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TITLE: Epidemiology and Outcomes of Combat-Relevant Prolonged Trauma Care: a Prospective Multicenter Prehospital Study in South Africa

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F13. SUPPLEMENTARY NOTES

14. ABSTRACT

Purpose: The overall objective of this study is to conduct an epidemiologic prehospital trauma study in an austere, combat-relevant, foreign environment that innovatively addresses many of the military's current scientific needs, and overcomes limitations experienced by prior U.S.-based prehospital trauma studies. Our primary hypothesis is that a sigmoidal relationship will exist between prehospital time and 7-day mortality. The inflexion point will represent a critical window of time for the patient to reach a trauma facility, after which 7-day mortality rates will accelerate from 'low' to 'high'. This inflexion point will be at 2-hours for non-compressible, and 4-hours for compressible, injuries. Our secondary hypothesis is that there will be non-linear associations between time (from injury to reaching trauma center) with postinjury morbidity endpoints.

Specific Aim 1: To assess how prolonged durations of time-to-trauma facility affects morbidity and mortality of trauma patients.

- Aim 1a: We will assess the effect of time on mortality amongst patients experiencing moderate and severe injury severities.
- Aim 1b: We will assess the effect of time on morbidity amongst patients experiencing moderate and severe injury severities. Morbidity will include: (i) organ failure scores [e.g., coagulopathy, acute kidney injury], (ii) rates of surgical interventions [e.g., fasciotomies, tube thoracostomies], and (iii) Rates of post-injury infections [e.g., wound infections, sepsis].

Specific Aim 2: To assess how key prehospital interventions affects morbidity and mortality of trauma patients.

- Aim 2a: To determine the association of key prehospital interventions on mortality, accounting for time-to-trauma facility arrival.
- Aim 2b: To determine the association of key prehospital interventions on morbidity, accounting for time-to-trauma facility arrival.

Significance: Our established research network in South Africa has the ideal civilian environment (dense urban and austere rural settings, high-volume/high-mortality trauma, resource-limited) to study combat-like injuries thereby making this work highly relevant to combat medicine and the U.S. military. This study will innovatively and directly fill critical military scientific gaps, and inform future interventional studies needed to reduce mortality in future conflicts. Our findings also bear direct relevance to injured persons in rural U.S. locations and in low-and-middle income countries across the globe, which have resource-limited and sparse trauma care systems.

15. SUBJECT TERMS

Prehospital, trauma, outcomes, epidemiology, mortality, resuscitation, prolonged care

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1. INTRODUCTION

This is an epidemiologic prehospital trauma study in an austere, combat-relevant, foreign environment that innovatively addresses some of the military's current scientific needs, and overcomes limitations experienced by prior U.S.-based prehospital trauma studies.

2. KEYWORDS

Prehospital, trauma, outcomes, epidemiology, mortality, resuscitation, prolonged care.

3. ACCOMPLISHMENTS

3.1. What were the major goals of the project?

The overarching purpose of this study is to assess the effect of early resuscitative interventions on morbidity and mortality outcomes, with a focus on those who experience prolonged field and casualty care (PFC and PCC). In general, this study focuses on contemporary outcomes that best reflect the effect of early resuscitation, including 7-day mortality (primary outcome), and multi-organ failure, rates of operative interventions, and infection rates (secondary outcomes).

The primary hypothesis is that a sigmoidal relationship will exist between prehospital time and 7-day mortality. The inflexion point will represent a critical window of time for the patient to reach a trauma facility, after which 7-day mortality rates will accelerate from 'low' to 'high'. This inflexion point will be at 2-hours for noncompressible, and 4-hours for compressible, injuries (Figure 1).

Figure 1: Sigmoid curve comparing 7-day mortality as a function of time (from injury to trauma center arrival), among patients with severe injuries. Both curves indicate that a critical inflexion point exists (around 2-hours for non-compressible, and around 4-hours for compressible, bleeding) after which 7-day mortality accelerates.

Our secondary hypothesis is that there will be non-linear associations between time (from injury to reaching trauma center) with post-injury morbidity endpoints.

Aim 1: To assess how prolonged durations of time-to-trauma facility affects morbidity and mortality of trauma patients.

- Aim 1a: We will assess the effect of time on mortality amongst patients experiencing moderate and severe injury severities.
- Aim 1b: We will assess the effect of time on morbidity amongst patients experiencing moderate and severe injury severities.

Aim 2: To analytically assess how key prehospital interventions affects morbidity and mortality of trauma patients.

- Aim 2a: To determine the association of key prehospital interventions on mortality, accounting for time-to-trauma facility arrival.
- Aim 2b: To determine the association of key prehospital interventions on morbidity, accounting for time-to-trauma facility arrival.

Mortality will be assessed prehospital or in-hospital. Morbidity will include: (i) organ failure scores [coagulopathy, acute kidney injury, acute lung injury, multi-organ failure], (ii) rates of surgical interventions [fasciotomies, thoracotomies, tube thoracostomies], and (iii) Rates of post-injury infections [wound infections, pneumonia, sepsis]. We will control for relevant confounders in our analyses.

Table 1: Statement of Work for relevant year 2 activities

	Original Timeline (month #)	**Actual Timeline (Months #)**	**Status**
MAJOR TASK 1: Preparatory work			
Prepare ethics applications and study protocols	1-2	1-2	Complete
Obtain relevant ethics & protocol approvals: • Stellenbosch University human research ethics • Colorado Multiple Institutional Review Board • Department of Defense HRPO	 2-4 5-6 6-9	 2-4 5-6 6-9	 Complete Complete Complete
Signed letters of approval from research locations: • EMS • Hospitals • Pathology Services	 5-9 5-9 5-9	 5-9 5-9 10-12	 Complete Complete Complete
Obtain Data Use/Share Agreements: • Stellenbosch University and UCD • Western Cape Department of Health and UCD	 6-12 6-12	 6-12 6-12	 Complete Complete
Hire and train data collectors at research locations	6-9	6-9	Complete
Milestone(s) Achieved: Final version of a detailed study protocol Approval by Stellenbosch & Colorado ethics boards Letters of approval from research locations Department of Defense HRPO approval	 6 9 9 9	 6 9 10-12	 Complete Complete Complete

Data Use/Share Agreements are executed Data collectors hired and fully trained at all locations	12 10	9 12 10	Complete Complete Complete
MAJOR TASK 2: Data Collection			
Troubleshoot data collection procedures	6-12	6-12	Complete
Collect hospital data (refine procedures, as needed)	9-45	12-45	In-progress
Collect EMS data (refine procedures, as needed)	9-45	12-45	In-progress
Collect autopsy data (refine procedures, as needed)	9-45	12-45	In-progress
Milestone(s) Achieved: Hospital data collection/enrollment starts EMS data collection/enrollment starts Autopsy (pathology) data collection starts	 10 10 10	 12 12 12	 Complete Complete Complete
MAJOR TASK 3: Quality checks/data analysis			
Assess enrollment, monthly (early in study)	10-18	13-20	Complete
Assess data quality, monthly (early in study)	10-18	13-20	Complete
Assess enrollment, every other quarter (later in study)	19-45	19-45	In-progress
Assess data quality, every other quarter (later in study)	19-45	19-45	In-progress
Interim outcome analyses (semi-annually)	19-45	19-45	In-progress
Interpretation of interim analyses (semi-annually)	19-45	19-45	In-progress
Data collector re-training (as needed)	13-15 21-24 33-36	13-15 21-24 33-36	Complete Complete Pending Y3
Final analysis & interpretation of results	46-48	46-48	Pending Y3
Milestone(s) Achieved: Completion of early interim outcome analyses Completion of semi-annual interim analyses Completion of final data analysis Interpretation of final results	 21 27,33,39,45 48 48	 21 27,33,39,4 5 48 48	 Pending Y3

LEGEND: Y3: project year 3. UCD: University of Colorado Denver. Light gray font text represents completed activities in year 1, and activities planned for year 3 and onwards that are irrelevant to this report. Black font text represents activities for year 2.

3.2 What was accomplished under these goals?

Major Task 1: Preparatory Work

(i) Study Protocol and Ethics Approvals:

- In each project year, including year 2, we received on-time approvals from the governing ethics and oversight boards, and continuing annual ethics renewals. In year 2 specifically, we received approvals for extension/renewal/continuing review of the study (Appendix 1). All relevant

approvals to this report include:

- ✓ Stellenbosch University, Health Research Ethics Committee (HREC), Office of Human Research Protections (OHRP) Institutional Review Board approved the addition of 2 study sites (Khayelitsha Site-B CHC and Delft CHC) and research Site Leads on 08-APR-2022.
- ✓ Stellenbosch University, Health Research Ethics Committee (HREC), Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO) Institutional Review Board approved extension/annual renewal of the study protocol on 21 JUL 2022 (approval extended to 24 AUG 2023).
- ✓ University of Colorado, Colorado Multiple Institutional Review Board (COMIRB) renewal of ceded oversight with Stellenbosch University serving as the primary "single IRB" ethics committee responsible. We received a letter of COMIRB confirmation on 25 JUL 2022.
- ✓ Stellenbosch University, Health Research Ethics Committee, Institutional Review Board approved an amendment to the protocol for a sub-study on TXA administration (Proposal Number RC210170, Award Number W81XWH-22-1-0883) on 12 AUG 2022.
- ✓ U.S. Army Medical Research and Development Command, Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO), continuing review acceptance memorandum: 22 AUG 2022.
- ✓ U.S. Army Medical Research and Development Command, Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO), approved the Sub-Study on TXA administration on 07 OCT 2022.

