heel-dragging,"* and had no specific cause attributed. Overall high participation rates (i.e., providers completing ≥80% of sessions) was facilitated by the organization and conduct of training sessions during official shift time, with the implicit understanding that their participation was a part of their duties, which was driven by the HEET Team. Last, the facilitators and learners explained that facilitators were well trained, prepared, and enthusiastic about the sessions, which translated to high quality delivery and fidelity of the HEET program.

Patient characteristics

A total of 770 patients, meeting inclusion criteria, received care from EMS provider participants in the intervention (329, 42.7%) and control (441, 57.3%) arm (Table 3). There were no significant differences in pre- or post-implementation patient demographic or physiologic characteristics in

the control versus intervention cohorts with respect to age, sex, blunt versus penetrating injury mechanism, shock index, SI*Age, and ambulance on-scene time.

Table 3. Pre- and post-intervention demographic and physiologic characteristics of patients.

Pre-Implementation (n=355)					
Variable	**Category**	**Overall (N=355)**	**Control (N=202)**	**Intervention (N=153)**	**P-value**
Median (IQR) patient age in years		30 (25-37)	30 (25-39)	30 (25-36)	0.34^
Patient sex	Female	24% (84)	22% (44)	26% (40)	0.34
	Male	76% (271)	78% (158)	74% (113)	
Primary injury mechanism	Blunt	47% (166)	48% (96)	46% (70)	0.74
	Penetrating	53% (189)	52% (106)	54% (83)	
Median (IQR) initial heart rate (BPM)		111 (102-118)	112 (104-118)	110 (98-119)	0.17^
Median (IQR) initial SBP (mm Hg)		112 (90-130)	114 (94-130)	110 (90-129)	0.12^
Median (IQR) Initial Shock Index*Age		29.1 (23.8-37.3)	29.3 (24.0-38.8)	28.8 (23.8-35.7)	0.23^
Shock stage defined by initial Shock Index*Age	Shock (>=36)	28% (101)	32% (64)	24% (37)	0.12
	Normal (<36)	72% (254)	68% (138)	76% (116)	
Median (IQR) change in Shock Index*Age from initial to final		-1.4 (-5.7-0.4)	-1.2 (-4.9-0.4)	-1.9 (-6.9-0.4)	0.36^
Median (IQR) minutes from scene arrival to scene departure		23 (13-35)	24 (12-36)	22 (14-32)	0.93^
Post-Implementation (n=415)					
Variable	**Category**	**Overall (N=415)**	**Control (N=239)**	**Intervention (N=176)**	**P-value**
Median (IQR) patient age in years		30 (24-36)	30 (24-36)	30 (24-37)	0.42^
Patient sex	Female	21% (85)	22% (53)	18% (32)	0.35
	Male	79% (326)	78% (185)	82% (141)	
Primary injury mechanism	Blunt	46% (191)	46% (109)	47% (82)	0.84
	Penetrating	54% (224)	54% (130)	53% (94)	
Median (IQR) initial heart rate (BPM)		111 (104-119)	111 (106-120)	110 (99-119)	0.06^
Median (IQR) initial SBP (mm Hg)		114 (91-130)	115 (100-130)	110 (90-129)	0.10^

Table 3. Pre- and post-intervention demographic and physiologic characteristics of patients.

Pre-Implementation (n=355)					
Variable	**Category**	**Overall (N=355)**	**Control (N=202)**	**Intervention (N=153)**	**P-value**
Median (IQR) Initial Shock Index*Age		28.9 (23.1-36.8)	28.7 (23.0-37.3)	28.9 (23.2-36.2)	0.92^
Shock stage defined by initial Shock Index*Age	Shock (>=36)	27% (110)	28% (66)	25% (44)	0.55
	Normal (<36)	73% (305)	72% (173)	75% (132)	
Median (IQR) change in Shock Index*Age from initial to final		-0.9 (-4.2-1.3)	-0.9 (-3.2-0.9)	-1.1 (-5.3-1.9)	0.61^
Median (IQR) minutes from scene arrival to scene departure		18 (9-27)	17 (7-28)	19 (10-26)	0.25^

^ *Wilcoxon Test*
BPM = beats per minute
IQR = interquartile range
Mm Hg = millimeters of mercury
SBP = systolic blood pressure

Clinical Effectiveness

A total of 755 of 770 (98%) trauma patients were analyzed (Table 4). 15 (2%) patients were missing data needed to calculate a shock index, hence excluded from the analysis. In the 4 months post-implementation compared to pre-implementation period, the intervention arm patients had more improved shock index*age compared to control arm, but the difference between the two groups was not statistically significant (0.8 change in control arm, -0.6 change in intervention arm; -1.4 difference-in-differences, P=0.35) (Figure 1a and Table 4). Further, there was no significant difference in change over time between the groups for any of the other time intervals (5-8 months: difference-in-differences -0.5, P=0.79; 9-13 months: difference-in-differences 0, P=0.99). Last, there were no differences in changes in shock index*age by ranks of EMS providers (BLS, ILS, or ALS) (Figure 1b-1d).

Table 4. Delta shock index*age by time interval and study group, for entire analysed cohort (N=755)[a]

Time Interval	Control		Intervention		D-I-D (95% CI) (Intervention-Control)	P-value
	n	Estimated ΔSI*Age (95% CI)	n	Estimated ΔSI*Age (95% CI)		
Before – All	200	-2.0 (-3.1, -0.9)	151	-3.0 (-4.2, -1.7)		
Post - 0-4 months	73	-1.2 (-3.0, 0.6)	69	-3.6 (-5.4, -1.7)	-1.4 (-4.4, 1.5)	0.35
Post - 5-8 months	62	-1.0 (-2.9, 0.9)	39	-2.5 (-4.9, -0.0)	-0.5 (-3.9, 3.0)	0.79
Post - 9-13 months	98	-1.3 (-2.8, 0.2)	63	-2.2 (-4.2, -0.3)	0.0 (-2.9, 2.9)	0.99

*ΔSI*Age = Change in Shock Index*Age. A more negative delta SI represents more improved shock.*

*D-I-D = Difference in Differences computed as (Change in ΔSI*Age from baseline in intervention group) – (Change in ΔSI*Age from baseline in control group)*

[a]15 cases from the original sample of N=770 were excluded from this analysis due to missing data.

Discussion

We successfully implemented EMS-TruShoC (simplified bundled care) in a pragmatic fashion using the HEET training approach. The overall implementation effectiveness was excellent (81%). The bundled care intervention did not significantly improve patient's change in SI*Age when compared to usual (non-bundled) care.

Our novel training program, HEET, achieved excellent implementation effectiveness overall. HEET was successful for effective on-the-job trauma re-training of providers in this resource-limited EMS system. We found similar findings in our prior single-site feasibility study.[12] There were several major factors contributing to the high implementation effectiveness, which were evidenced by the quantitative data and supported by the qualitative findings. First, short-burst (15 to 20-minute) trainings scheduled and protected at the beginning of shift time proved to be a strong operational fit for this EMS system. Second, the program was purposefully designed to be engaging for professional adult learners by using contextually relevant cases which were presented in a non-intimidating, structured discussion forum. Third, we used and simplified bundle of care, and skills practice, to help *"drill"* the core components of the bundle of care to help promote recall and translation from the 'class' to practice. Last, we intentionally used motivated peer paramedics as facilitators, instead of the traditional EMS educators – this approach helped to reduce learner anxiety and promoted more open communication and eagerness to learn. Consequently, we measured meaningfully improved educational outcomes attributable to the EMS-TruShoC training intervention.

While fidelity of the implementation overall was excellent, there were modest challenges in delivering the intervention to small groups of participants at the beginning of their shifts. The HEET Team felt that this was due to a combination of unavoidable logistic challenges which ultimately did not negatively impact delivery of the intervention. A critical factor underpinning the overall implementation success was advanced engagement and planning between the research team and the HEET Team. The HEET Team was comprised of a motivated multi-disciplinary group of EMS educators and quality assurance personnel who worked alongside the researchers to design, implement, and evaluate the program with a deliberate goal of pragmatic implementation, strong organizational tailoring, and sustainability.

Our clinical intervention of bundled care (EMS-TruShoC) did not measurably improve patients' shock physiology, measured by SI*Age, for several possible reasons. First, it is likely that three items in our core shock bundle (large IV catheter, scene time <10 minutes, and trauma center transport destination) may cause no direct change to heart rate nor systolic blood pressure. Second, it is possible that although the SI*Age performs better than traditional vital signs, it may have inadequate sensitivity and specificity to detect prehospital changes in physiology. A sentinel study by Zarzaur *et al.* demonstrated that SI*Age was a superior predictor of 48-hour mortality compared to systolic blood pressure, heart rate, or shock index.[32] In 2012, Bruijns and colleagues validated these findings in the United Kingdom's national trauma registry in which SI*Age achieved the highest area under the receiver operator curve (AUROC) of 0.79 for predicting 48-hour mortality compared to shock index and other age-based markers.[29] However, the SI*Age thresholds varied across these studies from ≥35.6 to ≥55. We used a threshold of ≥36, which was based upon Zarzaur's original study and is more appropriate for a younger trauma population.[33] However, further studies to establish a prehospital cutoff point would be useful, especially if conducted within a South African trauma population. Additionally, other hospital-based outcome measures, such as blood lactate, the need for blood transfusions, or 24-hour mortality, could potentially detect a change where SI*Age did not – these are possible avenues for future research. However, the advantage of using a shock index-based physiologic measure is it facilitates prehospital research by avoiding costly and logistically complicated in-hospital clinical data collection.

Our overall research design and approach (i.e., a hybrid type II quasi-experimental trial) and the research context (i.e., a South African prehospital system) are also noteworthy. Hybrid trials assess the implementation outcomes in tandem with the clinical effectiveness outcomes.[20] The rationale for conducting both in parallel is to test the intervention and implementation in a real-world context which improve the ability of findings to more rapidly translate into clinical practice settings.[20 27] Prior data suggests that it takes, on average, 17 years for 14% of biomedical research to translate from research into clinical practice which stifles advancements in clinical care worldwide.[39] Implementation science methodologies – such as the pragmatic hybrid trial design used in this study – are innovative and feasible approaches to narrowing this 'know-do' gap. The need for real-world data is arguably even more critical in lower-income settings which face the challenging

paradox of having extremely high burdens of injury yet have a shortage of biomedical research. Prehospital care is a neglected area of research, according to the World Health Organization and leading experts, necessitating more research to help improve care delivery and patient outcomes. In time-sensitive emergencies, such as traumatic shock, bringing basic yet essential treatment to the patient, at the scene of the event, is a cost-effective public health intervention to improve post-injury morbidity and mortality [40 41] – yet, where prehospital systems exist, there is a paucity of research, due to poor awareness or the technical challenges. This body of work directly addresses these practice and scientific evidence gaps.

Limitations

There are several limitations to this work aside from those of the SI*Age described earlier. Despite our best efforts to select similar sites, the intervention site had a significantly lower proportion of BLS providers compared to the control site which may have influenced our implementation outcomes. Educational assessments were designed to be quick and easy for the HEET Team assessors to administer, hence may have had limited sensitivity to detect changes in educational outcomes among the EMS participants, so may have under-estimated the true effect size. Additionally, the HEET Team assessors could not be practically blinded to whether an EMS participant received the intervention or not, which may have introduced bias in their assessments.

Conclusions

In this hybrid type II quasi-experimental trial of EMS-TruShoC (bundled care) using the novel HEET training approach, we found overall excellent implementation effectiveness but no overall statistically significant clinical effectiveness. HEET is an effective prehospital implementation strategy in a resource-constrained EMS setting, primarily explained by strong fit to the organization's operational needs and the adult-learner friendly approach to on-the-job training. Further clinical effectiveness studies are warranted to assess whether EMS-TruShoC confers a prehospital physiologic benefit for critically injured patients.

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Author Contributions:

All authors made substantive contributions to the work (i.e., the design or the acquisition, analysis, or interpretation), contributed to drafting or substantive revisions, approved the publishable version, and agree to be accountable for the accuracy and integrity of the work.

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Opinions, interpretations, conclusions, and recommendations are those of the authors and are not necessarily endorsed by, or the official opinions of, the NIH, the U.S. Department of Defense, the Western Cape Government Department of Health, or the University of Colorado.

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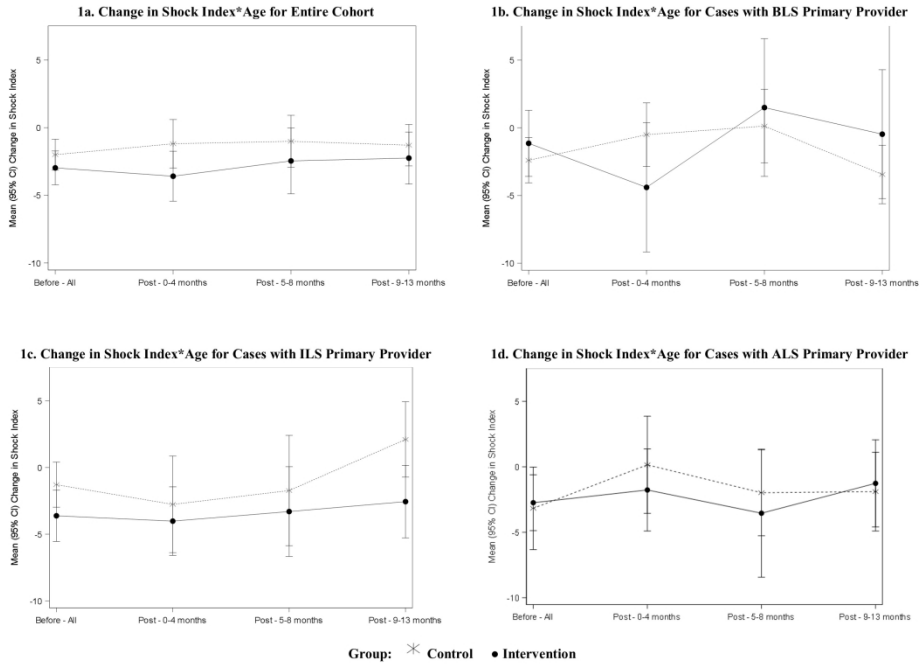
Figure 1. Mean change in shock from EMS arrival at the scene of injury to hospital arrival by whole cohort (1a), and for cases with BLS (1b), ILS (1c), and ALS (1d) providers. *The more negative the change in SI*Age value is, the more improved the shock. BLS = Basic Life Support. ILS = Intermediate Life Support. ALS = Advanced Life Support.*



279x215mm (300 x 300 DPI)

'EMS-TruShoC'

A Bundle of EMS Traumatic Shock Care

TRAUMA SHOCK RECOGNITION

In adult injury w/ high risk mechanism

RIGHT PATIENT?
High risk mechanism of injury
and
Age ≥16 years.

Yes

1 or more abnormal vitals screen for shock

VITAL SIGNS?
Pulse rate >100-bpm,
and/or
Systolic BP <100-mmHg,
and/or
Capillary refill time >2-secs,
and/or
Non-palpable radial pulse.

