BMJ Open

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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To cite: Mould-Millman N-K, Dixon J, Beaty BL, *et al*. Improving prehospital traumatic shock care: implementation and clinical effectiveness of a pragmatic, quasi-experimental trial in a resource-constrained South African setting. *BMJ Open* 2023;**13**:e060338. doi:10.1136/bmjopen-2021-060338

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2021-060338).

Received 30 December 2021
Accepted 13 April 2023

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ABSTRACT

Objectives This project seeks to improve providers' practices and patient outcomes from prehospital (ie, 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 five 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 cut-offs 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 organisation. A total of 770 patients were included: 329 (42.7%) interventions and 441 (57.3%) controls, with no baseline differences. Intervention arm patients had more improved SIxAge compared with 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.

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 organisational 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/middle-income countries (LMICs) experience a disproportionately large burden of global postinjury 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 (ie, 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 haemorrhage 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 (WCG) EMS system termed, High-Efficiency EMS Training (HEET).[12] HEET—the implementation strategy—is a low-dose, high-frequency, training and sensitisation programme, 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 with 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 randomise the intervention at the level of the provider because of concerns about crossover, and there were not enough sites available to randomise 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 (ie, 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, two times the global mortality rate from injury and loss of 1 million disability adjusted life years 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]

Organisation and participants

The organisational setting was a government-operated EMS system—WCG Department of Health EMS.[12 24] WCG EMS had previously established trauma as 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 course for BLS, a 12-week course for ILS and a 4-year (degree-earning) training for ALS providers.[25]

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.[26] 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 prehospital 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 centre. 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 (ie, 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 (eg, cervical spinal cord injury) (online supplemental material 1). The five items, each evidence-based, that comprised the bundle include: (1) scene times <10 min, (2) early haemorrhage control, (3) insertion of a large bore intravenous catheter, (4) oxygen delivery and (5) direct transport to a trauma centre.[12]

Implementation strategy

EMS-TruShoC was implemented among EMS providers using the HEET programme. HEET was designed as a low-dose (15–20 min), high-frequency (once biweekly) training programme 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 five modules. Each module was structured around a clinical case scenario and incorporated knowledge acquisition, self-efficacy conditioning and skills practice. Key learning objectives were emphasised using a facilitated discussion approach.

Measures

Implementation outcomes

The RE-AIM framework was used to plan the implementation and to evaluate outcomes.[18 19 27] Quantitative and qualitative data were collected for four of the five RE-AIM dimensions, defined as follows:

- **R**each is the extent to which the intervention reached the EMS providers and traumatic shock patients (example index: proportion of EMS providers participating in trainings).
- **E**ffectiveness is the educational performance of the EMS providers who received the educational intervention (example index: proportion of learners with improved educational assessments).
- **A**doption is the prospect of the programme becoming institutionalised within the organisation (example index: proportion of stakeholders who deem the programme fit for their organisation as-is).
- **I**mplementation fidelity is how well the programme was actually executed compared with the originally intended implementation (example index: proportion of training sessions conducted within the allotted time).
- **M**aintenance is defined as the existence of an institutionalised programme 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 on the conclusion of the study.

Clinical effectiveness outcomes

This was assessed by patient's physiological responses to onboard 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.[28–32] We previously published findings of our primary outcome using changes in patient's SI which demonstrated no significant difference between the intervention and control groups.[33] In this paper, we conduct a preplanned secondary analysis using the SIxAge outcome in the intervention group compared with the control group. An SIxAge ≥36 is the cut-off point for shock in younger trauma populations characteristic of the Western Cape.[12 31 32 34] 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 on facility arrival. The target effect of the study is the difference in delta SIxAge between the intervention and control groups from pre-implementation to

post implementation (ie, difference-in-differences (D-I-D)).[35] A more negative D-I-D, 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 were collected from training session participation and evaluation forms, postprogramme exit surveys and postprogramme exit interviews. All implementation data were organised 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, pretraning 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 were collected by reviewing and abstracting EMS medical records from trauma patients at both study sites. Pre-implementation and post implementation data were collected for the 13 consecutive months preceding (ie, August 2017 to August 2018) and following (ie, January 2019 to January 2020) implementation, respectively. We used a previously validated, standardised chart review and abstraction methodology.[36] 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 online research database.[37]

Analysis

Demographics

Baseline comparisons between EMS provider and patient characteristics in both groups, pre-implementation and post implementation, were performed using Wilcoxon, χ^2 and two-tailed t-tests, based on the type and distribution of the variable.

Implementation outcomes

Within each of the four 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. Cut-offs 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 summarised (with supporting quotes) and arranged according to the four RE-AIM domains assessed in this study. The researchers adopted a postpositivist stance in the qualitative analysis (ie, the quantitative data were believed to be real, but it was acknowledged that environmental, social and individual differences influenced the quantitative reality).