Note: The research ethics protocol and applications submitted to the various institutions for approval, covers activities for both the pilot study (award number W81XWH1920055) and this main study.

(ii) Obtain signed letters of approval from research locations:

- We have obtained signed letters of approval for all 12 research sites. 10 sites provided us with copies of written facility approval in year 1. 2 new sites were added to the study in year 2, and provided us with copies of written facility approval (Appendix 2 and 3). All the EpiC research sites are as follows:
  - ✓ Khayelitsha Site-B (urban, free-standing emergency department) **added in year 2
  - ✓ Delft (urban, free-standing emergency department) **added in year 2
  - ✓ Tygerberg Hospital (trauma center)
  - ✓ Khayelitsha Hospital (urban, district)
  - ✓ Ceres Hospital (rural, district)
  - ✓ Worcester Hospital (rural, regional)

- ✓ Western Cape Government EMS, covering:
  - Tygerberg EMS Base
  - Khayelitsha EMS Base
  - Worcester EMS Base
  - Ceres EMS Base
- ✓ Forensic and Pathology Services
  - Worcester Lab
  - Tygerberg lab

(iii) Obtained Data Use/Share Agreements:

- The negotiated data share agreement between Stellenbosch University and UCD from year 1 remains valid and in effect.

(iv) Hire and train data collectors at research locations and troubleshoot data collection procedures:

- In year 1 we hired the core research data collectors to conduct data collection at all our study sites and have trained them on study methods and processes.
- In year 2 we hired and trained 3 additional data collectors.
- We routinely assessed data collection challenges with the data collectors, which often resulted in developing a more efficient workflow, writing more precise procedures, and/or updating our data dictionary. There were no major issues noted overall.

Major Task 1 Summary of year 2 Outputs:

- Ethics amendments and renewals approved by Stellenbosch and Colorado ethics boards
- Approval of continuing renewal and amendments from U.S. Department of Defense OHRO (Appendix 1)
- 2 new research sites added with letters of facility approval (Appendices 2 and 3)
- Additional data collectors hired and fully trained

Major Task 1 Milestones Achieved:

- All milestones were achieved in year 1
- No Task 1 milestones relevant to year 2

<u>Major Task 2: Data Collection</u>

(i) Troubleshoot data collection procedures

- This was completed in year 1 and is non-applicable to year 2

Table showing projected quarterly enrollment of human subjects (n=13,872 cases will be included in our final analysis, but due to missing data and exclusions, N=30,000 will need to be screened i.e., a 46% yield):

	Year 1				Year 2				Year 3				Year 4			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Enrollment targets:																
Urban sites	-	-	-	976	976	976	976	976	976	976	976	976	976	976	976	-
Rural sites	-	-	-	180	180	180	180	180	180	180	180	180	180	180	180	-
Overall accrual	-	-	-	**1156**	**2312**	**3468**	**4624**	**5780**	**6936**	**8092**	**9248**	**10404**	**11560**	**12716**	**13872**	-

Note: N=20,000 was in our original Stmt of Work, however the ethics boards approved us to screen N=30,000.

Figure 2: Projected quarterly subject enrollments, copied from Statement of work.

(ii) Collect hospital data (refine procedures, as needed)

- We collected data corresponding to 2663 hospital and free-standing ED (CHC) cases in year 2 (unique hospital/CHC encounters)
- Of these, 311 (12%) were incomplete at the end of project year 2 (i.e., requested records not yet returned to us). The goal will be to complete early in project year 3.

(iii) Collect EMS data (refine procedures, as needed)

- We collected data corresponding to 1589 unique EMS cases (1063 Primary Response and 524 interfacility transfers, 2 unknowns) in year 2.
- Of these, 2 (0.1%) were incomplete at the end of project year 2 (i.e., requested records not yet returned to us). The goal will be to complete these early in project year 3.

(iv) Collect autopsy data (refine procedures, as needed)

- We collected data corresponding to 62 deaths in year 2 (broken down: 61 hospital and 1 EMS death).
- Of these, 51 (82%) were incomplete at the end of project year 2 (i.e., requested records not yet returned to us). The goal will be to complete early in project year 3.

(v) A year 2 enrollment flow chart (STROBE) is included in Appendix 6

Major Task 2 Milestones Achieved:

- All Task 2 milestones were achieved in year 1
- No Task 1 milestones relevant to year 2

Major Task 3: Quality checks/data analysis

(i) Assess enrollment, monthly (early in study)

- We assessed the type and numbers of subjects enrolled each month in the first 6 months of year 2. We made some slight changes to help increase the numbers of patients enrolled monthly. We also revised our approach to select a higher proportion of acute patients.

(ii) Assess data quality, monthly (early in study)

- We assessed quality each month of year 2 through our data quality program. In the data quality program, we assessed extreme or inaccurate values, confusing case entries, and missing fields or data values. Quality assessments were organized into constructive feedback for data collectors.

(iii) Assess enrollment, every other quarter (later in study)

- In the latter 6 months of year 2, we assessed enrollment quarterly. Overall, we have enrolled the required number of cases.

(iv) Assess data quality, every other quarter (later in study)

- In the latter 6 months of year 2, we continued to closely assess the quality of our data through our data quality program. In addition to assessing extreme or missing values, confusing case entries, and missing fields or data values, we also assess inter- and intra-rater agreement among our data collectors. At all stages, we provided the data collectors detailed feedback to further improve their accuracy and quality of abstractions. We found overall high agreement within and between our data collectors. (See Appendix 4)
- Our entire data quality program is summarized in Appendix 5.

(v) Interim outcome analyses (semi-annually)

- We performed an analysis in mid-year 2, focused on the PCC subpopulation, those who received TXA, and those with wound infections.
- Another interim analysis for the entire population was begun at the end of year 2 and is on-going into early year 3.

(vi) Interpretation of interim analyses (semi-annually)

- The outcome of our analyses were that our database has the right types of data with adequate quality. However, we realized that we still have a large proportion of incomplete post-mortem records, which prevented subgroup analyses by physiologic causes of death (those records are being retrieved, and a plan is in place to help address this in project year 3).
- We also realized that to study infectious complications, we need to extend collection of infections past hospital day 7. We will add these variables into REDCap to accomplish this in years 3 and 4.

Major Task 3 Summary of Outputs:

- Case abstraction audits were utilized to improve the skills of data collectors (findings of inter- and intra-rater assessments are in Appendix 4)
- Data Quality Program was established and integrated into our team's daily work (see the overall design of the data quality program in Appendix 5)
- We enhanced our REDCap data collection instrument (to Version 3.1) and the corresponding data dictionary (Appendix 7)

<u>Major Task 4: Dissemination</u>

(i) Quarterly & annual technical reports to DoD sponsor
    - All reports were submitted on time
(ii) Present at military & scientific meetings/conferences
    - We presented at several military conferences, including Shoresh 2022, SOMSA, and MHSRS (See Section 6.1 for presentation details)
    - We presented at one civilian conference, 2022 Society for Academic Emergency Medicine (SAEM) (See Section 6.1 for presentation details)
(iii) Present to DoD platforms (at least, once annually)
    - We have had several in-person meetings and presentations with leaders from the Combat Casualty Care Research Program (CDR Travis Polk and Program Officer, Kimberly Polk) to discuss our progress and future opportunities.
    - We routinely invited our Science Officer, Dr. Erin Sanders, to participate in several in-progress meetings of the EpiC collaborators.
    - In May 2022, we also presented findings to Brig. Gen. Katherine A. Simonson and her team during a visit to the University of Colorado.
    - In March 2022, we presented findings from our network to Colonel (Dr.) Matthew P. Hanson, Surgeon General for Air Force Special Operations Command.
(iv) Final report to DoD
    - Not applicable to this year.
(v) Prepare scientific manuscripts
    - Peer-reviewed journal publication on the EpiC biostatistical methods (relevant to both pilot and main). (See Section 6.1 for citation)
    - Peer-reviewed journal publication on the AIS-ISS study (relevant to both pilot and main) – this was submitted Sep 2022. (See Section 6.1 for citation)
    - Peer-reviewed journal publication on the Preventable Mortality study (we used both pilot and main data) - this was drafted in Aug 2022, and we plan to submit for publication early in year 3.