Yes

1 or more symptoms for decompensated shock.

CLINICAL PICTURE?
Active or suspected bleeding
and/or
Altered Mentation
and/or
Skin Color Change
and/or
Sweating/diaphoresis.

Mechanism of injury placing patient at high risk for shock:

- **PENETRATING:**
  Gunshot wound (head, neck, torso, groin, proximal extremity)
- **BLUNT:**
  Fall from height (>6m)
  Motor vehicle collision (high speed, ejection)
  Motor cycle crash
  Pedestrian struck by vehicle
  Assault (with high energy transfer)
- **AMPUTATION:**
  Of limbs (except fingers, toes)
- **ACTIVE BLEEDING:**
  Uncontrollable external bleeding
  Obvious/suspected internal hemorrhage

TRAUMA SHOCK MANAGEMENT

CORE BUNDLE OF CARE

1. On-scene time is ≤ 10-minutes
2. Destination is trauma center
3. Large bore IV (≥18G) catheter placed
4. Oxygen is administered (appropriate route)
5. External bleeding is controlled (per protocol)

*All 5 performed on 100% of shock trauma cases.

NON-CORE BUNDLE OF CARE

Circulation:
- Control hemorrhage
- Intravenous fluids

Airway:
- Open, Suction, & Secure

Breathing:
- Oxygenate & Ventilate

Disability:
- Prevent further neurologic injury

Continuous assessment
- Repeat: primary & secondary surveys
- Repeat vital signs (at least 2 sets)

↑ Perform C-A-B-D on 100% of cases ↑

Special considerations if shock and the ff:
- Uncontrolled arterial bleed = tourniquet
- Blunt pelvic injury = pelvic binding
- Tension PTX = needle decompression
- Loss of motor/sensory = cervical collar
- Cardiac arrest = consider CPR / ACLS
- Obvious pregnancy = left lateral decubitus

↑ Perform only when clinically indicated ↑

Checklist of items for reporting pragmatic trials

Section	Item	Standard CONSORT description	Extension for pragmatic trials	Manuscript page # that addresses the item
Title and abstract	1	How participants were allocated to interventions (eg, “random allocation,” “randomised,” or “randomly assigned”)		1, 2
Introduction				
Background	2	Scientific background and explanation of rationale	Describe the health or health service problem that the intervention is intended to address and other interventions that may commonly be aimed at this problem	4-5
Methods				
Participants	3	Eligibility criteria for participants; settings and locations where the data were collected	Eligibility criteria should be explicitly framed to show the degree to which they include typical participants and/or, where applicable, typical providers (eg, nurses), institutions (eg, hospitals), communities (or localities eg, towns) and settings of care (eg, different healthcare financing systems)	5-6
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered	Describe extra resources added to (or resources removed from) usual settings in order to implement intervention. Indicate if efforts were made to standardise the intervention or if the intervention and its delivery were allowed to vary between participants, practitioners, or study sites	6-7
			Describe the comparator in similar detail to the intervention	
Objectives	5	Specific objectives and hypotheses		4-5
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (eg, multiple observations, training of assessors)	Explain why the chosen outcomes and, when relevant, the length of follow-up are considered important to those who will use the results of the trial	7-8
Sample size	7	How sample size was determined; explanation of any interim analyses and stopping rules when applicable	If calculated using the smallest difference considered important by the target decision maker audience (the minimally important difference) then report where this difference was obtained	9-10
Randomisation—sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (eg, blocking, stratification)		N/A
Randomisation—allocation concealment	9	Method used to implement the random allocation sequence (eg, numbered containers or central telephone), clarifying whether the		N/A

Section	Item	Standard CONSORT description	Extension for pragmatic trials	Manuscript page # that addresses the item
		sequence was concealed until interventions were assigned		
Randomisation—implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups		8-9
Blinding (masking)	11	Whether participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment	If blinding was not done, or was not possible, explain why	N/A (explained on pg 24)
Statistical methods	12	Statistical methods used to compare groups for primary outcomes; methods for additional analyses, such as subgroup analyses and adjusted analyses		23
Results				
Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended)—specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analysed for the primary outcome; describe deviations from planned study protocol, together with reasons	The number of participants or units approached to take part in the trial, the number which were eligible, and reasons for non-participation should be reported	11 (providers) 16-20 (patients)
Recruitment	14	Dates defining the periods of recruitment and follow-up		7,8 (providers) 9,10 (patients)
Baseline data	15	Baseline demographic and clinical characteristics of each group		11,12 (providers) 16-17 (patients)
Numbers analysed	16	Number of participants (denominator) in each group included in each analysis and whether analysis was by "intention-to-treat"; state the results in absolute numbers when feasible (eg, 10/20, not 50%)		11-14 (providers) 18-20 (patients)
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision (eg, 95% CI)		12-14 (implementation) 16-20 (clinical effect)
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating which are prespecified and which are exploratory		20 (clinical effect)
Adverse events	19	All important adverse events or side effects in each intervention group		N/A
Discussion				

Section	Item	Standard CONSORT description	Extension for pragmatic trials	Manuscript page # that addresses the item
Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes		21-22
Generalisability	21	Generalisability (external validity) of the trial findings	Describe key aspects of the setting which determined the trial results. Discuss possible differences in other settings where clinical traditions, health service organisation, staffing, or resources may vary from those of the trial	22-23
Overall evidence	22	General interpretation of the results in the context of current evidence		21-24

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Improving Prehospital Traumatic Shock Care – Implementation and Clinical Effectiveness of a Pragmatic, Quasi-Experimental Trial in a Resource-Constrained South African Setting

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Improving Prehospital Traumatic Shock Care – Implementation and Clinical Effectiveness of a Pragmatic, Quasi-Experimental Trial in a Resource-Constrained South African Setting.

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ABSTRACT

Introduction

Improving prehospital (i.e. ambulance-based) care in low-and-middle income countries is one strategy to reducing the global post-injury morbidity and mortality. Yet, knowledge gaps exist regarding effective implementation strategies and clinical interventions to improve prehospital trauma care.

Methods

We conduct a two-arm, controlled, mixed-methods, hybrid type-II trial in the Western Cape of South Africa to assess the implementation effectiveness and clinical effectiveness resulting from the pragmatic implementation of a simplified prehospital bundle of trauma care using a novel workplace-based, rapid training format in a resource-constrained setting. Implementation effectiveness was assessed among EMS providers and stakeholders, using the RE-AIM framework. We assigned the intervention site. Clinical effectiveness was assessed at the patient level, using changes in Shock Index x Age (SIxAge). We performed a difference-in-differences (D-I-D) analysis with a multivariable mixed effects model.

Results

198 of 240 (82.5%) EMS providers participated, 93 (47%) intervention and 105 (53%) control, with similar baseline characteristics. The overall implementation effectiveness was excellent (80.6%), broken down as follows: Reach was good (65%), Effectiveness was excellent (87%), Implementation Fidelity was good (72%), and Adoption was excellent (87%). Participants and stakeholders generally reported very high satisfaction with the implementation strategy citing that it was a strong operational fit and effective educational model for their organization. A total of 770 patients were included: 329 (42.7%) intervention and 441 (57.3%) controls, with no baseline differences. Intervention arm patients had more improved SIxAge compared to control at 4 months, which was not statistically significant (-1.4 D-I-D; P=0.35). There was no significant difference in change of SIxAge over time between the groups for any of the other time intervals (P=0.99).

Conclusion

In this quasi-experimental trial of bundled care using the novel workplace rapid training approach, we found overall excellent implementation effectiveness but no overall statistically significant clinical effectiveness.

KEY WORDS:

Accident and Emergency Medicine; Trauma Management; International Health Services.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- We used a hybrid type II implementation science design to jointly assess implementation outcomes and clinical effectiveness which accelerates translation of knowledge into practice.
- Our pragmatic research approach promoted organizational embeddedness and the inclusion of 'usual' patients, both of which enhance the 'real-world' relevance of our findings.
- We used an educational approach to introduce a simplified bundle of care, and we uniquely assessed a full-spectrum of outcomes at the educational, implementation, and patient levels.
- Our patient-level outcome – change of Shock Index x Age – while a practical measure, may have had limited sensitivity to detect a meaningful change in prehospital shock in a convenience sample of trauma patients.

BACKGROUND

Injured persons in low- and middle-income countries (LMICs) experience a disproportionately large burden of global post-injury death and disability, in large part because of inadequate trauma care.[1-4] New care delivery strategies tailored for limited resource settings are therefore needed, especially considering that the global burden of trauma is rising.[3]

Improving the quality of prehospital (i.e. ambulance-based) care in LMICs is one such strategy. High quality prehospital care could avert 54% of all mortality from emergency conditions, including trauma.[5] While the efficacy of individual interventions, such as on-scene hemorrhage control and maintaining short scene times have been demonstrated, strategies to implement a package of these interventions in LMIC prehospital settings remain underdeveloped.[6-8] Less than 2% of Emergency Medicine guidelines are developed for LMICs.[9] [10] Understanding how best to implement prehospital trauma care in LMICs is a critical gap in the literature.[11]

To address this scientific gap, we previously created and pilot tested a simplified bundle of prehospital trauma care termed, Emergency Medical Services Traumatic Shock Care (EMS-TruShoC). EMS-TruShoC is both evidence-based and expert-ratified, and it is tailored for resource-limited settings.[12-14] The EMS-TruShoC bundle is designed to support EMS providers in identifying and managing traumatic shock, a major cause of preventable death after trauma, which requires immediate resuscitation to reduce morbidity and mortality.[15] EMS-TruShoC was designed and packaged to promote rapid clinical uptake and sustained use by prehospital providers. In a 2017 single-site pilot and feasibility study, we implemented EMS-TruShoC using a novel educational strategy developed for the Western Cape Government EMS system termed, High-Efficiency EMS Training (HEET).[12] HEET – the implementation strategy – is a low-dose, high-frequency, training and sensitization program, based on contemporary principles in adult-learning. In the pilot study, we demonstrated that it was feasible to implement EMS-TruShoC via the HEET educational platform at a single site.[12]

The purpose of this study is to gain more robust implementation and clinical effectiveness data by using a larger participant sample size and by introducing a comparator arm of both providers and patients. The specific objective is to conduct a two-group controlled trial to assess the

implementation effectiveness and clinical effectiveness resulting from a pragmatic implementation of EMS-TruShoC using HEET in a resource-constrained EMS system of the Western Cape of South Africa.

METHODS

Design

The study was designed as a pragmatic, hybrid type II, quasi-experimental trial to assess the implementation of EMS-TruShoC bundled care using the HEET strategy compared to traditional (classroom-based) training of equivalent content. Implementation and clinical effectiveness outcomes were assessed using a sequential explanatory, mixed-methods approach.[16 17] A mixed-methods evaluation allowed collecting experiences and perspectives that were important to better understand and explain the quantitative findings.[17] The sequential approach allowed the qualitative data to help explain quantitative trends identified.[16] The RE-AIM framework, a well-reported implementation science planning and evaluation framework, guided the project implementation and evaluation of outcomes.[18 19] RE-AIM consists of five core domains – reach, effectiveness, adoption, implementation fidelity, and maintenance – and is intended to comprehensively evaluate pragmatic interventions. A hybrid type II design allowed equal emphasis to be placed on assessing implementation outcomes as well as clinical effectiveness.[20] A quasi-experimental approach was used because it was not possible to randomize the intervention at the level of the provider because of concerns about crossover, and there were not enough sites available to randomize at the level of the site. Ambulance base matching was based on the number of EMS providers, ambulance fleet size, the annual trauma patient volume, and jurisdictional population-type (i.e., dense-urban) at each base. Clinical effectiveness was assessed in a convenience sample of adult trauma patients treated by EMS at both study sites.

Setting

The 2017 pilot study was conducted in the Western Cape of South Africa, a middle-income country with high income inequality, twice the global mortality rate from injury and loss of 1-million disability adjusted life years (DALYs) per annum.[2 21] The Western Cape, approximately 130,000-Km^2 with approximately 7-million people in 2019, has over 1-million persons estimated to live in

dense, informal settlements, where interpersonal violence, and road traffic collisions are major contributors to the trauma burden.[22 23]

Organization and Participants

The organizational setting was a government-operated EMS system – WCG Department of Health EMS.[24 25] WCG EMS had previously established trauma a high-priority focal condition for improvement efforts. Study-eligible providers were approximately 120 clinically-active EMS providers at each of the intervention and control ambulance bases with national qualifications of basic-, intermediate-, and advanced-life support (BLS, ILS, and ALS, respectively). At the time of this study, foundational education for WCG EMS providers from across the Western Cape Province included a 6-week certificate courses for BLS, a 12-week course for ILS, and a 4-year (degree-earning) training for ALS providers [26].

Inclusion and Exclusion Criteria

EMS providers eligible for participation were duty rostered at either the intervention or control site during the implementation period – no additional selection criteria were imposed to keep the approach pragmatic and to increase the external validity of the results.[27] New hires and temporary EMS staff who joined either site after the start date of implementation were excluded. Patients eligible for inclusion were ≥18 years of age, with a traumatic injury, had a minimum of two sets of vital signs (including first and last heart rate and systolic blood pressure) who received care from an EMS provider at either the intervention or control site. Patients were excluded if they were prisoners, pregnant, or had injuries classified as burns, hangings, drownings, or electrocutions.

Study Sites

The Khayelitsha and Mitchells Plain WCG EMS bases were identified as suitable research sites, and although either site was suitable to host the implementation activities, Khayelitsha was selected as the intervention site because it was more immediately administratively available. Each base had similar numbers and tiers of providers, trauma populations and caseloads, ambulance response times, and the same tertiary care trauma center. The intervention site (Khayelitsha) received the educational intervention from September to November, 2018. There were no

implementation activities at the control site (Mitchells Plain) except usual classroom-based trauma training with similar learning objectives as EMS-TruShoC.

Intervention

The intervention was EMS-TruShoC bundled care which was designed to promote both the recognition and early management of traumatic shock.[12 14] Components of the EMS-TruShoC bundle were not new interventions or novel concepts to Western Cape EMS providers; they were simply presented in a repackaged (bundled) format to improve recall and clinical application. Management of shock included five core (priority) interventions designed to be delivered in all cases of traumatic shock, and several non-core (optional) clinical interventions relevant to special circumstances (e.g., cervical spinal cord injury) (Supplementary Material 1). The five items, each evidence-based, that comprised the bundle include: (1) scene times <10 minutes, (2) early hemorrhage control, (3) insertion of a large bore intravenous catheter, (4) oxygen delivery, and (5) direct transport to a trauma center.[12]

Implementation Strategy

EMS-TruShoC was implemented among EMS providers using the HEET program. HEET was designed as a low-dose (15 to 20-minute), high-frequency (once biweekly) training program built on principles of professional adult learning.[12 14] Training was delivered by self-nominated trained paramedics peers, called "facilitators" instead of usual training officers. Each EMS provider participating in the study (the "learners") at the intervention site received one training module every other week, for a total of 5-modules. Each module was structured around a clinical case scenario and incorporated knowledge acquisition, self-efficacy conditioning, and skills practice. Key learning objectives were emphasized using a facilitated discussion approach.