Clinical outcomes (adjusted analyses)

The primary analysis was an adjusted D-I-D analysis to examine the difference between the control and intervention groups in changes in delta SIxAge over time.[35] A D-I-D analysis has the advantage of accounting for the effect of changes due to factors other than the intervention (eg, 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 D-I-D, 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:

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	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†

*Percentages may not add to 100% due to rounding.
†Wilcoxon test.
ALS, advanced life support; BLS, basic life support; ILS, intermediate life support.

qualification of provider (BLS, ILS, ALS), patient sex, injury mechanism (blunt or penetrating), initial SIxAge and prearrival minutes (time from injury to ambulance arrival). Subgroup analysis was conducted by provider qualification. All statistical analyses were conducted using SAS V.9.4 (SAS Institute).

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

One hundred and ninety-eight of two hunderd and forty (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 (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 with the control group.

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 favourable (compared with 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. Finally, facilitators mentioned that support from the station managers and dispatch centre was critical for protecting training time.

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 centre 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 haemorrhage control. Finally, 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-implementation 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 pretraining and post-training

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 intravenous
	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 programme?	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 organisational factors promoted your continued participation?	Managers and dispatch centre support. HEET team friendly. Learners eager
	Facilitators who feel very positive about the programme	9/9	100.0	What are some reasons you feel positively about the programme?	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 programme should be part of EMS education	13/13	66.7	Why should WCG EMS continue to use this programme 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 programme	9/9	100.0	What contributed (or hurt) your support of the programme?	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 organised us. In ambulance was convenient

Continued

Table 2 Continued

Index	Quantitative measure	Proportion	%	Qualitative assessment (sample questions)	Summary of key qualitative themes
	Training sessions with ≤3 learners in a group	119/180	66.1	What factors permitted small groups (two learners) versus 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 min 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.
ALS, advanced life support; BLS, basic life support; EMS, Emergency Medical Services; HEET, High-Efficiency EMS Training; WCG, Western Cape Government.

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 onboard 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 programme and EMS-TruShoC content as excellent operational fit for the organisation 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 programme 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, three out of nine 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 programme 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 with their usual educational programmes, and felt that it had a future role within the EMS organisation, 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 (ie, providers completing ≥80% of sessions) was facilitated by the organisation 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. Finally, 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 programme.

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-implementation or post implementation patient demographic or physiological characteristics in the control versus intervention cohorts with respect to age, sex, blunt versus penetrating injury mechanism, SI, SIxAge and ambulance on-scene time.

Clinical effectiveness

A total of 755 of 770 (98%) trauma patients were analysed (table 4). Fifteen (2%) patients were missing data needed to calculate a SI, hence, excluded from the analysis. In the 4 months post implementation compared with pre-implementation period, the intervention arm patients had more improved SIxAge compared with 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 D-I-D, 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: D-I-D −0.5, p=0.79; 9–13 months: D-I-D 0, p=0.99). Finally, there were no differences in changes in SIxAge by ranks of EMS providers (BLS, ILS or ALS) (figure 1B–D).

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 with usual (non-bundled) care.

Our novel training programme, 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 (15–20 min) trainings scheduled and protected at the beginning of shift time proved to be a strong operational fit for this EMS system. Second, the programme 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. Finally, 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 a motivated multidisciplinary group of EMS educators and quality assurance personnel who worked alongside the researchers to design, implement and evaluate the programme with a deliberate goal of pragmatic implementation, strong organisational 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 intravenous catheter, scene time <10 min and trauma centre transport destination) may cause no direct change to heart rate or 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 with systolic blood pressure, heart rate or SI.[31] In 2012, Bruijns and colleagues validated these findings in the UK's national trauma registry in which SIxAge achieved the highest area under the receiver operator curve of 0.79 for predicting 48-hour mortality compared with SI and other age-based markers.[28] However, the SIxAge thresholds varied across these studies from ≥35.6 to ≥55. We used a threshold of ≥36, which was based on Zarzaur's original study and is more appropriate for a younger trauma population.[32] However, further studies to establish a prehospital cut-off 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 an SI-based physiological measure is it facilitates prehospital research by avoiding costly and logistically complicated in-hospital clinical data collection.