Other Major Accomplishments:

- We were invited to present findings and experiences from our research network, including EpiC data, at the 2022 Shoresh Conference (USA-Israeli military medical biennial conference), in Rockville MD. (Appendix 8)
- Our abstracts were accepted for our team to present findings at the Special Operations Medical Assembly (SOMA) 2022 conference.
- Our project continues to be very positively received by South African trauma stakeholders and health community. The research collaboration continues to thrive. Examples of engagement activities that help to achieve this success include:
    - Preventable Trauma Death Review Panel: From 07-08 April 2022, we collaborated with the Stellenbosch Department of Surgery which convened a panel of 21 clinical experts in South Africa to review 140 traumatic deaths identified by the EpiC study to determine mechanisms/causes of death and preventability. We used a DOD death review methodology, and we were

closely advised by retired DOD medical examiner experts, Dr. Russ Kotwal and Dr. Edward Mazuchowski. South Africa trauma expert panelists determined preventability of death and scored each case. We compiled a report of results from the review panel, with a summary of key findings, preventability ratings, descriptive statistics of cases, and key recommendations. (Appendix 9).

- Preventable Trauma Summit: On 12 AUG 2022 we presented this report to South African study stakeholders, Emergency Medicine clinicians, and other interested parties (Appendix 10). Feedback from the South African stakeholders and participants involved in this sentinel mortality review was they perceived tremendous local value provided by the EpiC study. The findings we shared helped catalyze developments in the local trauma care system, including training efforts, resource allocation, and trauma staffing models.
- Khayelitsha & Ceres EMS Base Engagement: Members of our South Africa research team had engagements/meetings with the staff at two different EpiC EMS bases. Our goal was to sensitize the EMS staff about the EpiC study and to solidify their on-going endorsement and support of the EpiC study. Our research team presented some of the trauma findings from the study to catalyze discussion, build relationships, and gain their on-going support. The meeting was very successful. This engagement will be replicated at the other EMS bases.

3.3 What opportunities for training and professional development has the project provided?

The proposed study was not intended to provide formal training or professional development. Nonetheless, the following professional development activities have occurred:

South Africa Team Members

- Research staff: Research Medical Officers, Research Paramedics, Data Coordinator, and Project Manager participated in the case organization and preparation for the mortality panel review. Through their involvement and attendance on this panel, they gained expertise with clinical ethics and complex case presentations, as well as exposure to the social and health systems that intertwine with trauma.
- Collaborators (physicians): All collaborators participated in our quarterly meetings to discuss scientific progress and challenges, in which they enhanced their research knowledge. They also participated in technical writing (drafting and reviewing scientific manuscripts), including interpretation of results.
- Local trauma experts: Alongside our collaborators, there were over one dozen local experts in trauma, emergency, prehospital care, and pathology who all participated in our mortality panel review as experts. They learned the

methodology of conducting these reviews.

- Research staff: Gained expertise with anatomic injury severity scoring and high quality reviews and abstraction of medical records. They learned to present findings at weekly team meetings, and to work closely with international collaborators and scientists.

U.S Team Members

- UCD Program Manager (Chelsie Fleischer, MA)
  - Gained research, analytic, and scientific writing skills through participation and presentation in research/scientific conferences and report/manuscript writing.
- UCD research assistant (Chandni Patel, BS)
  - Gained research, analytic, and scientific writing skills via participation and presentation in the development of data collection tools, research/scientific conferences and report/manuscript writing.
  - Received training on designing and implementing a research data quality improvement program.
- UCD Research Associate, Epidemiologist (Navneet Baidwan, PhD)
  - Gained research, analytic, and scientific writing skills through participation and presentation in research and scientific conferences, writing grant submissions, writing manuscripts, and participation in analytic discussion, interpretations, and modeling.
- UCD Research Fellow (Smitha Bhaumik, MD)
  - Gained new knowledge and skills regarding technical writing, grant submissions, IRB applications, and protocol writing specifically involving trauma severity indicators and crush injury and syndrome.

3.4 How were the results disseminated to communities of interest?

- U.S. and South Africa research investigators meetings: We have held quarterly meetings with the EpiC study co-investigators and South Africa site leads in which updates on study status were presented, and study challenges are reviewed for solutions.
- Site visits by U.S. collaborators to South Africa: Dr. Mould-Millman (PI), Dr. Dixon (co-I), LTC Schauer (military co- I), Chandni Patel (research assistant), and Chelsie Fleischer (program manager) travelled to South Africa separately in FEB, APR, JUN, AUG, and SEP to conduct site visits, complete sub-projects, perform technical reviews, conduct focused re-training, and build relationships with South African stakeholders and collaborators. Team members, site leads and all collaborators were visited at all research sites and study processes were reviewed.
- Conferences/Symposiums: Our team has presented work at diverse scientific conferences and meetings to emergency medicine, prehospital medicine, and trauma field specialists, as well as to multiple military audiences (see Section 6 for a full list of conference presentation materials and journal publications).

3.5 What do you plan to do during the next reporting period to accomplish the goals?

Major task 3: Quality checks/data analysis

- Data collection will be continued until month 45 of the performance period.
- Data enrollment and quality will continue to be assessed throughout year 2 on a quarterly basis until the end of the study.
- We will complete interim outcome analyses and interpretation throughout the study and a final analysis and interpretation of data will be done at the end of the study.

Major task 4: Interpretation and Dissemination

- The outputs from this study will continue to be disseminated through quarterly and annual technical reports to the DoD, briefing to DoD leaders and commands, and disseminating our findings through scientific presentations and publications.

4. IMPACT

4.1 What was the impact on the development of the principal discipline(s) of the project?

- We continue to build a unique, high quality data set that can answer current and future questions in trauma resuscitation and prolonged care (both PFC and PCC). The dataset has relevance to the local South African system, to other resource-poor civilian settings, and to the U.S. military.
- We have developed a unique methodology and system to collect prolonged care data in a highly complex resource-poor civilian health system. Others may be able to learn from our successes and leverage the model we have created.
- We have used portions of our data to generate hypotheses useful to catalyze other areas of research, including: TXA, blood product resuscitation, antibiotic administration, pneumo-hemothorax management, and crush syndrome. These are topics of high interest to both the South African and the U.S. military health communities.
- We have generated some initial early findings that demonstrate that patients experiencing prolonged field or casualty care appear to have worse outcomes than those who do not experience prolonged care. This has military and civilian health relevance.

4.2 What was the impact on other disciplines?

Local medical communities affiliated with EpiC facilities are beneficiaries of the collaboration and the work. Forensic and Pathology medicine benefits from more detailed information on their cases via EpiC. Emergency and Trauma Care is solely managed by Family Medicine practitioners at some EpiC facilities. Public health in general benefits as the findings of this work are informing developments in trauma, which is a leading public health problem in South Africa.

4.3 What was the impact on technology transfer?

Not applicable

4.4 What was the impact on society beyond science and technology?

This project uses contemporary principles in global health and stakeholder engagement to help build enrichening, positive research collaborations and strengthen relationships between individuals and organizations in South Africa and the U.S. We have been able to provide relevant facility data on trauma outcomes directly back to study sites to support preventive efforts and better inform local public health policies. This project has already shown to further advance the worldwide image of the U.S. (both academic institutions and the U.S. government) as a collaborative and supportive global actor.

5. CHANGES/PROBLEMS:

Nothing to report

5.1 Changes in approach and reasons for change

Nothing to report

5.2 Actual or anticipated problems or delays and actions or plans to resolve them

A 2-month delay early in year 2 was the result of the Coronavirus (COVID-19) pandemic. We encountered several administrative, human resources, and enrollment issues associated with the COVID-19 pandemic in South Africa that slowed our progress. However, these were limited to the first 2-months of year 2 and the study is overall catching up nicely.

5.3 Changes that had a significant impact on expenditures

Nothing to report

5.4 Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to report

5.5 Significant changes in use or care of human subjects

Nothing to report

5.6 Significant changes in use or care of vertebrate animals

Not applicable

5.7 Significant changes in use of biohazards and/or select agents

Not applicable

6. PRODUCTS

6.1 Publications, conference papers, and presentations

Journal publications

1. Suresh K, Dixon JM, Patel C, Beaty B, Del Junco DJ, de Vries S, Lategan HJ, Steyn E, Verster J, Schauer SG, Becker TE, Cunningham C, Keenan S, Moore EE, Wallis LA, Baidwan N, Fosdick BK, Ginde AA, Bebarta VS, Mould-Millman NK. The epidemiology and outcomes of prolonged trauma care (EpiC) study: methodology of a prospective multicenter observational study in the Western Cape of South Africa. Scand J Trauma Resusc Emerg Med. 2022 Oct 17;30(1):55.