Measures

Implementation Outcomes: The RE-AIM framework was used to plan the implementation and to evaluate outcomes.[18 19 28] Quantitative and qualitative data were collected for 4 of the 5 RE-AIM dimensions, defined as follows:

- Reach is the extent to which the intervention reached the EMS providers and traumatic shock patients (example index: proportion of EMS providers participating in trainings);

- Effectiveness is the educational performance of the EMS providers who received the educational intervention (example index: proportion of learners with improved educational assessments);
- Adoption is the prospect of the program becoming institutionalized within the organization (example index: proportion of stakeholders who deem the program fit for their organization as-is); and
- Implementation fidelity is how well the program was actually executed compared to the originally intended implementation (example index: proportion of training sessions conducted within the allotted time).
- Maintenance is defined as the existence of an institutionalized program beyond 6 months.

Each RE-AIM dimension contained several indices. Maintenance, was non-applicable to this study, because trainings lasted 10 weeks and were deliberately intended to expire upon the conclusion of the study.

Clinical effectiveness outcomes: This was assessed by patient's physiologic responses to on-board ambulance care. Two relevant measures were considered: the Shock Index (SI), which is calculated by dividing the heart rate by systolic blood pressure, and the SI times the age of the patient (SIxAge). Both SI and SIxAge have been used to identify patients in traumatic shock, perform comparably, and are better than traditional vital signs in predicting trauma outcomes.[29-33] We previously published findings of our primary outcome using changes in patient's Shock Index which demonstrated no significant difference between the intervention and control groups.[34] In this paper, we conduct a pre-planned secondary analysis using the SIxAge outcome in the intervention group compared to the control group. A SIxAge ≥36 is the cutoff point for shock in younger trauma populations characteristic of the Western Cape.[12 32 33 35] In this study, a negative delta SIxAge (defined as SIxAge at facility arrival minus SIxAge at the scene) represents improved shock upon facility arrival. The target effect of the study is the difference in delta SIxAge between the intervention and control groups from pre- to post-implementation (i.e., difference-in-differences).[36] A more negative difference-in-differences, or improving SIxAge, indicates that the intervention is performing better than the control.

Data collection

Providers' demographics: All EMS provider participants provided their age, sex, current rank, years of experience, and EMS base after informed consent. Each participant was assigned a unique study identifying number used for tracking participation in training and collecting feedback. Providers who crossed over between intervention and control sites were tracked.

Implementation Processes: At the implementation site (Khayelitsha), implementation data was collected from training session participation and evaluation forms, post-program exit surveys, and post-program exit interviews. All implementation data were organized according to the RE-AIM framework domains and indices.

In particular, educational assessment data were used to evaluate the effectiveness domain of RE-AIM and were collected during assessments performed by the HEET Team. The HEET Team conducted all educational assessments, pre- and 13-months post-training. Each learner was assessed in three distinct areas: knowledge (maximum 13-points), skills (maximum 10-points), and self-efficacy (maximum 9-points). Assessors provided hand-written scored assessment sheets to a research assistant. All data was collected and tracked by the HEET Team on paper forms that were entered into a Microsoft Excel (Redmond, WA) tracking sheet by a research assistant. Interviews were conducted by two trained research assistants, who conducted exit interviews of a 20% random sample of learners and all facilitators and relevant stakeholders such as shift managers, station managers, and HEET Team members.

Clinical Effectiveness Outcomes: Clinical data was collected by reviewing and abstracting EMS medical records from trauma patients at both study sites. Pre- and post-implementation data were collected for the 13 consecutive months preceding (i.e., August, 2017 to August, 2018) and following (i.e., January, 2019 to January, 2020) implementation, respectively. We used a previously validated, standardized chart review and abstraction methodology.[37] The primary treating provider (documented in the EMS patient care report form) was given attribution for the care consistent with EMS field care. Data collected for each patient included demographics (age, sex), mechanism of injury, vital signs, time from scene to hospital, and prehospital interventions. We also collected ambulance base and treating provider name to attribute the case to the

intervention or control site. Clinical data were entered directly into a Research and Electronic Data Capture (REDCap) online research database.[38]

Analysis

Demographics: Baseline comparisons between EMS provider and patient characteristics in both groups, pre- and post-implementation, were performed using Wilcoxon, chi-squared, and two-tailed t-tests, based on the type and distribution of the variable.

Implementation Outcomes: Within each of the 4 RE-AIM domains, data for each index was calculated as a percentage. Indices were averaged to generate a mean effectiveness score for each domain. The overall implementation effectiveness score was calculated as the average of the mean effectiveness score for all domains. Cutoffs for implementation effectiveness were defined *a-priori* via consensus among the investigators, and defined similarly to the 2017 pilot study as: 80–100% is excellent; 60–79.9% is good; 40–59.9% is fair; and, <40% is poor.[12]

Qualitative data, designed to help explain any quantitative trends, were converged with the quantitative data.[16] Two experienced research assistants, who conducted the interviews, coded all interview notes. Interview notes were reviewed to identify emerging themes using a consensus discussion between the lead author and the two research assistants. Themes were summarized (with supporting quotes) and arranged according to the 4 RE-AIM domains assessed in this study. The researchers adopted a post-positivist stance in the qualitative analysis (i.e., the quantitative data were believed to be real, but it was acknowledge that environmental, social, and individual differences influenced the quantitative reality).

Clinical Outcomes: The primary analysis was a difference-in-differences analysis to examine the difference between the control and intervention groups in changes in delta SIxAge over time.[36] A difference-in-differences analysis has the advantage of accounting for the effect of changes due to factors other than the intervention (e.g., temporal trends that affect both the control and intervention site). This analysis was performed using a multivariable mixed effects model with a random effect for provider to account for clustering of outcomes for patients cared for by the same provider. Due to lack of variability between providers, as suggested by an estimated random

intercept variance closer to zero, a regression model assuming independence within providers was used. To estimate the difference-in-differences, an interaction between study period and group (Intervention/Control) was of primary interest. Study period for trauma cases was classified as pre-implementation, 0-4 months post-implementation, 5-8 months post-implementation, or 9-13 months post-implementation. We divided the study period into intervals to study the change in intervention effect over time. All models also adjusted for the following predictors: Qualification of provider (BLS, ILS, ALS), patient sex, injury mechanism (blunt or penetrating), initial SIxAge, and pre-arrival minutes (time from injury to ambulance arrival). Subgroup analysis was conducted by provider qualification. All statistical analyses were conducted using SAS version 9.4 (SAS Institute Inc., Cary, N.C.).

Ethics

Ethics approval was provided by the University of Cape Town Human Research Ethics Committee (HREC# 077/2018), the primary oversight ethics board, with a single-IRB reliance agreement with the Colorado Multiple Institutional Review Board (Protocol # 18-0607), and concurrence from the U.S. Department of Defense Human Research Protection Office. A waiver of informed consent for patients was granted; written informed consent was obtained for participating EMS providers.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

RESULTS

Provider characteristics

198 of 240 (82.5%) eligible EMS providers provided informed consent and participated. Of the 198, 93 (47%) were at the intervention site and 105 (53%) were at the control site (Table 1). There was no provider crossover. Each provider delivered care to a median of 3 (interquartile range [IQR]: 1-4) traumatic shock patients during the study, and 150 (76%) of providers cared for fewer than 5 traumatic shock patients during the study. EMS providers in both cohorts had similar age, sex, and years of experience in the pre-implementation (baseline) period. The intervention group had a significantly lower proportion of BLS providers compared to the control group.

Table 1. Providers' demographics and characteristics.

Variable	Category	Overall (N=198)	Study Group		P-value
			Control (N=105)[a]	Intervention (N=93)[a]	
Provider Sex	Male	107 (54%)	60 (57%)	47 (51%)	0.35
	Female	91 (46%)	45 (43%)	46 (49%)	
Provider Qualification	BLS	83 (42%)	57 (54%)	26 (28%)	<0.001
	ILS	83 (42%)	36 (34%)	47 (51%)	
	ALS	32 (16%)	12 (11%)	20 (22%)	
Mean (SD) age in years		37.2 (7.3)	37.6 (7.9)	36.6 (6.5)	0.38
Median (IQR) years of experience		8.0 (5.0-11.0)	8.0 (5.0-12.0)	8.0 (5.0-11.0)	0.56[b]

[a] *Percentages may not add to 100% due to rounding*
[b] *Wilcoxon Test*

Implementation Outcomes

The overall implementation effectiveness was 80.6% and interpreted as 'excellent' (Table 2). The Reach (65%) and Implementation Fidelity (72%) domains were 'good', whereas the Effectiveness (87%) and Adoption (87%) domains were 'excellent'. Quantitative findings, along with the key explanatory qualitative themes, are presented below for each domain.

Reach

Reach was the poorest scoring (65%) domain (Table 2). The participation rate for eligible learners was 70%, with 30% non-participatory primarily due to workplace leave which limited their participation in training sessions but was unavoidable. Fully participating providers who were interviewed explained that the on-shift timing of the HEET trainings was highly favorable (compared to traditional EMS trainings which were inconveniently scheduled on their days off and resulted in poor participation). One learner explained that HEET is *"… accommodating to all staff, as some were not always able to attend the CME's on specific dates."* Additionally, providers mentioned that the short duration of sessions allowed the trainings to be feasibly incorporated into their work day without disrupting ambulance operations. Last, facilitators mentioned that support from the station managers and dispatch center was critical for protecting training time.

Table 2. Evaluation of Implementation Effectiveness using the RE-AIM Framework

Index	Quantitative Measure	Proportion	%	Qualitative Assessment (sample questions)	Summary of Key Qualitative Themes
Reach					
	Learners who participated/total eligible	93/113	69.9%	What factors helped learners participate in training sessions?	Timing during shifts. Operational team support. Short sessions.
	Patients receiving TruShoC bundle from EMS providers	115/195	59.0%	What prevented/enabled learners to deliver TruShoC to patients?	Bundled care allows easy recall. Approach is simple. BLS crews cannot place IVs.
		Mean (SD) =	**64.5% (7.7)**		
Effectiveness					
	Learners with improved knowledge in ≥1 core bundle area^	73/93	76.8%	What helped you improve your knowledge?	Using relevant cases. Discussion format. Peer led is non-intimidating.
	Learners with improved skills in ≥1 core bundle area^	77/93	82.8%	What helped you improve your skills?	Skills practice during each session. Using own ambulance equipment.
	Learners with improved self-efficacy in ≥1 core confidence area^	93/93	100.0%	What helped you improve your confidence?	Discussions. Better understanding. I know when to call for ALS assistance.
	Learners' composite evaluations of training sessions (mean)	4.49/5	89.8%	What did you like/dislike about this training program?	Need more time for Q&A. Was pressure to get back into service. A bit rushed.
		Mean (SD) =	**87.4% (10.0)**		
Adoption					
	Facilitators who participated/total eligible	18/20	90.0%	What organizational factors promoted your continued participation?	Managers and Dispatch Center support. HEET Team friendly. Learners eager.
	Facilitators who feel very positive about the program	9/9	100.0%	What are some reasons you feel positively about the program?	Learners improve knowledge, skills, attitudes. Promotes peer communication.
	Facilitators who want to maintain their teaching role in future	6/9	66.7%	Why do you want to remain in (or leave) your role as a facilitator?	Feels nice to teach. Content is relevant. Break from the 'usual'.
	Stakeholders who felt program should be part of EMS education	13/13	66.7%	Why should WCG EMS continue to use this program in the future?	Fills many EMS training needs. Time and cost-effective. Trauma is relevant.
	Facilitators' composite evaluation scores of training sessions (mean)	4.65/5	93.0%	What did you like/dislike about the training approach and your role?	Intimidating to initially teach. Then grew confident. I feel like a peer mentor.
	Learners' who recommend their colleagues participate in HEET	82/86	95.3%	Why would you recommend your colleagues participate as learners?	Effective to acquire new knowledge and skills. Fun. Promotes team dialogue.
	Station and shift managers had a good attitude towards the program	9/9	100.0%	What contributed (or hurt) your support of the program?	Improved communication/rapport. Gain knowledge/skills. HEET Team helped.
		Mean (SD) =	**87.3% (14.6)**		
Implementation Fidelity					
	Eligible providers participating in >=80% of trainings	72/98	73.5%	What factors allowed you to sustain participation in trainings?	Trainings at shift start. Facilitators organized us. In ambulance was convenient.

Training sessions with <=3 learners in a group	119/180	66.1%	What factors permitted small groups (2 learners) vs large groups?	Absences due to sickness or leave, and relatively few trainers, caused large groups.
Teaching quality of the facilitators scored by learners (mean)	4.3/5	86.0%	What factors made the training sessions effective or ineffective?	Facilitators are familiar peers. Spoke in terms we understood. Felt like a peer chat.
Learners correctly demonstrated the skills in sessions, scored by facilitators (mean)	4.47/5	89.4%	What factors helped you to gain proficiency in skills?	Facilitators demonstrated. Used ambulance equipment. Practiced in each session.
Training sessions that started >15-mins late	83/180	46.1%	What factors allowed you to start trainings on time (or not)?	Learners arrive late. Foot-dragging. Trainings conflicted with ambulance prep.
	Mean (SD) =	**72.2% (17.4)**		
Overall Mean Effectiveness (SD)		**80.6% (15.8)**		

^ *Compared pre-implementation to 13-months post-implementation*
EMS = Emergency Medical Services
HEET = High-Efficiency EMS Training
SD = Standard Deviation
WCG = Western Cape Government

Providers delivered all elements of bundle of care to only 59% of eligible patients, which contributed to the poor overall reach. When asked, providers explained that one of their major challenges was transport to the trauma center due to *"pushback from staff"* especially for patients who met shock criteria but appeared well. Additionally, EMS providers had variable access to tourniquets for external hemorrhage control. Last, providers did endorse performing many procedures but often failed to record them in the clinical forms, which consequently impeded the ability to measure delivery of bundled care. Conversely, providers who delivered the bundle explained that its simplicity enabled recall and delivery, as opposed to complicated algorithms and protocols. One paramedic noted, *"I could see massive difference in BLS/ILS patient management when they call for backup."*

Effectiveness

Effectiveness scored 'excellent' (87%) predominantly due to high improvements in pre- versus post-implementation assessments of knowledge, skills, and attitudes, and also due to learners' high ratings of the quality of training sessions (Table 2). Ninety-three intervention site providers completed pre- and post-training assessments and were included in the analysis. Learners and facilitators explained that HEET used EMS-relevant cases in a discussion-based format led by non-intimidating peers which facilitated knowledge transfer. A BLS learner stated that, *"I can ask the stupid questions and I know I won't be looked down to."* Additionally, the skills practice using providers' usual on-board equipment helped to facilitate good skills acquisition and retention. An ILS learner stated, *"Enjoyed that it was in the back of the ambulance where we also treat patients."* Learners' mentioned that their confidence was improved due to group discussion format, which helped identify deficiencies and allay any concerns, including when to call for ALS backup during challenging cases. A BLS learner noted, *"I felt empowered and like a paramedic…"* and that it was, *"Nice to have own ALS do training."*

Adoption

Adoption scored 'excellent' predominantly because all tiers of EMS stakeholders (facilitators, HEET Team, station managers, learners) appraised the HEET program and EMS-TruShoC content as excellent operational fit for the organization and helped to overcome barriers to traditional training, including low attendance rates and low efficacy training formats (Table 2). Facilitators

explained their personal satisfaction with the HEET program included: *"Interaction with peers", "learning how to present", "refresher of information", "safe environment to learn", "feels nice to teach", and "I gained confidence as a teacher."* Of note, 3 out of 9 facilitators were unsure about resuming their role in future trainings specifically because they were unsure if they would be provided additional paid time to prepare for training sessions. Shift and station managers felt positively about the program because they noted an improvement in team-wide communication and rapport, in addition to knowledge and skills acquisition. EMS leaders felt that although cost-effectiveness was not formally assessed, their observation was that HEET was incredibly cost-effective compared to their usual educational programs, and felt that it had a future role within the EMS organization, insofar as it was appropriately integrated.