Our overall research design and approach (ie, a hybrid type II quasi-experimental trial) and the research context (ie, 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

Table 3 Preintervention and postintervention demographic and physiological 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)	
% (n) with scene time <10 min		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 centre 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 to 0.4)	−1.2 (−4.9 to 0.4)	−1.9 (−6.9 to 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 (25–37)	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 min		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 centre is destination		25% (105)	14% (34)	40% (71)	<0.0001
Median (IQR) initial heart rate (bpm)		111 (104–119)	111 (106–120)	110 (97–119)	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*

Continued

Table 3 Continued

Pre-implementation (n=355)					
Variable	Category	Overall (N=355)	Control (N=202)	Intervention (N=153)	P value
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 to 1.3)	−0.9 (−3.2 to 0.9)	−1.1 (−5.8 to 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; SBP, systolic blood pressure.

rapidly translate into clinical practice settings.[20 26] Prior data suggest 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.[38] 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 WHO 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 postinjury morbidity and mortality[39 40]—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 with 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

Table 4 Delta Shock Index x Age by time interval and study group, (A) for entire analysed cohort (N=755)*, (B) for subgroup of patients in shock, that is, Shock Index x Age ≥36 (N=206)

	Control		Intervention			
Time interval	n	Estimated ΔSIxAge (95% CI)	n	Estimated ΔSIxAge (95% CI)	D-I-D (95% CI) (intervention-control)	P value
(A)						
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
(B)						
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 denotes the change in Shock Index x Age. A more negative delta Shock Index represents more improved shock.
D-I-D denotes the difference-in-differences computed as (change in ΔSIxAge in intervention group)–(change in ΔSIxAge in control group).
*Fifteen cases from the original sample of N=770 were excluded from this analysis due to missing data.

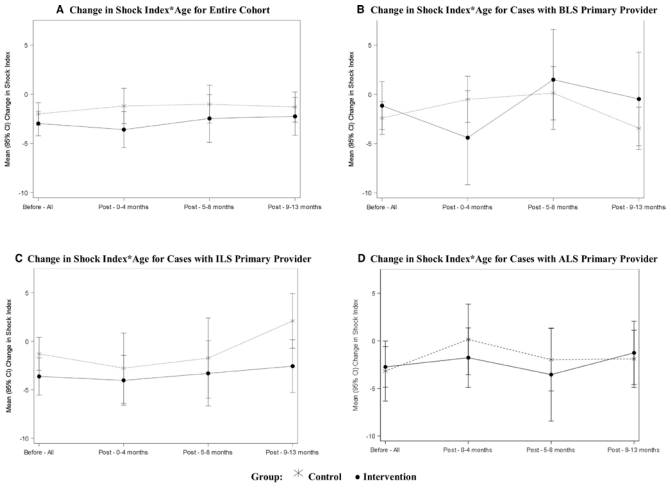

Figure 1 Mean change in shock from Emergency Medical Services arrival at the scene of injury to hospital arrival by whole cohort (A), and for cases with BLS (B), ILS (C) and ALS (D) providers. The more negative the change in Shock Index x Age value is, the more improved the shock. ALS, advanced life support; BLS, basic life support; ILS, intermediate life support.

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 organisation'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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Acknowledgements We deeply appreciate the substantive implementation and evaluation contributions to this project by the Western Cape EMS HEET Steering Committee, namely (in alphabetical order): Mr Michael Lee, CCA; Mr Peter Lesch, CCA; Mr Aldrin Mackier, BEMC; Mr Wayne Philander, BEMC; Mr Nico van Nierkerk, BTech; Mr Chrishando Staines, CCA; Mr Bradley van Ster, BTech; and Mr Craig Williams, BEMC. We would also like to express our immense gratitude to all the operational staff and managers at the Eastern and Western Divisions of Western Cape Government Emergency Medical Services. We are also thankful for the logistic and administrative support provided by several Western Cape Government EMS staff, including Mrs Tanisha Morris and Mrs Noorifah Narker. Finally, we recognise the critical support provided by key leaders of Western Cape Government EMS namely, Dr Shaheem de Vries, MBChB, MPhil, Mr Kubendhren Moodley, MSHS and Mr Radomir Cermak, MHS.

Contributors N-KM-M was involved in all aspects of the article, including planning and design, data acquisition, analysis, interpretation, and manuscript writing. N-KM-M also serves as the guarantor for the overall content of this work. JD was involved in planning and design, data acquisition, analysis and manuscript writing. BLB and KS were involved in data analysis, interpretation and manuscript writing. SdV, BB, FM, CC, KM and RC were involved in planning, access to subjects, data acquisition and manuscript writing. CBB and EPH were involved in interpretation and manuscript writing. SGS, JKM, VSB and AAG 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.

Funding Grant funding was provided by the following sources: United States Defense Health Agency (J9, Research and Development Directorate), award # FA8650-18-2-6934 (PI: N-KM-M); National Institutes of Health National Heart, Lung, and Blood Institute, grant number 1K12HL137862-01 (PI: Russel E Glasgow; EPH. Scholar: N-KM-M); and the Emergency Medicine Foundation 2017-2019 research fellowship award (PI: N-KM-M). Use of Research Electronic Data Capture (REDCap) was supported by National Institutes of Health National Center for Advancing Translational Sciences Grant Number UL1 TR002535.

Disclaimer None of the funding sources had any role in the study design, collection, analysis, interpretation of findings, writing the manuscript or the decision to submit the paper for publication.

Competing interests None declared.

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.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and 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 US 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. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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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 ↑