2. Bhaumik S, Suresh K, Lategan H, Steyn E, Mould-Millman NK. The New Injury Severity Score Underestimates True Injury Severity in A Low Resource Setting. Submitted to Injury 28 SEP 2022.

3. Mould-Millman NK, Keenan S; Dixon J, Steyn E, Lategan HJ, de Vries S, Mata LV, Patel C, Schauer SG, Fisher AD, April MD, Ginde AG, Bebarta VS. An Innovative Civilian Research Model to Inform Combat-Relevant Prolonged Casualty Care. U.S. Army Medical Journal. April-June 2022; 62-72.

4. Mould-Millman NK, Baidwan NK, Beaty B, Suresh K, Dixon JM, Patel C, de Vries S, Lategan HJ, Steyn E, Verster J, Schauer SG, Becker TE, Cunningham C, Keenan S, Moore EE, Wallis LA, Ginde AA, Bebarta VS. Prolonged casualty care: Extrapolating civilian data to the military context. J Trauma Acute Care Surg. 2022 Aug 1;93(2S Suppl 1):S78-S85.

Conference Abstract Posters and Oral Presentations: (Appendix 11)

1. Abstract Poster Presentation: *"Outcomes from Tranexamic Acid (TXA) in Traumatic Intracranial and Torso Hemorrhage: A Prospective Cohort Study in a High Trauma, Austere, Prolonged Care Setting."* *Presented* during the Special Operations Medical Association Scientific Assembly (SOMSA) Conference 2022, 03 MAY to 06 MAY 2022.

2. Abstract Poster Presentation: “Survivability of Trauma Patients Receiving Blood Products in a Civilian Prolonged Care Setting in the Western Cape Province of South Africa.” ***Presented*** during the Special Operations Medical Association Scientific Assembly (SOMSA) Conference 2022, 03 MAY to 06 MAY 2022.

3. Abstract Poster Presentation: “An Innovative Civilian Research Model to Inform Combat-Relevant Prolonged Casualty Care.” ***Presented*** during the Special Operations Medical Association Scientific Assembly (SOMSA) Conference 2022, 03 MAY to 06 MAY 2022.

4. Abstract Poster Presentation: “Survivability of Trauma Patients Receiving Blood Products in a High-Trauma International Setting.” ***Presented*** during The Society for Academic Emergency Medicine (SAEM) Conference 2022, 10 May to 13 May 2022.

5. Abstract Oral Presentation: “Tranexamic Acid (TXA) in Traumatic Hemorrhage: A Prospective Cohort Study in a High Trauma Setting.” ***Presented*** (oral) during The Society for Academic Emergency Medicine (SAEM) Conference 2022 on 09 May to 13 May 2022.

6. Abstract Oral Presentation: “The Injury Severity Score Under-estimates True Injury Severity in a Low Resource Setting.” ***Presented*** during The Society for Academic Emergency Medicine (SAEM) Conference 2022 on 12 May 2022.

7. Abstract oral presentation: “Extrapolating Civilian Prolonged Casualty Care Data to the Military Context.” Submitted to Military Health System Research Symposium (MHSRS) 13 SEP 2022.

8. Abstract poster presentation: Tranexamic Acid (TXA) in Traumatic Hemorrhage: A Prospective Cohort Study in a High Trauma Setting.” Submitted to Military Health System Research Symposium (MHSRS) 13 SEP 2022.

9. Abstract poster presentation acceptance: “Epidemiology and Outcomes of Prolonged Trauma Care (EpiC): Overview of a Major Trauma Cohort.” Accepted to the African Conference on Emergency Medicine 18 SEP 2022. To be presented 16 NOV 2022.

10. Abstract poster presentation acceptance: “Epidemiology and Outcomes of Prolonged Trauma Care (EpiC): Overview of the Prehospital Cohort.” Accepted to the African Conference on Emergency Medicine 18 SEP 2022. To be presented 16 NOV 2022.

11. Abstract oral presentation acceptance: “An Innovative Civilian Research Model to Inform Combat-Relevant Prolonged Casualty Care.” Accepted to the African Conference on Emergency Medicine (AfCEM) 18 SEP 2022. To be presented 16

NOV 2022.

12. Abstract oral presentation acceptance: “Survival from Tranexamic Acid (TXA) in Traumatic Hemorrhage: A Prospective Cohort Study in a High Trauma Setting.” Accepted to the African Conference on Emergency Medicine (AfCEM) 18 SEP 2022. To be presented 17 NOV 2022.

13. Abstract oral presentation acceptance: “Survival of Trauma Patients Receiving Blood Products in the Western Cape Province of South Africa.” Accepted to the African Conference on Emergency Medicine (AfCEM) 18 SEP 2022. To be presented 17 NOV 2022.

6.2 Books or other non-periodical, one-time publications.

Segar, S. (2022, Sep 08). High trauma caseload impedes delivery of healthcare services. Stellenbosch University News. http://www.sun.ac.za/english/Lists/news/DispForm.aspx?ID=9459 (See Appendix 12) ** Note: this was an effort by the South African collaborators, and this online publication was not an EpiC study product nor DOD-sponsored.

6.3 Other publications, conference papers and presentations.

Oral Presentation given by Dr. Nee-Kofi Mould-Millman: “Cape-Colorado-Combat (C3) Global Trauma Network: A Prolonged Civilian Casualty Care Research Platform.” 21 SEP 2022 Shoresh Military Medicine Conference. Rockville, MD. (Appendix 8)

6.4 Website(s) or other Internet site(s)

Nothing to report

6.5 Technologies or techniques

Nothing to report

6.6 Inventions, patent applications, and/or licenses

Nothing to report

6.7 Other Products

See appendices

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

7.1. What individuals have worked on the project?

Name:	Nee-Kofi Mould-Millman, MD PhD MSCS
Project Role:	Principal Investigator (UCD)
Researcher Identifier (ORCID ID):	0000-0003-4303-6903
Level of effort:	40% FTE
Contribution to Project:	Dr. Mould-Millman leads and oversees all aspects of the project activities.
Name:	Adit A. Ginde, MD MPH
Project Role:	Co-Primary Investigator (UCD)
Researcher Identifier (ORCID ID):	0000-0003-2325-206X
Level of effort:	3.0% FTE
Contribution to Project:	Dr. Ginde co-leads the project. He contributes content expertise in critical care and shock resuscitation, clinical research methodology and epidemiology.
Name:	Vikhyat S. Bebarta, MD
Project Role:	Co-Investigator (UCD)
Researcher Identifier (ORCID ID):	0000-0001-8816-1199
Level of effort:	1.5% FTE
Contribution to Project:	Dr. Bebarta provides content expertise in combat trauma casualty care and serves as civilian-military liaison. He assists with ensuring the study design and content are military-relevant and will guide the analysis and interpretation of results.
Name:	Julia Dixon, MD, MPH
Project Role:	Global Health Collaborator (UCD)
Researcher Identifier (ORCID ID):	0000-0002-9229-2658
Level of effort:	15% FTE
Contribution to Project:	Dr. Dixon's expertise is global health and trauma research in South Africa. She helps the PIs oversee day-to-day data collection, troubleshoots, and re-trains the data collection team as needed.
Name:	Steven G. Schauer, DO MSC
Project Role:	Co-Investigator (DoD)
Researcher Identifier (ORCID ID):	0000-0002-2322-5216
Level of effort:	N/A (DoD personnel)
Contribution to Project:	Dr. Schauer is the military subject matter expert in combat casualty care, emergency medicine, and prehospital medicine. He assists with study design, planning, military-relevant data collection, analysis, and interpretation of results.

Name:	Cord W. Cunningham, MD MPH
Project Role:	Co-Investigator (DoD)
Researcher Identifier (ORCID ID):	n/a
Level of effort:	N/A (DoD personnel)
Contribution to Project:	Dr. Cunningham provides military expertise in en route and prolonged trauma care. He assists with the design, planning, analysis, and interpretation of results, focusing on prolonged field care and EMS resuscitation.
Name:	Tyson Becker, MD
Project Role:	Co-Investigator (DoD)
Researcher Identifier (ORCID ID):	n/a
Level of effort:	N/A (DoD personnel)
Contribution to Project:	Dr. Becker provides military trauma surgical and critical care expertise. He assists with the design, planning, analysis, interpretation, and dissemination of results.
Name:	Krithika Suresh, PhD
Project Role:	Senior Biostatistician
Researcher Identifier:	n/a
Level of effort:	5% FTE
Contribution to Project:	Dr. Suresh provides expertise in biostatistics and has been preparing and reviewing the study database including statistical models that will be used in the study. She left UCD in July 2022.
Name:	Bailey Fosdick, PhD
Project Role:	Senior Biostatistician
Researcher Identifier:	n/a
Level of effort:	5% FTE
Contribution to Project:	Dr. Fosdick provides expertise in biostatistics and advises on data quality oversight, statistical models, and analytical methodology. She joined the team upon Dr. Suresh's exit.
Name:	Brenda Beaty, MS
Project Role:	Senior Data Analyst
Researcher Identifier:	n/a
Level of effort:	10% FTE
Contribution to Project:	Ms. Beaty has been developing, testing, and validating the study database in close coordination with the investigators and biostatistician.