Implementation Fidelity

Implementation Fidelity had a lower score of 'good' mainly because of logistic challenges associated with keeping the number of learners in small groups at three or less, and also due to delayed training start times (Table 2). The issue of >3 learners in a training session arose because when providers missed trainings (most often due to leave), they would jump into another crew's training session to *"catch up so we don't get left behind,"* even though make up training sessions were offered. The latter issue of delayed start times was attributable to providers having a sluggish start to their work day which was termed, *"heel-dragging,"* and had no specific cause attributed. Overall high participation rates (i.e., providers completing ≥80% of sessions) was facilitated by the organization and conduct of training sessions during official shift time, with the implicit understanding that their participation was a part of their duties, which was driven by the HEET Team. Last, the facilitators and learners explained that facilitators were well trained, prepared, and enthusiastic about the sessions, which translated to high quality delivery and fidelity of the HEET program.

Patient characteristics

A total of 770 patients, meeting inclusion criteria, received care from EMS provider participants in the intervention (329, 42.7%) and control (441, 57.3%) arm (Table 3). There were no significant differences in pre- or post-implementation patient demographic or physiologic characteristics in

the control versus intervention cohorts with respect to age, sex, blunt versus penetrating injury mechanism, SI, SIxAge, and ambulance on-scene time.

Table 3. Pre- and post-intervention demographic and physiologic characteristics of patients.

Pre-Implementation (n=355)					
Variable	**Category**	**Overall (N=355)**	**Control (N=202)**	**Intervention (N=153)**	**P-value**
Median (IQR) patient age in years		30 (25-37)	30 (25-39)	30 (28-36)	0.34^
Patient sex	Female	24% (84)	22% (44)	26% (40)	0.34
	Male	76% (271)	78% (158)	74% (113)	
Primary injury mechanism	Blunt	47% (166)	48% (96)	46% (70)	0.74
	Penetrating	53% (189)	52% (106)	54% (83)	
% (n) with scene time <10 minutes		16% (58)	19% (39)	12% (19)	0.08
% (n) with oxygen given or documentation why not		32% (115)	36% (72)	28% (43)	0.13
% (n) with large bore catheter placed when provider is qualified to do so (n=236)		39% (92)	46% (55)	32% (37)	0.03
% (n) with bleeding control method documented in cases where external bleeding is present (n=252)		64% (161)	63% (86)	65% (75)	0.82
% (n) with Trauma center is destination		32% (113)	26% (52)	40% (61)	0.005
Median (IQR) initial heart rate (BPM)		111 (102-118)	112 (104-118)	110 (98-119)	0.17^
Median (IQR) initial SBP (mm Hg)		112 (90-130)	114 (94-130)	110 (90-129)	0.12^
Median (IQR) Initial Shock Index x Age		29.1 (23.8-37.3)	29.3 (24.0-38.8)	28.8 (23.8-35.7)	0.23^
Shock stage defined by initial Shock Index x Age	Shock (>=36)	28% (101)	32% (64)	24% (37)	0.12
	Normal (<36)	72% (254)	68% (138)	76% (116)	
% (n) with deteriorating Shock Index x Age		31% (109)	33% (66)	28% (43)	0.36
% (n) in shock with deteriorating Shock Index x Age		15% (15)	14% (9)	16% (6)	0.77
Median (IQR) change in Shock Index x Age from initial to final		-1.4 (-5.7-0.4)	-1.2 (-4.9-0.4)	-1.9 (-6.9-0.4)	0.36^
Median (IQR) minutes from scene arrival to scene departure		23 (13-35)	24 (12-36)	22 (14-32)	0.93^
Post-Implementation (n=415)					

Variable	Category	Overall (N=415)	Control (N=239)	Intervention (N=176)	P-value
Median (IQR) patient age in years		30 (24-36)	30 (24-36)	30 (24-37)	0.42^
Patient sex	Female	21% (85)	22% (53)	18% (32)	0.35
	Male	79% (326)	78% (185)	82% (141)	
Primary injury mechanism	Blunt	46% (191)	46% (109)	47% (82)	0.84
	Penetrating	54% (224)	54% (130)	53% (94)	
% (n) with scene time <10 minutes		25% (104)	29% (69)	20% (35)	0.04
% (n) with oxygen given or documentation why not		36% (148)	40% (95)	30% (53)	0.04
% (n) with large bore catheter placed when provider is qualified to do so (n=275)		38% (104)	33% (41)	42% (63)	0.10
% (n) with bleeding control method documented in cases where external bleeding is present (n=263)		69% (182)	73% (102)	65% (80)	0.17
% (n) with Trauma center is destination		25% (105)	14% (34)	40% (71)	<.0001
Median (IQR) initial heart rate (BPM)		111 (104-119)	111 (106-120)	110 (99-119)	0.06^
Median (IQR) initial SBP (mm Hg)		114 (91-130)	115 (100-130)	110 (90-129)	0.10^
Median (IQR) Initial Shock Index x Age		28.9 (23.1-36.8)	28.7 (23.0-37.3)	28.9 (23.2-36.0)	0.92^
Shock stage defined by initial Shock Index x Age	Shock (>=36)	27% (110)	28% (66)	25% (44)	0.55
	Normal (<36)	73% (305)	72% (173)	75% (132)	
% (n) with deteriorating Shock Index x Age		37% (153)	35% (84)	39% (69)	0.40
% (n) in shock with deteriorating Shock Index x Age		17% (19)	15% (10)	20% (9)	0.47
Median (IQR) change in Shock Index x Age from initial to final		-0.9 (-4.2-1.3)	-0.9 (-3.2-0.9)	-1.1 (-5.8-1.9)	0.61^
Median (IQR) minutes from scene arrival to scene departure		18 (9-27)	17 (7-28)	19 (10-26)	0.25^

^ *Wilcoxon Test*

BPM = beats per minute

IQR = interquartile range

Mm Hg = millimeters of mercury

SBP = systolic blood pressure

Clinical Effectiveness

A total of 755 of 770 (98%) trauma patients were analyzed (Table 4). 15 (2%) patients were missing data needed to calculate a Shock Index, hence excluded from the analysis. In the 4 months post-implementation compared to pre-implementation period, the intervention arm patients had more improved SIxAge compared to control arm, but the difference between the two groups was not statistically significant (0.8 change in control arm, -0.6 change in intervention arm; -1.4 difference-in-differences, P=0.35) (Figure 1a and Table 4). Further, there was no significant difference in change over time between the groups for any of the other time intervals (5-8 months: difference-in-differences -0.5, P=0.79; 9-13 months: difference-in-differences 0, P=0.99). Last, there were no differences in changes in SIxAge by ranks of EMS providers (BLS, ILS, or ALS) (Figure 1b-1d).

Table 4a. Delta Shock Index x Age by time interval and study group, for entire analysed cohort (N=755)[a]

Time Interval	Control		Intervention		D-I-D (95% CI) (Intervention-Control)	P-value
	n	Estimated ΔSIxAge (95% CI)	n	Estimated ΔSIxAge (95% CI)		
Before – All	200	-2.0 (-3.1, -0.9)	151	-3.0 (-4.2, -1.7)		
Post - 0-4 months	73	-1.2 (-3.0, 0.6)	69	-3.6 (-5.4, -1.7)	-1.4 (-4.4, 1.5)	0.35
Post - 5-8 months	62	-1.0 (-2.9, 0.9)	39	-2.5 (-4.9, -0.0)	-0.5 (-3.9, 3.0)	0.79
Post - 9-13 months	98	-1.3 (-2.8, 0.2)	63	-2.2 (-4.2, -0.3)	0.0 (-2.9, 2.9)	0.99

Table 4b. Delta Shock Index x age by time interval and study group, for sub-group of patients in shock i.e., Shock Index x Age >= 36 (N=206).

Time Interval	Control		Intervention		D-I-D (95% CI) (Intervention-Control)	P-value
	n	Estimated ΔSIxAge (95% CI)	n	Estimated ΔSIxAge (95% CI)		
Before – All	64	-5.8 (-8.7, -2.9)	35	-6.8 (-10.6, -3.0)		
Post - 0-4 months	22	-3.8 (-8.4, 0.9)	19	-12.4 (-17.6, -7.3)	-7.7 (-15.8, 0.3)	0.06
Post - 5-8 months	17	-3.2 (-8.7, 2.3)	10	-9.7 (-16.7, -2.8)	-5.5 (-15.1, 4.1)	0.26
Post - 9-13 months	26	-4.9 (-9.2, -0.6)	13	-4.9 (-10.9, 1.2)	1.0 (-7.5, 9.4)	0.82

ΔSIxAge = Change in Shock Index x Age. A more negative delta SI represents more improved shock.
D-I-D = Difference in Differences computed as (Change in ΔSIxAge in intervention group) – (Change in ΔSIxAge in control group)
[a]15 cases from the original sample of N=770 were excluded from this analysis due to missing data.

Discussion

We successfully implemented EMS-TruShoC (simplified bundled care) in a pragmatic fashion using the HEET training approach. The overall implementation effectiveness was excellent (81%). The bundled care intervention did not significantly improve patient's change in SIxAge when compared to usual (non-bundled) care.

Our novel training program, HEET, achieved excellent implementation effectiveness overall. HEET was successful for effective on-the-job trauma re-training of providers in this resource-limited EMS system. We found similar findings in our prior single-site feasibility study.[12] There were several major factors contributing to the high implementation effectiveness, which were evidenced by the quantitative data and supported by the qualitative findings. First, short-burst (15 to 20-minute) trainings scheduled and protected at the beginning of shift time proved to be a strong operational fit for this EMS system. Second, the program was purposefully designed to be engaging for professional adult learners by using contextually relevant cases which were presented in a non-intimidating, structured discussion forum. Third, we used and simplified bundle of care, and skills practice, to help *"drill"* the core components of the bundle of care to help promote recall and translation from the 'class' to practice. Last, we intentionally used motivated peer paramedics as facilitators, instead of the traditional EMS educators – this approach helped to reduce learner anxiety and promoted more open communication and eagerness to learn. Consequently, we measured meaningfully improved educational outcomes attributable to the EMS-TruShoC training intervention.

While fidelity of the implementation overall was excellent, there were modest challenges in delivering the intervention to small groups of participants at the beginning of their shifts. The HEET Team felt that this was due to a combination of unavoidable logistic challenges which ultimately did not negatively impact delivery of the intervention. A critical factor underpinning the overall implementation success was advanced engagement and planning between the research team and the HEET Team. The HEET Team was comprised of a motivated multi-disciplinary group of EMS educators and quality assurance personnel who worked alongside the researchers to design, implement, and evaluate the program with a deliberate goal of pragmatic implementation, strong organizational tailoring, and sustainability.

Our clinical intervention of bundled care (EMS-TruShoC) did not measurably improve patients' shock physiology, measured by SIxAge, for several possible reasons. First, it is likely that three items in our core shock bundle (large IV catheter, scene time <10 minutes, and trauma center transport destination) may cause no direct change to heart rate nor systolic blood pressure. Second, it is possible that although the SIxAge performs better than traditional vital signs, it may have inadequate sensitivity and specificity to detect prehospital changes in physiology. A sentinel study by Zarzaur *et al.* demonstrated that SIxAge was a superior predictor of 48-hour mortality compared to systolic blood pressure, heart rate, or Shock Index.[32] In 2012, Bruijns and colleagues validated these findings in the United Kingdom's national trauma registry in which SIxAge achieved the highest area under the receiver operator curve (AUROC) of 0.79 for predicting 48-hour mortality compared to Shock Index and other age-based markers.[29] However, the SIxAge thresholds varied across these studies from ≥35.6 to ≥55. We used a threshold of ≥36, which was based upon Zarzaur's original study and is more appropriate for a younger trauma population.[33] However, further studies to establish a prehospital cutoff point would be useful, especially if conducted within a South African trauma population. Additionally, other hospital-based outcome measures, such as blood lactate, the need for blood transfusions, or 24-hour mortality, could potentially detect a change where SIxAge did not – these are possible avenues for future research. However, the advantage of using a Shock Index-based physiologic measure is it facilitates prehospital research by avoiding costly and logistically complicated in-hospital clinical data collection.

Our overall research design and approach (i.e., a hybrid type II quasi-experimental trial) and the research context (i.e., a South African prehospital system) are also noteworthy. Hybrid trials assess the implementation outcomes in tandem with the clinical effectiveness outcomes.[20] The rationale for conducting both in parallel is to test the intervention and implementation in a real-world context which improve the ability of findings to more rapidly translate into clinical practice settings.[20 27] Prior data suggests that it takes, on average, 17 years for 14% of biomedical research to translate from research into clinical practice which stifles advancements in clinical care worldwide.[39] Implementation science methodologies – such as the pragmatic hybrid trial design used in this study – are innovative and feasible approaches to narrowing this 'know-do' gap. The need for real-world data is arguably even more critical in lower-income settings which face the challenging

paradox of having extremely high burdens of injury yet have a shortage of biomedical research. Prehospital care is a neglected area of research, according to the World Health Organization and leading experts, necessitating more research to help improve care delivery and patient outcomes. In time-sensitive emergencies, such as traumatic shock, bringing basic yet essential treatment to the patient, at the scene of the event, is a cost-effective public health intervention to improve post-injury morbidity and mortality [40 41] – yet, where prehospital systems exist, there is a paucity of research, due to poor awareness or the technical challenges. This body of work directly addresses these practice and scientific evidence gaps.