Name: Project Role: Researcher Identifier: Level of effort: Contribution to Project:	Navneet Baidwan, PhD Injury Epidemiologist/Research Associate n/a 75% Dr. Baidwan has been assisting Dr. Suresh and Ms Beaty with the analysis, interpretation, modelling, and doing sub-investigations on TXA and blood products.
Name: Project Role: Researcher Identifier: Level of effort: Contribution to Project:	Chelsie Fleischer, MA Program Manager n/a 75% Ms. Fleischer has been managing project activities in Denver and South Africa and helping the co-PIs, investigators, and all collaborators to manage overall scientific progress.
Name: Project Role: Researcher Identifier: Level of effort: Contribution to Project:	Chandni Patel, BPH Research Associate n/a 50% Ms. Patel has been assisting the study team with IRB applications, development of REDCap data entry tools, REDCap database management, and development of a data quality program

7.2. Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Professor Lee Wallis (University of Cape Town site PI) left South Africa to pursue other career opportunities, his position was filled by Dr. Willem Stassen (faculty and research lead), Division of Emergency Medicine, University of Cape Town.

7.3. What other organizations were involved as partners?

1. **Stellenbosch University (SUN)**
   Location: Western Cape, South Africa
   Partner's contribution to the project: The Division of Emergency Medicine at SUN generally supports active emergency care, trauma, and prehospital research by providing administrative support, technical assistance and expert consultation and advice. SUN has provided human resources support for our team and has provided efforts to hiring relevant personnel for data collection. In addition, SUN has faculty who have clinical and research expertise in emergency medicine such as the site principal investigator (PI) for this project Dr. Hendrick J. Lategan. Dr. Lategan has conducted activities such as providing support to prime site PI, ethics documentation submissions, engage and sustain participation of facility collaborators and meet with study staff and

investigators. SUN also provides additional collaborators with expertise in trauma care, surgery, and forensic pathology. In addition, SUN has also hired a project manager Ms. Gadija Khan who ensures coordination and timely completion of all proposed research related activities across multiple sites in the Western Cape.

2. **University of Cape Town (UCT)**
   Location: Western Cape, South Africa
   Partner's contributions to the project: The Division of Emergency Medicine at UCT also supports over one dozen active emergency and prehospital care research protocols by providing administrative support, technical assistance and expert advice. Site PI Professor Lee Wallis (head of the Division of Emergency Medicine) has worked closely with the University of Colorado Denver on prior projects since 2011. Lee Wallis has served to recruit and retain participating hospitals proposed in this study. In JUL 2022 Willem Stassen, PhD, (Faculty of Emergency Medicine, University of Cape Town) joined EpiC as Site PI upon Professor Wallis' departure.

3. **Organization Name: Western Cape Government (WCG) Emergency Medical Services (EMS)**
   Location of Organization: Western Cape, South Africa
   Partner's contribution to the project: WCG EMS is the government operated EMS system in the Western Cape which provides primary and interfacility transports of trauma patients. Site PI, Dr. Shaheem de Vries, is the Medical Director of WCG EMS, and helps oversee the work performed at WCG EMS. Dr. de Vries' activities will include: ensuring continued WCG EMS institutional support of the study; ensuring EMS data is made available to data collectors; ensuring EMS study personnel are conducting study activities on schedule; ensuring timely and accurate reports are generated; ensuring local relevance and stakeholder support of the project.

4. **Organization Name: Denver Health and Hospital Authority**
   Location of Organization: Denver, Colorado
   Partner's contribution to the project: Co-Investigator Dr. Ernest Moore is a Professor of Surgery in the Division of Trauma within the Department of Surgery at Denver Health Medical Center. He is an independent federally-funded physician scientist with expertise in trauma care, post-injury coagulopathy, hemorrhagic shock, post-injury multiple organ failure, and prolonged field care. His previous appointments have included Chief of Division of Trauma and Chair of the Department of Surgery, at Denver Health. During his 40 years at Denver Health, he has over 1450 publications, been editor of the standard text Trauma. He has provided content advice and expertise in hemorrhagic shock and organ failure, as well as assisting in advice of the study design, future analysis, interpretation, and writing of results.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: Not applicable

QUAD CHARTS: See Appendix 13

9. APPENDICES

- Appendix 1 – Department of Defense OHRO Ethics Approval
- Appendix 2 – Site Approval for Khayelitsha Site B
- Appendix 3 – Site Approval for Delft
- Appendix 4 – Inter/Intra-rater Audit Report
- Appendix 5 – Data Quality Program
- Appendix 6 – STROBE enrollment diagram
- Appendix 7 – REDCap Version 3.1 Collection Forms
- Appendix 8 – Shoresh Presentation
- Appendix 9 – Mortality Panel Example Case
- Appendix 10 – Preventable Trauma Deaths Report
- Appendix 11 – Combined Abstract Posters and Oral Presentations
- Appendix 12 – SU News Article on Trauma Caseload
- Appendix 13 – QUAD Chart

Appendix 1 - DOD OHRO Ethics Approval

From:	Nancy Englar
To:	Hendrick Lategan; Mould-Millman, Nee-Kofi
Cc:	Tracey Harris; Kelsey Kilmon; Nancy Englar; Martin Escalona; Jennifer Shankle; Andrea Kline; Kimberly Odam
Subject:	E01863 Series - Continuing Review Acceptance Memorandum (Proposal Number BA190049, Award Number W81XWH-20-2-0042)
Date:	Tuesday, August 30, 2022 12:50:23 PM

[External Email - Use Caution]

SUBJECT: Continuing Review Acceptance for the Protocol, "Epidemiology and Outcomes of Prolonged Trauma Care (Epic): A Multicentre Prehospital Observational Study in the Western Cape.," Submitted by Hendrick Lategan, University of Stellenbosch, Stellenbosch, South Africa, in Support of the Proposal, "Epidemiology and Outcomes of Combat-Relevant Prolonged Trauma Care: a Prospective Multicenter Prehospital Study in South Africa," Submitted by Nee-Kofi Mould-Millman, M.D., University of Colorado Denver, Denver, Colorado, Proposal Log Number BA190049, Award Number W81XWH-20-2-0042, OHRO Log Number E01863 Series

1. The U.S. Army Medical Research and Development Command (USAMRDC), Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO) approved the following institutions which all rely on the Stellenbosch University Health Research Ethics Committee (HREC) for review, approval, and oversight of the above-referenced multi-site protocol. The OHRO received a continuing review report for the protocol on 11 August 2022. The Stellenbosch University HREC approved continuation of the protocol at the following sites on 25 August 2022; this approval will expire on 24 August 2023.

a. OHRO log number E01863.1a, University of Colorado Denver, Nee-Kofi Mould-Millman, MD, Non-enrolling site

b. OHRO log number E01863.1b, University of Stellenbosch, Hendrick J. Lategan, Site Enrollment 4295

2. This study has approval to enroll 30,000 subjects across all sites. As of the date of the continuing review report submission, the total number of subjects enrolled in this study was 4,295.

3. The Principal Investigator must provide the following post-approval submissions to the OHRO via email to usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil. **Failure to comply could result in suspension of funding.**

a. Substantive modifications to the research protocol and any modifications that could potentially increase risk to subjects must be submitted to the OHRO for approval prior to implementation. The USAMRDC OHARO OHRO defines a substantive modification as a change in Principal Investigator, change or addition of an institution, elimination or alteration of the consent process, change in the IRB of Record, change to the study population that has regulatory implications (e.g. adding children, adding active duty population, etc.), significant change in study design (i.e. would prompt additional scientific review), or a change that could potentially increase risks to subjects.

b. A copy of the IRB continuing review approval letter must be submitted to the OHRO as

soon as possible after receipt of approval. Please note that the OHRO conducts random audits at the time of continuing review and additional information and documentation may be requested at that time.

c. The final study report submitted to the IRB, including a copy of any acknowledgement documentation and any supporting documents, must be submitted to the OHRO as soon as all documents become available.

d. The following study events must be promptly reported to the OHRO by telephone (301-619-2165), by email (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil), or by facsimile (301-619-7803) or mail to the U.S. Army Medical Research and Development Command, ATTN: MCMR-RP, 810 Schreider Street, Fort Detrick, Maryland 21702-5000.

(1) All unanticipated problems involving risk to subjects or others.

(2) Suspensions, clinical holds (voluntary or involuntary), or terminations of this research by the IRB, the institution, the sponsor, or regulatory agencies.

(3) Any instances of serious or continuing noncompliance with the federal regulations or IRB requirements.

(4) The knowledge of any pending compliance inspection/visit by the Food and Drug Administration (FDA), Office for Human Research Protections, or other government agency concerning this clinical investigation or research.

(5) The issuance of inspection reports, FDA Form 483, warning letters, or actions taken by any government regulatory agencies.

(6) Change in subject status when a previously enrolled human subject becomes a prisoner must be promptly reported to the USAMRDC OHARO OHRO. The report must include actions taken by the institution and the IRB.

e. Events or protocol reports received by the OHRO that do not meet reporting requirements identified within this memorandum will be included in the OHRO study file but will not be acknowledged.

4. Please note: The USAMRDC OHARO OHRO conducts site visits as part of its responsibility for compliance oversight. Accurate and complete study records must be maintained and made available to representatives of the USAMRDC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.

5. Do not construe this correspondence as approval for any contract or grant/cooperative agreement funding. Only the Contracting Officer/Grants Officer can authorize expenditure of funds by notice of official award documentation. It is recommended that you contact the appropriate contract/grants specialist or Contracting/Grants Officer regarding the expenditure of funds for your project.

6. The OHRO point of contact for this study is Mrs. Kelsey Kilmon, B.S., Human Subjects Protection Scientist, at 301-619-2166/kelsey.a.kilmon.ctr@health.mil.

Nancy Englar, MHL, BSN, CIP
Chief, Clinical and Combat Casualty Care Research Review
Office of Human Research Oversight
Office of Human and Animal Research Oversight
Headquarters, U.S. Army Medical Research and Development Command
Fort Detrick, MD
https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo
nancy.e.englar.civ@health.mil

Please note: The Office of Research Protections (ORP) is now the Office of Human and Animal Research Oversight (OHARO). This name change communicates our mission to enable and oversee critical human and animal research within the command.

Appendix 2 - Site B approval

STRATEGY & HEALTH SUPPORT
Health.Research@westerncape.gov.za
tel: +27 21 483 0866: fax: +27 21 483 6058
5th Floor, Norton Rose House,, 8 Riebeek Street, Cape Town, 8001
www.capegateway.gov.za)

REFERENCE: WC_202008_107
ENQUIRIES: Dr Sabela Petros

Francie van Zijl Drive
Tygerberg
7505
Cape Town
South Africa

For attention: Prof Nee-Kofi Mould-Millman, Dr Hendrick Lategan, Dr Shaheem De Vries, Dr Lesley Hodsdon, Dr Sa'ad Lahri, Prof Johan Dempers, Dr Adeloye Adeniji, Prof Adit Ginde, Prof Vikhyat Bebarta, Dr Julia Dixon, Prof Ernest Moore, Dr Tyson Becker, Dr Cord Cunningham, Dr Steven Schauer, Prof Lee Wallis, Dr Willem Stassen, Dr Jaco Botes, Prof Elmin Steyn

Re: Epidemiology and Outcomes of Prolonged Trauma Care (EpiC): A Multicentre Prehospital Observational Study in the Western Cape.

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research.
Please contact the following people to assist you with any further enquiries in accessing the following sites:

Khayelitsha (Site B) CHC	**Dr Leigh Wagner**	**021 360 5228/ 5238**

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted and the constraints caused by the Covid-19 epidemic above are respected and adhered to.
2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final feedback (**Annexure 9**) within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
3. In the event where the research project goes beyond the *estimated completion* date which was submitted, researchers are expected to complete and submit a progress report (**Annexure 8**) and an updated ethics clearance letter to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
4. The reference number above should be quoted in all future correspondence.

Yours sincerely

PROF. V ZWEIGENTHAL
DIRECTORATE: HEALTH INTELLIGENCE
DATE: 8 April 2022
CC

Appendix 3 - Delft site approval

Western Cape Government
Health

STRATEGY & HEALTH SUPPORT
Health.Research@westerncape.gov.za
tel: +27 21 483 0866: fax: +27 21 483 6058
5th Floor, Norton Rose House,, 8 Riebeek Street, Cape Town, 8001
www.capegateway.gov.za)

REFERENCE: WC_202008_107
ENQUIRIES: Dr Sabela Petros

Francie van Zijl Drive
Tygerberg
7505
Cape Town
South Africa

For attention: Prof Nee-Kofi Mould-Millman, Dr Hendrick Lategan, Dr Shaheem De Vries, Dr Lesley Hodsdon, Dr Sa'ad Lahri, Prof Johan Dempers, Dr Adeloye Adeniji, Prof Adit Ginde, Prof Vikhyat Bebarta, Dr Julia Dixon, Prof Ernest Moore, Dr Tyson Becker, Dr Cord Cunningham, Dr Steven Schauer, Prof Lee Wallis, Dr Willem Stassen, Dr Jaco Botes, Prof Elmin Steyn

Re: Epidemiology and Outcomes of Prolonged Trauma Care (EpiC): A Multicentre Prehospital Observational Study in the Western Cape.

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research.
Please contact the following people to assist you with any further enquiries in accessing the following sites:

Delft CHC	**Ms Nolubabalo Fatyela**	**0219542237/82**

Kindly ensure that the following are adhered to:

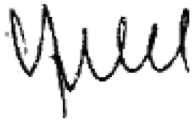
1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted and the constraints caused by the Covid-19 epidemic above are respected and adhered to.
2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final feedback (**Annexure 9**) within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
3. In the event where the research project goes beyond the *estimated completion* date which was submitted, researchers are expected to complete and submit a progress report

(**Annexure 8**) and an updated ethics clearance letter to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).

4. The reference number above should be quoted in all future correspondence.

5. You are required to notify the substructure office when you commence with your study at the above-mentioned facility(ies) and inform them when you have completed the study at the facility. **Northern- Tygerberg Substructure:** Ms Terri Lemmetjies - 021 815 8559 Terri.Lemmetjies@westerncape.gov.za.

Yours sincerely



PROF. V ZWEIGENTHAL
DIRECTORATE: HEALTH INTELLIGENCE
DATE: 8 April 2022
CC

Appendix 4 - Inter/Intra-rater Audit Report

Internal Audit Assessing the Reliability of Data Entry for Randomly Selected EpiC Cases

Date of Audit: July 25-27, 2022 (analysis conducted in August 2022)

Approach: The presence and strength of associations observed in large scale epidemiologic studies strongly depends on the quality of the data collected. A key component of quality is reliability (or consistency) of data entry amongst a team of data collectors. Standardization of procedures is crucial in multicenter studies to ensure all data collectors are abstracting information from medical records into the REDCap study database in a uniform way to avoid misclassification bias and ensure reproducibility. A good quality management program includes quality assurance activities to ensure quality before data collection begins (i.e., detailed manual of operations to reduce bias) and quality control activities to monitor and maintain the quality of the data during the conduct of the study (i.e., inter-rater reliability assessments). Additionally, quality improvement activities (i.e., re-training staff) are essential to remediate errors found during quality control.

Each quarter, EpiC performs an inter- and intra-rater reliability (i.e., consistency of entry within and among data collectors) assessment as part of a larger quality management program. Four completed cases are identified from REDCap that meet the following criteria:

1. High Complexity Case, defined as any case with an Intensive Care Unit (ICU) admission that falls within 73hour-7day after injury.
2. Medium Complexity Case, defined as any case with an ICU admission up to 72-hours, or ward admission beyond 72-hours, or any deceased case.
3. Low Complexity Case, defined as anything below moderate complexity.

At least 1 low, 1 moderate, and 1 low complexity case is chosen each quarter for review. A fourth case may be selected based on particular variables of interest (i.e., a crush injury patient, or a case that is seen at multiple hospitals) and dependent on time constraints (ex: if the length of one case is 10+ days, a fourth case will not be included). All cases must have originally been entered 3+ months prior to the activity to avoid bias resulting from the data collector remembering the case and how they originally abstracted it. Cases are hand delivered to each data collector to mimic their every-day process of using printed medical charts for abstraction (versus an electronic medical record). The data collectors are given a 3-day window to complete this activity between their day-to-day tasks, and the U.S. team PRA will immediately download and analyze the data.

Analysis

In Microsoft Excel all cases were compared for discrepancies. Entries that differed amongst 5 Hospital Data Collectors (AK, SW, SB, AA, AA, SM) for hospital data, and amongst the 2 EMS Data Collectors (FM, DV) for the pre-hospital data, were flagged as an inter-rater disagreement. Additionally, the original REDCap entry was compared to the re-entry for this activity and any discrepancies were flagged as an intra-rater disagreement. The total % Agreement is calculated for each form and as an overall total. Moreover, the trend is compared to previous activities to ensure continued improvement.

Any variables that differed across the group will be discussed at a team-wide meeting. At which time, any corrections to the original case entered in REDCap will be performed. The study PIs will determine if additionally all applicable cases need to be reviewed as well.