Limitations

There are several limitations to this work aside from those of the SIxAge described earlier. Despite our best efforts to select similar sites, the intervention site had a significantly lower proportion of BLS providers compared to the control site which may have influenced our implementation outcomes. Educational assessments were designed to be quick and easy for the HEET Team assessors to administer, hence may have had limited sensitivity to detect changes in educational outcomes among the EMS participants, so may have under-estimated the true effect size. Additionally, the HEET Team assessors could not be practically blinded to whether an EMS participant received the intervention or not, which may have introduced bias in their assessments.

Conclusions

In this hybrid type II quasi-experimental trial of EMS-TruShoC (bundled care) using the novel HEET training approach, we found overall excellent implementation effectiveness but no overall statistically significant clinical effectiveness. HEET is an effective prehospital implementation strategy in a resource-constrained EMS setting, primarily explained by strong fit to the organization's operational needs and the adult-learner friendly approach to on-the-job training. Further clinical effectiveness studies are warranted to assess whether EMS-TruShoC confers a prehospital physiologic benefit for critically injured patients.

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All authors made substantive contributions to the work (i.e., the design or the acquisition, analysis, or interpretation), contributed to drafting or substantive revisions, approved the publishable version, and agree to be accountable for the accuracy and integrity of the work.

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License Statement:

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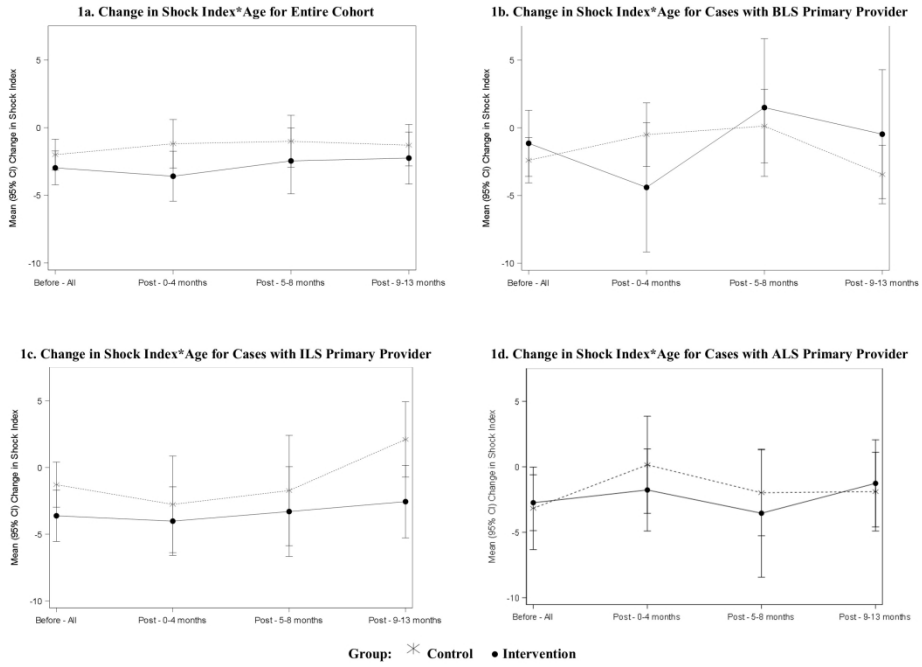
Figure 1. Mean change in shock from EMS arrival at the scene of injury to hospital arrival by whole cohort (1a), and for cases with BLS (1b), ILS (1c), and ALS (1d) providers. *The more negative the change in SIxAge value is, the more improved the shock. BLS = Basic Life Support. ILS = Intermediate Life Support. ALS = Advanced Life Support.*



279x215mm (300 x 300 DPI)

'EMS-TruShoC'

A Bundle of EMS Traumatic Shock Care

TRAUMA SHOCK RECOGNITION

In adult injury w/ high risk mechanism

RIGHT PATIENT?
High risk mechanism of injury
and
Age ≥16 years.

Yes

1 or more abnormal vitals screen for shock

VITAL SIGNS?
Pulse rate >100-bpm,
and/or
Systolic BP <100-mmHg,
and/or
Capillary refill time >2-secs,
and/or
Non-palpable radial pulse.

Yes

1 or more symptoms for decompensated shock.

CLINICAL PICTURE?
Active or suspected bleeding
and/or
Altered Mentation
and/or
Skin Color Change
and/or
Sweating/diaphoresis.

Mechanism of injury placing patient at high risk for shock:

- **PENETRATING:**
  Gunshot wound (head, neck, torso, groin, proximal extremity)
- **BLUNT:**
  Fall from height (>6m)
  Motor vehicle collision (high speed, ejection)
  Motor cycle crash
  Pedestrian struck by vehicle
  Assault (with high energy transfer)
- **AMPUTATION:**
  Of limbs (except fingers, toes)
- **ACTIVE BLEEDING:**
  Uncontrollable external bleeding
  Obvious/suspected internal hemorrhage

TRAUMA SHOCK MANAGEMENT

CORE BUNDLE OF CARE

1. On-scene time is ≤ 10-minutes
2. Destination is trauma center
3. Large bore IV (≥18G) catheter placed
4. Oxygen is administered (appropriate route)
5. External bleeding is controlled (per protocol)

*All 5 performed on 100% of shock trauma cases.

NON-CORE BUNDLE OF CARE

Circulation:
- Control hemorrhage
- Intravenous fluids

Airway:
- Open, Suction, & Secure

Breathing:
- Oxygenate & Ventilate

Disability:
- Prevent further neurologic injury

Continuous assessment
- Repeat: primary & secondary surveys
- Repeat vital signs (at least 2 sets)

↑ Perform C-A-B-D on 100% of cases ↑

Special considerations if shock and the ff:
- Uncontrolled arterial bleed = tourniquet
- Blunt pelvic injury = pelvic binding
- Tension PTX = needle decompression
- Loss of motor/sensory = cervical collar
- Cardiac arrest = consider CPR / ACLS
- Obvious pregnancy = left lateral decubitus

↑ Perform only when clinically indicated ↑

Checklist of items for reporting pragmatic trials

Section	Item	Standard CONSORT description	Extension for pragmatic trials	Manuscript page # that addresses the item
Title and abstract	1	How participants were allocated to interventions (eg, “random allocation,” “randomised,” or “randomly assigned”)		1, 2
Introduction				
Background	2	Scientific background and explanation of rationale	Describe the health or health service problem that the intervention is intended to address and other interventions that may commonly be aimed at this problem	4-5
Methods				
Participants	3	Eligibility criteria for participants; settings and locations where the data were collected	Eligibility criteria should be explicitly framed to show the degree to which they include typical participants and/or, where applicable, typical providers (eg, nurses), institutions (eg, hospitals), communities (or localities eg, towns) and settings of care (eg, different healthcare financing systems)	5-6
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered	Describe extra resources added to (or resources removed from) usual settings in order to implement intervention. Indicate if efforts were made to standardise the intervention or if the intervention and its delivery were allowed to vary between participants, practitioners, or study sites	6-7
			Describe the comparator in similar detail to the intervention	
Objectives	5	Specific objectives and hypotheses		4-5
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (eg, multiple observations, training of assessors)	Explain why the chosen outcomes and, when relevant, the length of follow-up are considered important to those who will use the results of the trial	7-8
Sample size	7	How sample size was determined; explanation of any interim analyses and stopping rules when applicable	If calculated using the smallest difference considered important by the target decision maker audience (the minimally important difference) then report where this difference was obtained	9-10
Randomisation—sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (eg, blocking, stratification)		N/A
Randomisation—allocation concealment	9	Method used to implement the random allocation sequence (eg, numbered containers or central telephone), clarifying whether the		N/A

Section	Item	Standard CONSORT description	Extension for pragmatic trials	Manuscript page # that addresses the item
		sequence was concealed until interventions were assigned		
Randomisation—implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups		8-9
Blinding (masking)	11	Whether participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment	If blinding was not done, or was not possible, explain why	N/A (explained on pg 24)
Statistical methods	12	Statistical methods used to compare groups for primary outcomes; methods for additional analyses, such as subgroup analyses and adjusted analyses		23
Results				
Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended)—specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analysed for the primary outcome; describe deviations from planned study protocol, together with reasons	The number of participants or units approached to take part in the trial, the number which were eligible, and reasons for non-participation should be reported	11 (providers) 16-20 (patients)
Recruitment	14	Dates defining the periods of recruitment and follow-up		7,8 (providers) 9,10 (patients)
Baseline data	15	Baseline demographic and clinical characteristics of each group		11,12 (providers) 16-17 (patients)
Numbers analysed	16	Number of participants (denominator) in each group included in each analysis and whether analysis was by "intention-to-treat"; state the results in absolute numbers when feasible (eg, 10/20, not 50%)		11-14 (providers) 18-20 (patients)
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision (eg, 95% CI)		12-14 (implementation) 16-20 (clinical effect)
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating which are prespecified and which are exploratory		20 (clinical effect)
Adverse events	19	All important adverse events or side effects in each intervention group		N/A
Discussion				

Section	Item	Standard CONSORT description	Extension for pragmatic trials	Manuscript page # that addresses the item
Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes		21-22
Generalisability	21	Generalisability (external validity) of the trial findings	Describe key aspects of the setting which determined the trial results. Discuss possible differences in other settings where clinical traditions, health service organisation, staffing, or resources may vary from those of the trial	22-23
Overall evidence	22	General interpretation of the results in the context of current evidence		21-24

Cite as: *Zwarenstein M, Treweek S, Gagnier JJ, Altman DG, Tunis S, Haynes B, Oxman AD, Moher D for the CONSORT and Pragmatic Trials in Healthcare (Practihc) group. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. BMJ 2008; 337;a2390.*

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Improving Prehospital Traumatic Shock Care – Implementation and Clinical Effectiveness of a Pragmatic, Quasi-Experimental Trial in a Resource-Constrained South African Setting

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Improving Prehospital Traumatic Shock Care – Implementation and Clinical Effectiveness of a Pragmatic, Quasi-Experimental Trial in a Resource-Constrained South African Setting.

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ABSTRACT

Objectives

This project seeks to improve providers' practices and patient outcomes from prehospital (i.e. ambulance-based) trauma care in a middle income country using a novel implementation strategy to introduce a bundled clinical intervention.

Design

We conduct a two-arm, controlled, mixed-methods, hybrid type-II study.

Setting

This study was conducted in the Western Cape Government Emergency Medical Services (EMS) system of South Africa.

Interventions

We pragmatically implemented a simplified prehospital bundle of trauma care (with 5 core elements) using a novel workplace-based, peer-to-peer, rapid training format. We assigned the intervention and control sites.

Outcome Measures

We assessed implementation effectiveness among EMS providers and stakeholders, using the RE-AIM framework. Clinical effectiveness was assessed at the patient level, using changes in Shock Index x Age (SIxAge). Indices and cutoffs were established *a-priori.* We performed a difference-in-differences (D-I-D) analysis with a multivariable mixed effects model.

Results

198 of 240 (82.5%) EMS providers participated, 93 (47%) intervention and 105 (53%) control, with similar baseline characteristics. The overall implementation effectiveness was excellent (80.6%): Reach was good (65%), Effectiveness was excellent (87%), Implementation Fidelity was good (72%), and Adoption was excellent (87%). Participants and stakeholders generally reported very high satisfaction with the implementation strategy citing that it was a strong operational fit and effective educational model for their organization. A total of 770 patients were included: 329 (42.7%) intervention and 441 (57.3%) controls, with no baseline differences. Intervention arm patients had more improved SIxAge compared to control at 4 months, which was not statistically significant (-1.4 D-I-D; P=0.35). There was no significant difference in change of SIxAge over time between the groups for any of the other time intervals (P=0.99).

Conclusions

In this quasi-experimental trial of bundled care using the novel workplace rapid training approach, we found overall excellent implementation effectiveness but no overall statistically significant clinical effectiveness.

KEY WORDS:

Accident and Emergency Medicine; Trauma Management; International Health Services.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- We used a hybrid type II implementation science design to jointly assess implementation outcomes and clinical effectiveness which accelerates translation of knowledge into practice.
- Our pragmatic research approach promoted organizational embeddedness and the inclusion of 'usual' patients, both of which enhance the 'real-world' relevance of our findings.
- We used an educational approach to introduce a simplified bundle of care, and we uniquely assessed a full-spectrum of outcomes at the educational, implementation, and patient levels.
- Our patient-level outcome – change of Shock Index x Age – while a practical measure, may have had limited sensitivity to detect a meaningful change in prehospital shock in a convenience sample of trauma patients.

BACKGROUND

Injured persons in low- and middle-income countries (LMICs) experience a disproportionately large burden of global post-injury death and disability, in large part because of inadequate trauma care.[1-4] New care delivery strategies tailored for limited resource settings are therefore needed, especially considering that the global burden of trauma is rising.[3]

Improving the quality of prehospital (i.e. ambulance-based) care in LMICs is one such strategy. High quality prehospital care could avert 54% of all mortality from emergency conditions, including trauma.[5] While the efficacy of individual interventions, such as on-scene hemorrhage control and maintaining short scene times have been demonstrated, strategies to implement a package of these interventions in LMIC prehospital settings remain underdeveloped.[6-8] Less than 2% of Emergency Medicine guidelines are developed for LMICs.[9] [10] Understanding how best to implement prehospital trauma care in LMICs is a critical gap in the literature.[11]

To address this scientific gap, we previously created and pilot tested a simplified bundle of prehospital trauma care termed, Emergency Medical Services Traumatic Shock Care (EMS-TruShoC). EMS-TruShoC is both evidence-based and expert-ratified, and it is tailored for resource-limited settings.[12-14] The EMS-TruShoC bundle is designed to support EMS providers in identifying and managing traumatic shock, a major cause of preventable death after trauma, which requires immediate resuscitation to reduce morbidity and mortality.[15] EMS-TruShoC was designed and packaged to promote rapid clinical uptake and sustained use by prehospital providers. In a 2017 single-site pilot and feasibility study, we implemented EMS-TruShoC using a novel educational strategy developed for the Western Cape Government EMS system termed, High-Efficiency EMS Training (HEET).[12] HEET – the implementation strategy – is a low-dose, high-frequency, training and sensitization program, based on contemporary principles in adult-learning. In the pilot study, we demonstrated that it was feasible to implement EMS-TruShoC via the HEET educational platform at a single site.[12]

The purpose of this study is to gain more robust implementation and clinical effectiveness data by using a larger participant sample size and by introducing a comparator arm of both providers and patients. The specific objective is to conduct a two-group controlled trial to assess the

implementation effectiveness and clinical effectiveness resulting from a pragmatic implementation of EMS-TruShoC using HEET in a resource-constrained EMS system of the Western Cape of South Africa.