Findings:

From the July 25-27, 2022 Audit, 2 cases were reviewed instead of 3-4 because both were lengthy hospital stays and one of them touched multiple hospital sites.

- ***Case 1:*** This was a high complexity, long stay case that involved Site B Community Health Centre, Khayelitsha Hospital, and Tygerberg Hospital. This case included many variables of interest (unknown injury time, various interventions and surgeries, and a long ICU stay).
- ***Case 2:*** This was a moderate complexity case that was only seen at Ceres Hospital, but it covered an important variable of interest – crush injury.

From this audit, the inter-rater percent agreement was 83.5%, which has stayed stable in the main phase of EpiC. The Intra-rater agreement went down (by 2.9%), but this cannot be interpreted as a downward trend due to team turnaround. In October 2021 AK, AD, and SB conducted the audit, whereas in July 2022 AK, SB, SW, AA, AA, and SM conducted the audit.

The following categories were identified as areas for improvement:

- Incident Location Details
- Diagnoses
- Infectious Complications
- Vital Sign Ranges
- Phase of Care and Unit of Care Start/End times
- Crush Syndrome Coding

	% Agreement		
Overall Agreement	**October 2021**	**April 2022**	**July 2022**
Inter-Rater			
Hospital	83.5%	N/A (Mortality Panel)	83.5%
EMS	N/A	N/A	95.9%
Intra-Rater			
Hospital	93.9%		91.0%
EMS	N/A		95.9%

Next steps:

After the audit, an in-person meeting was held where all flagged variables were thoroughly reviewed by the study investigators and discussed as a team. Over the next 2-weeks, updates to the data dictionary and REDCap were made to add clarity on how EpiC would like these variables captured. Additionally, the original cases were updated in REDCap and there was no major change that impacted cases entered up to this point.

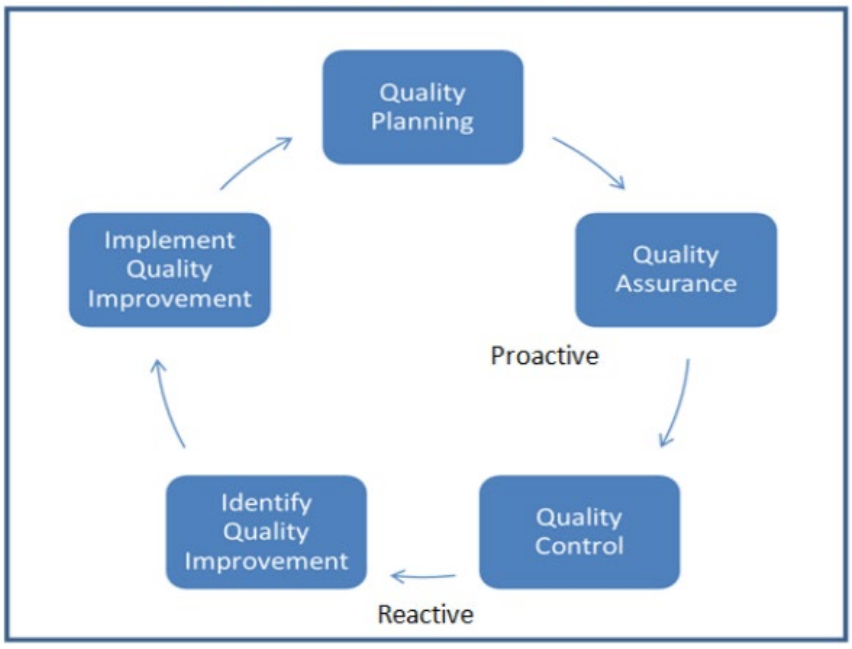
Appendix 5 - Data Quality Program

EpiC Data Quality Management Program

Quality Control	Quality Assurance	Quality Improvement
• Systematically ongoing process to check protocol and regulatory adherence • During and after data collection • Identify and correct sources of data errors • **Example: Completeness checks and site visits**	• To ensure data are of highest quality at the time of collection • Undertaken before data collection • Ensure data is collected in accordance with procedures and that the data stored in the registry database meet the set standards of quality, which are generally defined based on the intended purposes • **Examples: clear and extensive study design and training of data collectors**	• Involves Evaluation and education

Quality Management Program: a plan or system, including structure and defined responsibilities, which provides a framework for all quality management activities. Components of quality management plan: [1] Quality Assurance, [2] Quality Improvement, and [3] Quality Control, as well as reporting these activities.

Figure 1: Quality Management Cycle



Source: http://capmf.cio.ca.gov/pdf/templates/samples/STO_DMSII_QualityManagementPlan.pdf

Quality Assurance Tier	Process	Frequency of Process	Implementation Date	Who?
Ensuring quality prior to data collection	• Training/Onboarding all data collectors	Upon hire	Dec 2020	JD, NK, GK
	• Ensuring all staff have access to up to date study protocol, data dictionary, and all relevant study procedural documentation.	Upon hire and as updates are made	Dec 2020	CP
	• Data limit warning messages in REDCap (e.g., max., min, integers only) to reduce transcription errors.	Pre-data collection	Dec 2020	LM, CP
Ensuring data quality at point of data collection and data entry	• Data collector reviewing their work prior to marking the REDCap form as complete.	Daily - per each form	Dec 2020	SRA
	• Secure communication system between all data collectors, particularly for complex cases (i.e., those transferred to multiple sites in a single medical encounter).	Daily - case by case	Dec 2020	SRA
	• Prompt communication by project managers to study team about new study procedural changes, updates in variable definitions, changes in value options, etc.	As changes are made	Dec 2020	NK, JD, CP
Peer support/ Ongoing Training	• Team meetings between all data collectors to pose challenging situations/cases to each other and discuss consistent approaches for data abstraction and brainstorm solutions for any discrepancies identified.	As cases/issues are identified (typically this occurs weekly)	Jan 2021	SRA, CP
	• Twice a year take the entire team offline for re-training activities. One activity will be a study review, which includes reviewing the data dictionary and all pertinent study procedural documentation and e-mailing the project managers with the following: (1) questions that came up, (2) what new information did the learn, and (3) what updates they suggest should be made.	Bi-annually	Jan 2021	SRA, NK, JD, CP
	• Detailed process and infrastructure for training new staff (materials for training should always be available to account for any unanticipated turnover of data collectors).	Yearly	Jan 2020	LM, GK, NK, JD
Physician-investigator engagement	• Data collectors will present challenging cases to review with physician-investigators; this ensures data are satisfying purpose of the study and variables are being entered consistently.	Bi-weekly	Jan 2020	RMOs, NK, JD
	• Study Investigators, Study Site Leads, and Project Managers will shadow data collectors' day-to-day processes. At least one study staff member will be on site every month to monitor activity.	Monthly	Jan 2021	NK, JD
	• Project Managers and Study Investigators to review challenging cases flagged by the SA Data Coordinator.	As cases come up	Jan 2020	LM, FM, NK, JD

Data Quality Control	Process	Frequency of Process	Implementation Date	Who?
Data Cleaning	• Correction of data problems, including missing values, incorrect or out of range (outlier) values, responses that are logically inconsistent with other responses in the database, and duplicate patient records. • See Appendix # for a list of all applicable variables	Weekly	Mar 2021	NB, CP

	• **invalid entries** (multiple selections in a single-choice field, alphabetic data in a numeric field)
	  • REDCap limits on choice selection (if none is selected, other options cannot be selected), restrictions on numeric value fields to only allow numbers to be inputted.
	  • See Appendix # for a list of all applicable variables
		Pre-data collection	Mar 2021	LM, CP

	• **Erroneous entries** (e.g., patients of the wrong gender answering gender-based questions)
	  • This can be captured from SAS reports.
	  • See Appendix # for a list of all applicable variables
		Monthly	Feb 1 2022	NB

	• **Inconsistent data** (e.g., an answer to one question contradicting the answer to another question) • See Appendix # for a list of all applicable variables	Monthly	Feb 1 2022	NB, CP
	• **Data Frequency Reports** (to identify which variables have more missingness and remediate any problematic variables) • These reports are run on all variables	Every 3 months	Jan 2021	BB, CP

Detecting Outliers	• Perform statistical summaries, such as means and standard errors. Use graphical methods (normal probability plots, regression plots, or scatter plots) using SAS or Excel. We can also subtract values from the mean of that particular variable, presence of outliers can become apparent using SAS or Excel.
	  • This will help detect Errors in data entry — for example, a laboratory value of 2.0 entered as 20, that are not caught through REDCap min and max ranges.
	  • See Appendix # for a list of all applicable variables
		Bi-weekly	Jan 10 2022	NB, CP