METHODS

Design

The study was designed as a pragmatic, hybrid type II, quasi-experimental trial to assess the implementation of EMS-TruShoC bundled care using the HEET strategy compared to traditional (classroom-based) training of equivalent content. Implementation and clinical effectiveness outcomes were assessed using a sequential explanatory, mixed-methods approach.[16 17] A mixed-methods evaluation allowed collecting experiences and perspectives that were important to better understand and explain the quantitative findings.[17] The sequential approach allowed the qualitative data to help explain quantitative trends identified.[16] The RE-AIM framework, a well-reported implementation science planning and evaluation framework, guided the project implementation and evaluation of outcomes.[18 19] RE-AIM consists of five core domains – reach, effectiveness, adoption, implementation fidelity, and maintenance – and is intended to comprehensively evaluate pragmatic interventions. A hybrid type II design allowed equal emphasis to be placed on assessing implementation outcomes as well as clinical effectiveness.[20] A quasi-experimental approach was used because it was not possible to randomize the intervention at the level of the provider because of concerns about crossover, and there were not enough sites available to randomize at the level of the site. Ambulance base matching was based on the number of EMS providers, ambulance fleet size, the annual trauma patient volume, and jurisdictional population-type (i.e., dense-urban) at each base. Clinical effectiveness was assessed in a convenience sample of adult trauma patients treated by EMS at both study sites.

Setting

The 2017 pilot study was conducted in the Western Cape of South Africa, a middle-income country with high income inequality, twice the global mortality rate from injury and loss of 1-million disability adjusted life years (DALYs) per annum.[2 21] The Western Cape, approximately 130,000-Km^2 with approximately 7-million people in 2019, has over 1-million persons estimated to live in

dense, informal settlements, where interpersonal violence, and road traffic collisions are major contributors to the trauma burden.[22 23]

Organization and Participants

The organizational setting was a government-operated EMS system – WCG Department of Health EMS.[24 25] WCG EMS had previously established trauma a high-priority focal condition for improvement efforts. Study-eligible providers were approximately 120 clinically-active EMS providers at each of the intervention and control ambulance bases with national qualifications of basic-, intermediate-, and advanced-life support (BLS, ILS, and ALS, respectively). At the time of this study, foundational education for WCG EMS providers from across the Western Cape Province included a 6-week certificate courses for BLS, a 12-week course for ILS, and a 4-year (degree-earning) training for ALS providers [26].

Inclusion and Exclusion Criteria

EMS providers eligible for participation were duty rostered at either the intervention or control site during the implementation period – no additional selection criteria were imposed to keep the approach pragmatic and to increase the external validity of the results.[27] New hires and temporary EMS staff who joined either site after the start date of implementation were excluded. Patients eligible for inclusion were ≥18 years of age, with a traumatic injury, had a minimum of two sets of vital signs (including first and last heart rate and systolic blood pressure) who received care from an EMS provider at either the intervention or control site. Patients were excluded if they were prisoners, pregnant, or had injuries classified as burns, hangings, drownings, or electrocutions.

Study Sites

The Khayelitsha and Mitchells Plain WCG EMS bases were identified as suitable research sites, and although either site was suitable to host the implementation activities, Khayelitsha was selected as the intervention site because it was more immediately administratively available. Each base had similar numbers and tiers of providers, trauma populations and caseloads, ambulance response times, and the same tertiary care trauma center. The intervention site (Khayelitsha) received the educational intervention from September to November, 2018. There were no

implementation activities at the control site (Mitchells Plain) except usual classroom-based trauma training with similar learning objectives as EMS-TruShoC.

Grouping

All actively rostered EMS providers at the implementation site ambulance base (Khayelitsha) were eligible to receive the intervention, hence eligible for inclusion in the intervention group after informed consent. All actively rostered EMS providers at the control site ambulance base (Mitchells Plain) were ineligible for the intervention (i.e., received traditional training), so were eligible for inclusion in the control group after informed consent.

Intervention

The intervention was EMS-TruShoC bundled care which was designed to promote both the recognition and early management of traumatic shock.[12 14] Components of the EMS-TruShoC bundle were not new interventions or novel concepts to Western Cape EMS providers; they were simply presented in a repackaged (bundled) format to improve recall and clinical application. Management of shock included five core (priority) interventions designed to be delivered in all cases of traumatic shock, and several non-core (optional) clinical interventions relevant to special circumstances (e.g., cervical spinal cord injury) (Supplementary Material 1). The five items, each evidence-based, that comprised the bundle include: (1) scene times <10 minutes, (2) early hemorrhage control, (3) insertion of a large bore intravenous catheter, (4) oxygen delivery, and (5) direct transport to a trauma center.[12]

Implementation Strategy

EMS-TruShoC was implemented among EMS providers using the HEET program. HEET was designed as a low-dose (15 to 20-minute), high-frequency (once biweekly) training program built on principles of professional adult learning.[12 14] Training was delivered by self-nominated trained paramedics peers, called "facilitators" instead of usual training officers. Each EMS provider participating in the study (the "learners") at the intervention site received one training module every other week, for a total of 5-modules. Each module was structured around a clinical case scenario and incorporated knowledge acquisition, self-efficacy conditioning, and skills practice. Key learning objectives were emphasized using a facilitated discussion approach.

Measures

Implementation Outcomes: The RE-AIM framework was used to plan the implementation and to evaluate outcomes.[18 19 28] Quantitative and qualitative data were collected for 4 of the 5 RE-AIM dimensions, defined as follows:

- Reach is the extent to which the intervention reached the EMS providers and traumatic shock patients (example index: proportion of EMS providers participating in trainings);
- Effectiveness is the educational performance of the EMS providers who received the educational intervention (example index: proportion of learners with improved educational assessments);
- Adoption is the prospect of the program becoming institutionalized within the organization (example index: proportion of stakeholders who deem the program fit for their organization as-is); and
- Implementation fidelity is how well the program was actually executed compared to the originally intended implementation (example index: proportion of training sessions conducted within the allotted time).
- Maintenance is defined as the existence of an institutionalized program beyond 6 months.

Each RE-AIM dimension contained several indices. Maintenance, was non-applicable to this study, because trainings lasted 10 weeks and were deliberately intended to expire upon the conclusion of the study.

Clinical effectiveness outcomes: This was assessed by patient's physiologic responses to on-board ambulance care. Two relevant measures were considered: the Shock Index (SI), which is calculated by dividing the heart rate by systolic blood pressure, and the SI times the age of the patient (SIxAge). Both SI and SIxAge have been used to identify patients in traumatic shock, perform comparably, and are better than traditional vital signs in predicting trauma outcomes.[29-33] We previously published findings of our primary outcome using changes in patient's Shock Index which demonstrated no significant difference between the intervention and control groups.[34] In this paper, we conduct a pre-planned secondary analysis using the SIxAge outcome in the intervention group compared to the control group. A SIxAge ≥36 is the cutoff point for shock in younger trauma populations characteristic of the Western Cape.[12 32 33 35] The delta SIxAge is the

change of SIxAge calculated by the difference of SIxAge at (or close to) facility arrival minus the SIxAge at the scene of injury. In this study, a negative delta SIxAge (defined as SIxAge at facility arrival minus SIxAge at the scene) represents improved shock upon facility arrival. The target effect of the study is the difference in delta SIxAge between the intervention and control groups from pre- to post-implementation (i.e., difference-in-differences).[36] A more negative difference-in-differences, or improving SIxAge, indicates that the intervention is performing better than the control.

Data collection

Providers' demographics: All EMS provider participants provided their age, sex, current rank, years of experience, and EMS base after informed consent. Each participant was assigned a unique study identifying number used for tracking participation in training and collecting feedback. Providers who crossed over between intervention and control sites were tracked.

Implementation Processes: At the implementation site (Khayelitsha), implementation data was collected from training session participation and evaluation forms, post-program exit surveys, and post-program exit interviews. All implementation data were organized according to the RE-AIM framework domains and indices.

In particular, educational assessment data were used to evaluate the effectiveness domain of RE-AIM and were collected during assessments performed by the HEET Team. The HEET Team conducted all educational assessments, pre- and 13-months post-training. Each learner was assessed in three distinct areas: knowledge (maximum 13-points), skills (maximum 10-points), and self-efficacy (maximum 9-points). Assessors provided hand-written scored assessment sheets to a research assistant. All data was collected and tracked by the HEET Team on paper forms that were entered into a Microsoft Excel (Redmond, WA) tracking sheet by a research assistant. Interviews were conducted by two trained research assistants, who conducted exit interviews of a 20% random sample of learners and all facilitators and relevant stakeholders such as shift managers, station managers, and HEET Team members.

Clinical Effectiveness Outcomes: Clinical data was collected by reviewing and abstracting EMS medical records from trauma patients at both study sites. Pre- and post-implementation data were collected for the 13 consecutive months preceding (i.e., August, 2017 to August, 2018) and following (i.e., January, 2019 to January, 2020) implementation, respectively. We used a previously validated, standardized chart review and abstraction methodology.[37] The primary treating provider (documented in the EMS patient care report form) was given attribution for the care consistent with EMS field care. Data collected for each patient included demographics (age, sex), mechanism of injury, vital signs, time from scene to hospital, and prehospital interventions. We also collected ambulance base and treating provider name to attribute the case to the intervention or control site. Clinical data were entered directly into a Research and Electronic Data Capture (REDCap) online research database.[38]

Analysis

Demographics: Baseline comparisons between EMS provider and patient characteristics in both groups, pre- and post-implementation, were performed using Wilcoxon, chi-squared, and two-tailed t-tests, based on the type and distribution of the variable.

Implementation Outcomes: Within each of the 4 RE-AIM domains, data for each index was calculated as a percentage. Indices were averaged to generate a mean effectiveness score for each domain. The overall implementation effectiveness score was calculated as the average of the mean effectiveness score for all domains. Cutoffs for implementation effectiveness were defined *a-priori* via consensus among the investigators, and defined similarly to the 2017 pilot study as: 80–100% is excellent; 60–79.9% is good; 40–59.9% is fair; and, <40% is poor.[12]

Qualitative data, designed to help explain any quantitative trends, were converged with the quantitative data.[16] Two experienced research assistants, who conducted the interviews, coded all interview notes. Interview notes were reviewed to identify emerging themes using a consensus discussion between the lead author and the two research assistants. Themes were summarized (with supporting quotes) and arranged according to the 4 RE-AIM domains assessed in this study. The researchers adopted a post-positivist stance in the qualitative analysis (i.e., the quantitative

data were believed to be real, but it was acknowledge that environmental, social, and individual differences influenced the quantitative reality).

Clinical Outcomes (adjusted analyses): The primary analysis was an adjusted difference-in-differences analysis to examine the difference between the control and intervention groups in changes in delta SIxAge over time.[36] A difference-in-differences analysis has the advantage of accounting for the effect of changes due to factors other than the intervention (e.g., temporal trends that affect both the control and intervention site). This analysis was performed using a multivariable mixed effects model with a random effect for provider to account for clustering of outcomes for patients cared for by the same provider. Due to lack of variability between providers, as suggested by an estimated random intercept variance closer to zero, a regression model assuming independence within providers was used. To estimate the difference-in-differences, an interaction between study period and group (Intervention/Control) was of primary interest. Study period for trauma cases was classified as pre-implementation, 0-4 months post-implementation, 5-8 months post-implementation, or 9-13 months post-implementation. We divided the study period into intervals to study the change in intervention effect over time. All models also adjusted for the following predictors: Qualification of provider (BLS, ILS, ALS), patient sex, injury mechanism (blunt or penetrating), initial SIxAge, and pre-arrival minutes (time from injury to ambulance arrival). Subgroup analysis was conducted by provider qualification. All statistical analyses were conducted using SAS version 9.4 (SAS Institute Inc., Cary, N.C.).

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

RESULTS

Provider characteristics

198 of 240 (82.5%) eligible EMS providers provided informed consent and participated. Of the 198, 93 (47%) were at the intervention site and 105 (53%) were at the control site (Table 1). There was no provider crossover. Each provider delivered care to a median of 3 (interquartile range

[IQR]: 1-4) traumatic shock patients during the study, and 150 (76%) of providers cared for fewer than 5 traumatic shock patients during the study. EMS providers in both cohorts had similar age, sex, and years of experience in the pre-implementation (baseline) period. The intervention group had a significantly lower proportion of BLS providers compared to the control group.

Table 1. Providers' demographics and characteristics.

Variable	Category	Overall (N=198)	Study Group		P-value
			Control (N=105)[a]	Intervention (N=93)[a]	
Provider Sex	Male	107 (54%)	60 (57%)	47 (51%)	0.35
	Female	91 (46%)	45 (43%)	46 (49%)	
Provider Qualification	BLS	83 (42%)	57 (54%)	26 (28%)	<0.001
	ILS	83 (42%)	36 (34%)	47 (51%)	
	ALS	32 (16%)	12 (11%)	20 (22%)	
Mean (SD) age in years		37.2 (7.3)	37.6 (7.9)	36.6 (6.5)	0.38
Median (IQR) years of experience		8.0 (5.0-11.0)	8.0 (5.0-12.0)	8.0 (5.0-11.0)	0.56[b]

[a] *Percentages may not add to 100% due to rounding*
[b] *Wilcoxon Test*

Implementation Outcomes

The overall implementation effectiveness was 80.6% and interpreted as 'excellent' (Table 2). The Reach (65%) and Implementation Fidelity (72%) domains were 'good', whereas the Effectiveness (87%) and Adoption (87%) domains were 'excellent'. Quantitative findings, along with the key explanatory qualitative themes, are presented below for each domain.

Reach

Reach was the poorest scoring (65%) domain (Table 2). The participation rate for eligible learners was 70%, with 30% non-participatory primarily due to workplace leave which limited their participation in training sessions but was unavoidable. Fully participating providers who were interviewed explained that the on-shift timing of the HEET trainings was highly favorable (compared to traditional EMS trainings which were inconveniently scheduled on their days off and resulted in poor participation). One learner explained that HEET is *"… accommodating to all staff, as some were not always able to attend the CME's on specific dates."* Additionally, providers mentioned that the short duration of sessions allowed the trainings to be feasibly incorporated into their work day without disrupting ambulance operations. Last, facilitators mentioned that support from the station managers and dispatch center was critical for protecting training time.

Table 2. Evaluation of Implementation Effectiveness using the RE-AIM Framework

Index	Quantitative Measure	Proportion	%	Qualitative Assessment (sample questions)	Summary of Key Qualitative Themes
Reach					
	Learners who participated/total eligible	93/113	69.9%	What factors helped learners participate in training sessions?	Timing during shifts. Operational team support. Short sessions.
	Patients receiving TruShoC bundle from EMS providers	115/195	59.0%	What prevented/enabled learners to deliver TruShoC to patients?	Bundled care allows easy recall. Approach is simple. BLS crews cannot place IVs.
		Mean (SD) =	**64.5% (7.7)**		
Effectiveness					
	Learners with improved knowledge in ≥1 core bundle area^	73/93	76.8%	What helped you improve your knowledge?	Using relevant cases. Discussion format. Peer led is non-intimidating.
	Learners with improved skills in ≥1 core bundle area^	77/93	82.8%	What helped you improve your skills?	Skills practice during each session. Using own ambulance equipment.
	Learners with improved self-efficacy in ≥1 core confidence area^	93/93	100.0%	What helped you improve your confidence?	Discussions. Better understanding. I know when to call for ALS assistance.
	Learners' composite evaluations of training sessions (mean)	4.49/5	89.8%	What did you like/dislike about this training program?	Need more time for Q&A. Was pressure to get back into service. A bit rushed.
		Mean (SD) =	**87.4% (10.0)**		
Adoption					
	Facilitators who participated/total eligible	18/20	90.0%	What organizational factors promoted your continued participation?	Managers and Dispatch Center support. HEET Team friendly. Learners eager.
	Facilitators who feel very positive about the program	9/9	100.0%	What are some reasons you feel positively about the program?	Learners improve knowledge, skills, attitudes. Promotes peer communication.
	Facilitators who want to maintain their teaching role in future	6/9	66.7%	Why do you want to remain in (or leave) your role as a facilitator?	Feels nice to teach. Content is relevant. Break from the 'usual'.
	Stakeholders who felt program should be part of EMS education	13/13	66.7%	Why should WCG EMS continue to use this program in the future?	Fills many EMS training needs. Time and cost-effective. Trauma is relevant.
	Facilitators' composite evaluation scores of training sessions (mean)	4.65/5	93.0%	What did you like/dislike about the training approach and your role?	Intimidating to initially teach. Then grew confident. I feel like a peer mentor.
	Learners' who recommend their colleagues participate in HEET	82/86	95.3%	Why would you recommend your colleagues participate as learners?	Effective to acquire new knowledge and skills. Fun. Promotes team dialogue.
	Station and shift managers had a good attitude towards the program	9/9	100.0%	What contributed (or hurt) your support of the program?	Improved communication/rapport. Gain knowledge/skills. HEET Team helped.
		Mean (SD) =	**87.3% (14.6)**		
Implementation Fidelity					
	Eligible providers participating in >=80% of trainings	72/98	73.5%	What factors allowed you to sustain participation in trainings?	Trainings at shift start. Facilitators organized us. In ambulance was convenient.

Training sessions with <=3 learners in a group	119/180	66.1%	What factors permitted small groups (2 learners) vs large groups?	Absences due to sickness or leave, and relatively few trainers, caused large groups.
Teaching quality of the facilitators scored by learners (mean)	4.3/5	86.0%	What factors made the training sessions effective or ineffective?	Facilitators are familiar peers. Spoke in terms we understood. Felt like a peer chat.
Learners correctly demonstrated the skills in sessions, scored by facilitators (mean)	4.47/5	89.4%	What factors helped you to gain proficiency in skills?	Facilitators demonstrated. Used ambulance equipment. Practiced in each session.
Training sessions that started >15-mins late	83/180	46.1%	What factors allowed you to start trainings on time (or not)?	Learners arrive late. Foot-dragging. Trainings conflicted with ambulance prep.
	Mean (SD) =	**72.2% (17.4)**		
Overall Mean Effectiveness (SD)		**80.6% (15.8)**		

^ *Compared pre-implementation to 13-months post-implementation*
EMS = Emergency Medical Services
HEET = High-Efficiency EMS Training
SD = Standard Deviation
WCG = Western Cape Government

Providers delivered all elements of bundle of care to only 59% of eligible patients, which contributed to the poor overall reach. When asked, providers explained that one of their major challenges was transport to the trauma center due to *"pushback from staff"* especially for patients who met shock criteria but appeared well. Additionally, EMS providers had variable access to tourniquets for external hemorrhage control. Last, providers did endorse performing many procedures but often failed to record them in the clinical forms, which consequently impeded the ability to measure delivery of bundled care. Conversely, providers who delivered the bundle explained that its simplicity enabled recall and delivery, as opposed to complicated algorithms and protocols. One paramedic noted, *"I could see massive difference in BLS/ILS patient management when they call for backup."*

Effectiveness

Effectiveness scored 'excellent' (87%) predominantly due to high improvements in pre- versus post-implementation assessments of knowledge, skills, and attitudes, and also due to learners' high ratings of the quality of training sessions (Table 2). Ninety-three intervention site providers completed pre- and post-training assessments and were included in the analysis. Learners and facilitators explained that HEET used EMS-relevant cases in a discussion-based format led by non-intimidating peers which facilitated knowledge transfer. A BLS learner stated that, *"I can ask the stupid questions and I know I won't be looked down to."* Additionally, the skills practice using providers' usual on-board equipment helped to facilitate good skills acquisition and retention. An ILS learner stated, *"Enjoyed that it was in the back of the ambulance where we also treat patients."* Learners' mentioned that their confidence was improved due to group discussion format, which helped identify deficiencies and allay any concerns, including when to call for ALS backup during challenging cases. A BLS learner noted, *"I felt empowered and like a paramedic…"* and that it was, *"Nice to have own ALS do training."*

Adoption

Adoption scored 'excellent' predominantly because all tiers of EMS stakeholders (facilitators, HEET Team, station managers, learners) appraised the HEET program and EMS-TruShoC content as excellent operational fit for the organization and helped to overcome barriers to traditional training, including low attendance rates and low efficacy training formats (Table 2). Facilitators

explained their personal satisfaction with the HEET program included: *"Interaction with peers", "learning how to present", "refresher of information", "safe environment to learn", "feels nice to teach", and "I gained confidence as a teacher."* Of note, 3 out of 9 facilitators were unsure about resuming their role in future trainings specifically because they were unsure if they would be provided additional paid time to prepare for training sessions. Shift and station managers felt positively about the program because they noted an improvement in team-wide communication and rapport, in addition to knowledge and skills acquisition. EMS leaders felt that although cost-effectiveness was not formally assessed, their observation was that HEET was incredibly cost-effective compared to their usual educational programs, and felt that it had a future role within the EMS organization, insofar as it was appropriately integrated.

Implementation Fidelity

Implementation Fidelity had a lower score of 'good' mainly because of logistic challenges associated with keeping the number of learners in small groups at three or less, and also due to delayed training start times (Table 2). The issue of >3 learners in a training session arose because when providers missed trainings (most often due to leave), they would jump into another crew's training session to *"catch up so we don't get left behind,"* even though make up training sessions were offered. The latter issue of delayed start times was attributable to providers having a sluggish start to their work day which was termed, *"heel-dragging,"* and had no specific cause attributed. Overall high participation rates (i.e., providers completing ≥80% of sessions) was facilitated by the organization and conduct of training sessions during official shift time, with the implicit understanding that their participation was a part of their duties, which was driven by the HEET Team. Last, the facilitators and learners explained that facilitators were well trained, prepared, and enthusiastic about the sessions, which translated to high quality delivery and fidelity of the HEET program.

Patient characteristics

A total of 770 patients, meeting inclusion criteria, received care from EMS provider participants in the intervention (329, 42.7%) and control (441, 57.3%) arm (Table 3). There were no significant differences in pre- or post-implementation patient demographic or physiologic characteristics in

the control versus intervention cohorts with respect to age, sex, blunt versus penetrating injury mechanism, SI, SIxAge, and ambulance on-scene time.

Table 3. Pre- and post-intervention demographic and physiologic characteristics of patients.

Pre-Implementation (n=355)					
Variable	**Category**	**Overall (N=355)**	**Control (N=202)**	**Intervention (N=153)**	**P-value**
Median (IQR) patient age in years		30 (25-37)	30 (25-39)	30 (28-36)	0.34^
Patient sex	Female	24% (84)	22% (44)	26% (40)	0.34
	Male	76% (271)	78% (158)	74% (113)	
Primary injury mechanism	Blunt	47% (166)	48% (96)	46% (70)	0.74
	Penetrating	53% (189)	52% (106)	54% (83)	
% (n) with scene time <10 minutes		16% (58)	19% (39)	12% (19)	0.08
% (n) with oxygen given or documentation why not		32% (115)	36% (72)	28% (43)	0.13
% (n) with large bore catheter placed when provider is qualified to do so (n=236)		39% (92)	46% (55)	32% (37)	0.03
% (n) with bleeding control method documented in cases where external bleeding is present (n=252)		64% (161)	63% (86)	65% (75)	0.82
% (n) with Trauma center is destination		32% (113)	26% (52)	40% (61)	0.005
Median (IQR) initial heart rate (BPM)		111 (102-118)	112 (104-118)	110 (98-119)	0.17^
Median (IQR) initial SBP (mm Hg)		112 (90-130)	114 (94-130)	110 (90-129)	0.12^
Median (IQR) Initial Shock Index x Age		29.1 (23.8-37.3)	29.3 (24.0-38.8)	28.8 (23.8-35.7)	0.23^
Shock stage defined by initial Shock Index x Age	Shock (>=36)	28% (101)	32% (64)	24% (37)	0.12
	Normal (<36)	72% (254)	68% (138)	76% (116)	
% (n) with deteriorating Shock Index x Age		31% (109)	33% (66)	28% (43)	0.36
% (n) in shock with deteriorating Shock Index x Age		15% (15)	14% (9)	16% (6)	0.77
Median (IQR) change in Shock Index x Age from initial to final		-1.4 (-5.7-0.4)	-1.2 (-4.9-0.4)	-1.9 (-6.9-0.4)	0.36^
Median (IQR) minutes from scene arrival to scene departure		23 (13-35)	24 (12-36)	22 (14-32)	0.93^
Post-Implementation (n=415)					

Variable	Category	Overall (N=415)	Control (N=239)	Intervention (N=176)	P-value
Median (IQR) patient age in years		30 (24-36)	30 (24-36)	30 (24-37)	0.42^
Patient sex	Female	21% (85)	22% (53)	18% (32)	0.35
	Male	79% (326)	78% (185)	82% (141)	
Primary injury mechanism	Blunt	46% (191)	46% (109)	47% (82)	0.84
	Penetrating	54% (224)	54% (130)	53% (94)	
% (n) with scene time <10 minutes		25% (104)	29% (69)	20% (35)	0.04
% (n) with oxygen given or documentation why not		36% (148)	40% (95)	30% (53)	0.04
% (n) with large bore catheter placed when provider is qualified to do so (n=275)		38% (104)	33% (41)	42% (63)	0.10
% (n) with bleeding control method documented in cases where external bleeding is present (n=263)		69% (182)	73% (102)	65% (80)	0.17
% (n) with Trauma center is destination		25% (105)	14% (34)	40% (71)	<.0001
Median (IQR) initial heart rate (BPM)		111 (104-119)	111 (106-120)	110 (99-119)	0.06^
Median (IQR) initial SBP (mm Hg)		114 (91-130)	115 (100-130)	110 (90-129)	0.10^
Median (IQR) Initial Shock Index x Age		28.9 (23.1-36.8)	28.7 (23.0-37.3)	28.9 (23.2-36.0)	0.92^
Shock stage defined by initial Shock Index x Age	Shock (>=36)	27% (110)	28% (66)	25% (44)	0.55
	Normal (<36)	73% (305)	72% (173)	75% (132)	
% (n) with deteriorating Shock Index x Age		37% (153)	35% (84)	39% (69)	0.40
% (n) in shock with deteriorating Shock Index x Age		17% (19)	15% (10)	20% (9)	0.47
Median (IQR) change in Shock Index x Age from initial to final		-0.9 (-4.2-1.3)	-0.9 (-3.2-0.9)	-1.1 (-5.8-1.9)	0.61^
Median (IQR) minutes from scene arrival to scene departure		18 (9-27)	17 (7-28)	19 (10-26)	0.25^

^ *Wilcoxon Test*

BPM = beats per minute

IQR = interquartile range

Mm Hg = millimeters of mercury

SBP = systolic blood pressure

Clinical Effectiveness

A total of 755 of 770 (98%) trauma patients were analyzed (Table 4). 15 (2%) patients were missing data needed to calculate a Shock Index, hence excluded from the analysis. In the 4 months post-implementation compared to pre-implementation period, the intervention arm patients had more improved SIxAge compared to control arm, but the difference between the two groups was not statistically significant (0.8 change in control arm, -0.6 change in intervention arm; -1.4 difference-in-differences, P=0.35) (Figure 1a and Table 4). Further, there was no significant difference in change over time between the groups for any of the other time intervals (5-8 months: difference-in-differences -0.5, P=0.79; 9-13 months: difference-in-differences 0, P=0.99). Last, there were no differences in changes in SIxAge by ranks of EMS providers (BLS, ILS, or ALS) (Figure 1b-1d).

Table 4a. Delta Shock Index x Age by time interval and study group, for entire analysed cohort (N=755)[a]

Time Interval	Control		Intervention		D-I-D (95% CI) (Intervention-Control)	P-value
	n	Estimated ΔSIxAge (95% CI)	n	Estimated ΔSIxAge (95% CI)		
Before – All	200	-2.0 (-3.1, -0.9)	151	-3.0 (-4.2, -1.7)		
Post - 0-4 months	73	-1.2 (-3.0, 0.6)	69	-3.6 (-5.4, -1.7)	-1.4 (-4.4, 1.5)	0.35
Post - 5-8 months	62	-1.0 (-2.9, 0.9)	39	-2.5 (-4.9, -0.0)	-0.5 (-3.9, 3.0)	0.79
Post - 9-13 months	98	-1.3 (-2.8, 0.2)	63	-2.2 (-4.2, -0.3)	0.0 (-2.9, 2.9)	0.99

Table 4b. Delta Shock Index x age by time interval and study group, for sub-group of patients in shock i.e., Shock Index x Age >= 36 (N=206).

Time Interval	Control		Intervention		D-I-D (95% CI) (Intervention-Control)	P-value
	n	Estimated ΔSIxAge (95% CI)	n	Estimated ΔSIxAge (95% CI)		
Before – All	64	-5.8 (-8.7, -2.9)	35	-6.8 (-10.6, -3.0)		
Post - 0-4 months	22	-3.8 (-8.4, 0.9)	19	-12.4 (-17.6, -7.3)	-7.7 (-15.8, 0.3)	0.06
Post - 5-8 months	17	-3.2 (-8.7, 2.3)	10	-9.7 (-16.7, -2.8)	-5.5 (-15.1, 4.1)	0.26
Post - 9-13 months	26	-4.9 (-9.2, -0.6)	13	-4.9 (-10.9, 1.2)	1.0 (-7.5, 9.4)	0.82

ΔSIxAge = Change in Shock Index x Age. A more negative delta SI represents more improved shock.
D-I-D = Difference in Differences computed as (Change in ΔSIxAge in intervention group) – (Change in ΔSIxAge in control group)
[a]15 cases from the original sample of N=770 were excluded from this analysis due to missing data.

Discussion

We successfully implemented EMS-TruShoC (simplified bundled care) in a pragmatic fashion using the HEET training approach. The overall implementation effectiveness was excellent (81%). The bundled care intervention did not significantly improve patient's change in SIxAge when compared to usual (non-bundled) care.

Our novel training program, HEET, achieved excellent implementation effectiveness overall. HEET was successful for effective on-the-job trauma re-training of providers in this resource-limited EMS system. We found similar findings in our prior single-site feasibility study.[12] There were several major factors contributing to the high implementation effectiveness, which were evidenced by the quantitative data and supported by the qualitative findings. First, short-burst (15 to 20-minute) trainings scheduled and protected at the beginning of shift time proved to be a strong operational fit for this EMS system. Second, the program was purposefully designed to be engaging for professional adult learners by using contextually relevant cases which were presented in a non-intimidating, structured discussion forum. Third, we used and simplified bundle of care, and skills practice, to help *"drill"* the core components of the bundle of care to help promote recall and translation from the 'class' to practice. Last, we intentionally used motivated peer paramedics as facilitators, instead of the traditional EMS educators – this approach helped to reduce learner anxiety and promoted more open communication and eagerness to learn. Consequently, we measured meaningfully improved educational outcomes attributable to the EMS-TruShoC training intervention.

While fidelity of the implementation overall was excellent, there were modest challenges in delivering the intervention to small groups of participants at the beginning of their shifts. The HEET Team felt that this was due to a combination of unavoidable logistic challenges which ultimately did not negatively impact delivery of the intervention. A critical factor underpinning the overall implementation success was advanced engagement and planning between the research team and the HEET Team. The HEET Team was comprised of a motivated multi-disciplinary group of EMS educators and quality assurance personnel who worked alongside the researchers to design, implement, and evaluate the program with a deliberate goal of pragmatic implementation, strong organizational tailoring, and sustainability.

Our clinical intervention of bundled care (EMS-TruShoC) did not measurably improve patients' shock physiology, measured by SIxAge, for several possible reasons. First, it is likely that three items in our core shock bundle (large IV catheter, scene time <10 minutes, and trauma center transport destination) may cause no direct change to heart rate nor systolic blood pressure. Second, it is possible that although the SIxAge performs better than traditional vital signs, it may have inadequate sensitivity and specificity to detect prehospital changes in physiology. A sentinel study by Zarzaur *et al.* demonstrated that SIxAge was a superior predictor of 48-hour mortality compared to systolic blood pressure, heart rate, or Shock Index.[32] In 2012, Bruijns and colleagues validated these findings in the United Kingdom's national trauma registry in which SIxAge achieved the highest area under the receiver operator curve (AUROC) of 0.79 for predicting 48-hour mortality compared to Shock Index and other age-based markers.[29] However, the SIxAge thresholds varied across these studies from ≥35.6 to ≥55. We used a threshold of ≥36, which was based upon Zarzaur's original study and is more appropriate for a younger trauma population.[33] However, further studies to establish a prehospital cutoff point would be useful, especially if conducted within a South African trauma population. Additionally, other hospital-based outcome measures, such as blood lactate, the need for blood transfusions, or 24-hour mortality, could potentially detect a change where SIxAge did not – these are possible avenues for future research. However, the advantage of using a Shock Index-based physiologic measure is it facilitates prehospital research by avoiding costly and logistically complicated in-hospital clinical data collection.

Our overall research design and approach (i.e., a hybrid type II quasi-experimental trial) and the research context (i.e., a South African prehospital system) are also noteworthy. Hybrid trials assess the implementation outcomes in tandem with the clinical effectiveness outcomes.[20] The rationale for conducting both in parallel is to test the intervention and implementation in a real-world context which improve the ability of findings to more rapidly translate into clinical practice settings.[20 27] Prior data suggests that it takes, on average, 17 years for 14% of biomedical research to translate from research into clinical practice which stifles advancements in clinical care worldwide.[39] Implementation science methodologies – such as the pragmatic hybrid trial design used in this study – are innovative and feasible approaches to narrowing this 'know-do' gap. The need for real-world data is arguably even more critical in lower-income settings which face the challenging

paradox of having extremely high burdens of injury yet have a shortage of biomedical research. Prehospital care is a neglected area of research, according to the World Health Organization and leading experts, necessitating more research to help improve care delivery and patient outcomes. In time-sensitive emergencies, such as traumatic shock, bringing basic yet essential treatment to the patient, at the scene of the event, is a cost-effective public health intervention to improve post-injury morbidity and mortality [40 41] – yet, where prehospital systems exist, there is a paucity of research, due to poor awareness or the technical challenges. This body of work directly addresses these practice and scientific evidence gaps.

Limitations

There are several limitations to this work aside from those of the SIxAge described earlier. Despite our best efforts to select similar sites, the intervention site had a significantly lower proportion of BLS providers compared to the control site which may have influenced our implementation outcomes. Educational assessments were designed to be quick and easy for the HEET Team assessors to administer, hence may have had limited sensitivity to detect changes in educational outcomes among the EMS participants, so may have under-estimated the true effect size. Additionally, the HEET Team assessors could not be practically blinded to whether an EMS participant received the intervention or not, which may have introduced bias in their assessments.

Conclusions

In this hybrid type II quasi-experimental trial of EMS-TruShoC (bundled care) using the novel HEET training approach, we found overall excellent implementation effectiveness but no overall statistically significant clinical effectiveness. HEET is an effective prehospital implementation strategy in a resource-constrained EMS setting, primarily explained by strong fit to the organization's operational needs and the adult-learner friendly approach to on-the-job training. Further clinical effectiveness studies are warranted to assess whether EMS-TruShoC confers a prehospital physiologic benefit for critically injured patients.

DECLARATIONS

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Authors' Contributions:

Mould-Millman was involved in all aspects of the article, including planning and design, data acquisition, analysis, interpretation, and manuscript writing. Dixon was involved in planning and design, data acquisition, analysis and manuscript writing. Beaty and Suresh were involved in data analysis, interpretation, and manuscript writing. De Vries, Bester, Moreira, Cunningham, Moodley, and Cermak were involved in planning, access to subjects, data acquisition, and manuscript writing. Bills and Havranek were involved in interpretation and manuscript writing. Schauer, Maddry, Bebarta, and Ginde were involved in planning, design, interpretation, and manuscript writing. Therefore, all authors made substantive contributions to the work, contributed to drafting or substantive revisions, approved the publishable version, and agree to be accountable for the accuracy and integrity of the work.

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Competing interests:

The authors declare that they have no competing interests. The views expressed in this article are those of the authors and do not reflect the official policy or position of any listed institution, including the U.S. Army Medical Department, U.S. Department of the Army, U.S. Department of Defense, or the U.S. Government.

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The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Disclaimer:

Opinions, interpretations, conclusions, and recommendations are those of the authors and are not necessarily endorsed by, or the official opinions of, the NIH, the U.S. Department of Defense, the Western Cape Government Department of Health, or the University of Colorado.

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Ethics Approval

Ethics approval was provided by the University of Cape Town Human Research Ethics Committee (HREC# 077/2018), the primary oversight ethics board, with a single-IRB reliance agreement with the Colorado Multiple Institutional Review Board (Protocol # 18-0607), and concurrence from the U.S. Department of Defense Human Research Protection Office. A waiver of informed consent for patients was granted; written informed consent was obtained for participating EMS providers.

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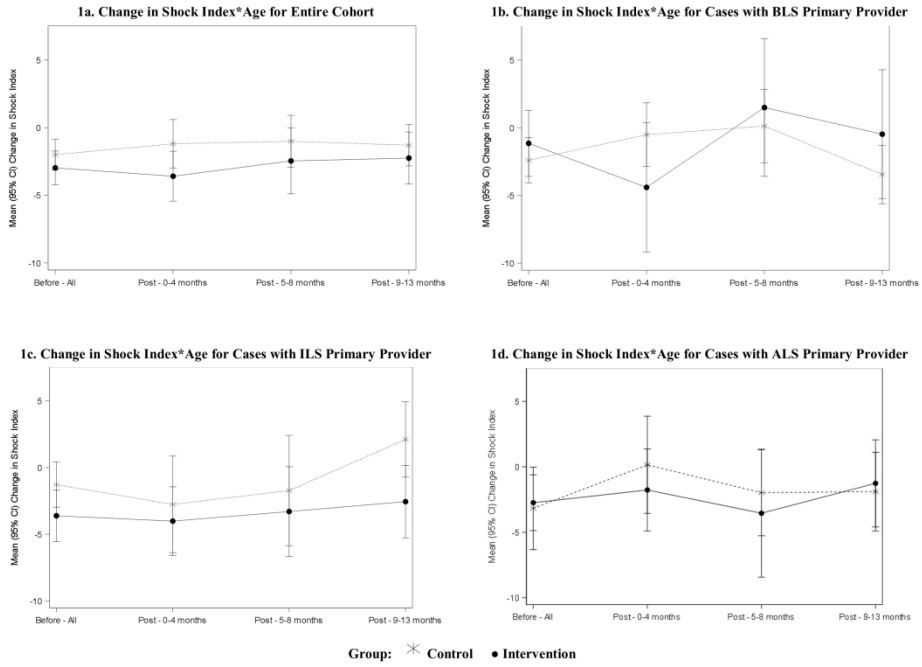
Figure 1. Mean change in shock from EMS arrival at the scene of injury to hospital arrival by whole cohort (1a), and for cases with BLS (1b), ILS (1c), and ALS (1d) providers. *The more negative the change in SIxAge value is, the more improved the shock. BLS = Basic Life Support. ILS = Intermediate Life Support. ALS = Advanced Life Support.*



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'EMS-TruShoC'

A Bundle of EMS Traumatic Shock Care

TRAUMA SHOCK RECOGNITION

In adult injury w/ high risk mechanism

RIGHT PATIENT?
High risk mechanism of injury
and
Age ≥16 years.

Yes

1 or more abnormal vitals screen for shock

VITAL SIGNS?
Pulse rate >100-bpm,
and/or
Systolic BP <100-mmHg,
and/or
Capillary refill time >2-secs,
and/or
Non-palpable radial pulse.

Yes

1 or more symptoms for decompensated shock.

CLINICAL PICTURE?
Active or suspected bleeding
and/or
Altered Mentation
and/or
Skin Color Change
and/or
Sweating/diaphoresis.

Mechanism of injury placing patient at high risk for shock:

- **PENETRATING:**
  Gunshot wound (head, neck, torso, groin, proximal extremity)
- **BLUNT:**
  Fall from height (>6m)
  Motor vehicle collision (high speed, ejection)
  Motor cycle crash
  Pedestrian struck by vehicle
  Assault (with high energy transfer)
- **AMPUTATION:**
  Of limbs (except fingers, toes)
- **ACTIVE BLEEDING:**
  Uncontrollable external bleeding
  Obvious/suspected internal hemorrhage

TRAUMA SHOCK MANAGEMENT

CORE BUNDLE OF CARE

1. On-scene time is ≤ 10-minutes
2. Destination is trauma center
3. Large bore IV (≥18G) catheter placed
4. Oxygen is administered (appropriate route)
5. External bleeding is controlled (per protocol)

*All 5 performed on 100% of shock trauma cases.

NON-CORE BUNDLE OF CARE

Circulation:
- Control hemorrhage
- Intravenous fluids

Airway:
- Open, Suction, & Secure

Breathing:
- Oxygenate & Ventilate

Disability:
- Prevent further neurologic injury

Continuous assessment
- Repeat: primary & secondary surveys
- Repeat vital signs (at least 2 sets)

↑ Perform C-A-B-D on 100% of cases ↑

Special considerations if shock and the ff:
- Uncontrolled arterial bleed = tourniquet
- Blunt pelvic injury = pelvic binding
- Tension PTX = needle decompression
- Loss of motor/sensory = cervical collar
- Cardiac arrest = consider CPR / ACLS
- Obvious pregnancy = left lateral decubitus

↑ Perform only when clinically indicated ↑

Checklist of items for reporting pragmatic trials

Section	Item	Standard CONSORT description	Extension for pragmatic trials	Manuscript page # that addresses the item
Title and abstract	1	How participants were allocated to interventions (eg, “random allocation,” “randomised,” or “randomly assigned”)		1, 2
Introduction				
Background	2	Scientific background and explanation of rationale	Describe the health or health service problem that the intervention is intended to address and other interventions that may commonly be aimed at this problem	4-5
Methods				
Participants	3	Eligibility criteria for participants; settings and locations where the data were collected	Eligibility criteria should be explicitly framed to show the degree to which they include typical participants and/or, where applicable, typical providers (eg, nurses), institutions (eg, hospitals), communities (or localities eg, towns) and settings of care (eg, different healthcare financing systems)	5-6
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered	Describe extra resources added to (or resources removed from) usual settings in order to implement intervention. Indicate if efforts were made to standardise the intervention or if the intervention and its delivery were allowed to vary between participants, practitioners, or study sites	6-7
			Describe the comparator in similar detail to the intervention	
Objectives	5	Specific objectives and hypotheses		4-5
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (eg, multiple observations, training of assessors)	Explain why the chosen outcomes and, when relevant, the length of follow-up are considered important to those who will use the results of the trial	7-8
Sample size	7	How sample size was determined; explanation of any interim analyses and stopping rules when applicable	If calculated using the smallest difference considered important by the target decision maker audience (the minimally important difference) then report where this difference was obtained	9-10
Randomisation—sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (eg, blocking, stratification)		N/A
Randomisation—allocation concealment	9	Method used to implement the random allocation sequence (eg, numbered containers or central telephone), clarifying whether the		N/A

Section	Item	Standard CONSORT description	Extension for pragmatic trials	Manuscript page # that addresses the item
		sequence was concealed until interventions were assigned		
Randomisation—implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups		8-9
Blinding (masking)	11	Whether participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment	If blinding was not done, or was not possible, explain why	N/A (explained on pg 24)
Statistical methods	12	Statistical methods used to compare groups for primary outcomes; methods for additional analyses, such as subgroup analyses and adjusted analyses		23
Results				
Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended)—specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analysed for the primary outcome; describe deviations from planned study protocol, together with reasons	The number of participants or units approached to take part in the trial, the number which were eligible, and reasons for non-participation should be reported	11 (providers) 16-20 (patients)
Recruitment	14	Dates defining the periods of recruitment and follow-up		7,8 (providers) 9,10 (patients)
Baseline data	15	Baseline demographic and clinical characteristics of each group		11,12 (providers) 16-17 (patients)
Numbers analysed	16	Number of participants (denominator) in each group included in each analysis and whether analysis was by "intention-to-treat"; state the results in absolute numbers when feasible (eg, 10/20, not 50%)		11-14 (providers) 18-20 (patients)
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision (eg, 95% CI)		12-14 (implementation) 16-20 (clinical effect)
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating which are prespecified and which are exploratory		20 (clinical effect)
Adverse events	19	All important adverse events or side effects in each intervention group		N/A
Discussion				

Section	Item	Standard CONSORT description	Extension for pragmatic trials	Manuscript page # that addresses the item
Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes		21-22
Generalisability	21	Generalisability (external validity) of the trial findings	Describe key aspects of the setting which determined the trial results. Discuss possible differences in other settings where clinical traditions, health service organisation, staffing, or resources may vary from those of the trial	22-23
Overall evidence	22	General interpretation of the results in the context of current evidence		21-24

Cite as: *Zwarenstein M, Treweek S, Gagnier JJ, Altman DG, Tunis S, Haynes B, Oxman AD, Moher D for the CONSORT and Pragmatic Trials in Healthcare (Practihc) group. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. BMJ 2008; 337;a2390.*