Site Visits	• Site visits to monitor data abstraction and data entry processes. ○ Project Managers and Study Investigators to complete this.	Quarterly	March 2020	NK, JD, SS
Remediate Data Problems	• Query the data collector to resolve the problem through DQL. Documentation of any data review activity and remediation efforts, including dates, times, and results of the query, should be maintained. Query reports in REDCap will be generated on a weekly basis.	Weekly – as queries are identified		CP, RMOs

Ensuring inter- and intra-rater reliability (consistency)	• **Intra-rater agreement:** Each data collectors re-abstract one of their own records to monitor variations in their own data entry. These records will be selected randomly by the US Team.
	  • All findings will be discussed in a team meeting
	  • Data agreement is determined to be very high (≥95%), high (94%–90%), high-moderate (89%–85%), moderate (84%–80%), low-moderate (79%–75%), low (74%–70%), and very low (>70%).
	  ➢ If data agreement falls below 90%, the cause of error will be investigated and remediated.
		Every other month	Jan 2020	CP, GK, NB

	• **Inter-rater agreement:** All team members enter the same case to ensure they are 95% consistent. This task is beneficial to recognize errors in interpretation or coding of variables.
	  • Cases will be randomly selected by the US Team (4 cases every other month).
	  • Randomly selected from a pre-defined list of cases, which includes:
	  i. All deaths
	  ii. All CPR Cases
	  iii. All Cases with an ICU admission AND days 3-7 forms
	  iv. All Cases with an ICU admission u to 72 hours or ward admission beyond 72hours
	  • Data agreement is determined to be very high (≥95%), high (94%–90%), high-moderate (89%–85%), moderate (84%–80%), low-moderate (79%–75%), low (74%–70%), and very low (>70%).
	  ➢ If data agreement falls below 95%, the cause of error will be investigated and remediated.
		Every other Month	Jan 2021	CP, NB, GK, RMOs,

	An example of benefit of this activity: two abstracters looking for the same data element in a patient's medical record but extracting different values from the same chart. Variations in coding of specific variables falls under the category of interpretive errors and impacts the reliability of data. Avoidance or detection of			

	interpretive error includes adequate training on definitions, testing against standard charts, reporting from intra-rater and inter-rater reliability activities.			

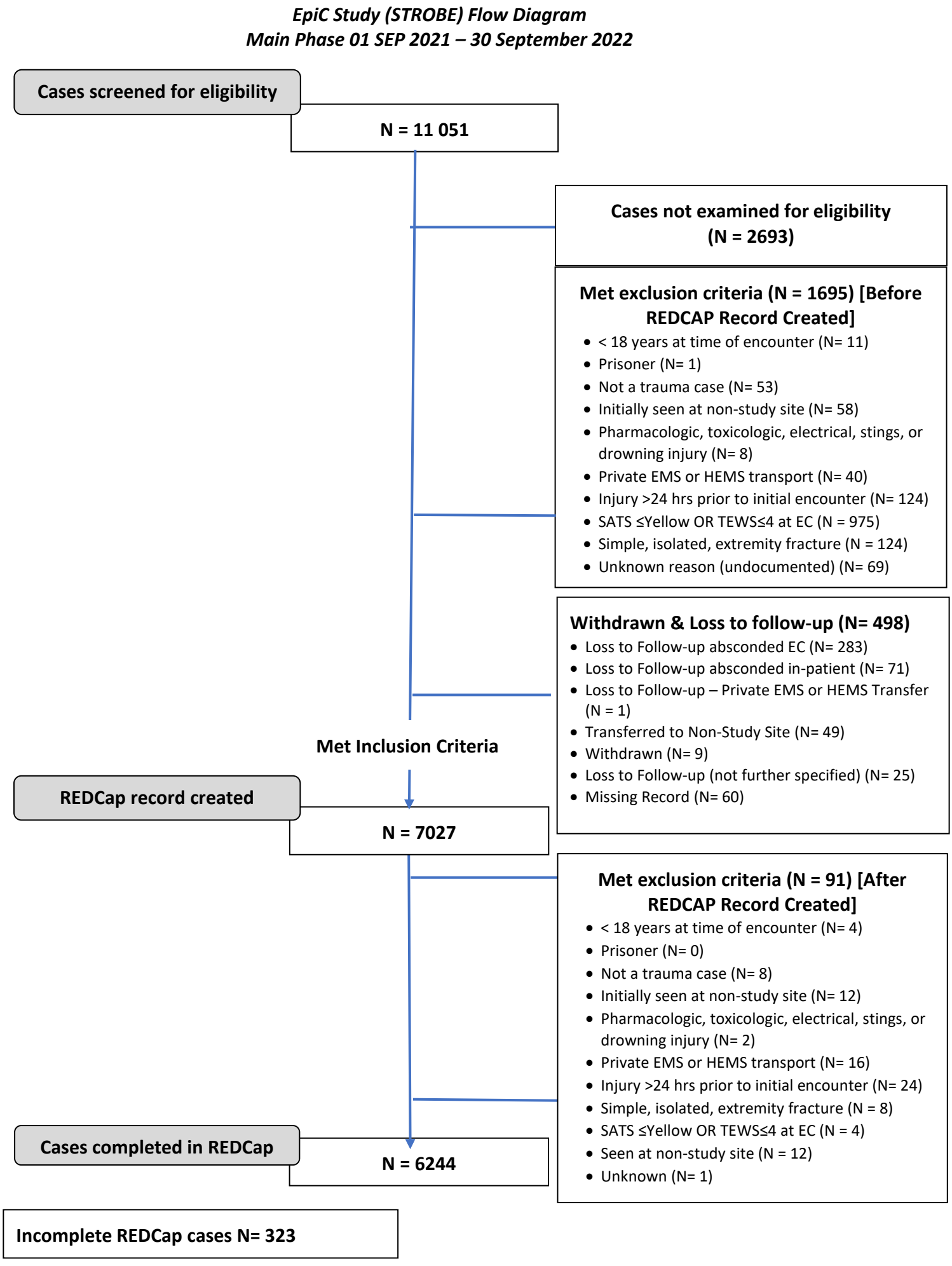
Accuracy: Extent to which collected data are in conformity to the truth. JD CP every other month

Key Components of Data Quality Improvement	Process	Frequency of Process	Implementation Date	Who?
Completeness	• Monitoring of screened patients to ensure the correct cases are being partially or fully abstracted (and to review cases by inclusion and exclusion criteria, in case some were accidentally included).	Weekly	Jan 2022	CP

	• The frequency of unknown variables:
	  • "When completeness rate falls below 80-90%, the possibility of unknown selection bias compromises the integrity of the database." Review any variable marked as unknown for more than 10-20% of cases. Pre-set coding will be created which will automate this process and distinguish between variables that are appropriately versus inappropriately missing.
	  • Data completeness is determined to be very high (≥95%), high (94%–90%), high-moderate (89%–85%), moderate (84%–80%), low-moderate (79%–75%), low (74%–70%), and very low (>70%).
		Every 3 months	Jan 2021	BB

Case Log Review & STROBE reporting	• Case Log will be cleaned weekly to remove all excluded cases from the study database and to ensure all relevant fields are completed. Team members will be re-trained if errors are consistently identified. • A STROBE diagram will be created monthly to visually represent the flow of patients.	Weekly Monthly	Jan 2021 Mar 2021	CP, FM FM, CP
Weekly Metrics	• Ensure REDCap and Case Log consistency • Re-training	Weekly As needed	Dec 2021 Dec 2021	CP CP
Corrections	• All inaccurate data will be corrected and incomplete data filled in within 1 week of identifying the issue when the patient's chart is available.	Weekly	Jan 2021	RMOs

Appendix 6 - STROBE enrollment flow diagram



Appendix 7 - REDCap Collection Forms V3.1

Demographic and Injury Information

Record ID Field 4999

Patient Case Information

Study ID No. 6 characters remaining	**PMI (Folder No.)** 9 characters remaining
Initial Encounter Date (WC EMS or Hospital) D-M-Y	**Initial Encounter Time (WC EMS or Hospital)** H:M
Highest TEWS Score	**Worst SATS Color** ○ Red ○ Orange ○ Yellow ○ Green ○ Blue
Patient transported by WCG EMS? ○ Yes ○ No	**Patient Receiving Facility (Initial Facility)** ○ Ceres Hospital ○ Delft CHC ○ Khayelitsha Hospital ○ Site B CHC ○ Tygerberg Hospital ○ Worcester Hospital

Demographic Information

Patient's First Name	**Patient's Surname**
Date of Birth D-M-Y	**Patient's Calculated Age** **Patient's Estimated Age**
Patient's Sex ○ Male ○ Female	**Uniform Patient Fee Schedule** ○ H0 (or F) Full Subsidisation ○ H1 Partial Subsidisation ○ H2 Partial Subsidisation ○ H3 Partial Subsidisation ○ P Full paying patient

Past Medical History

Comorbidities / Pre-Existing Conditions			
Diabetes Mellitus		**HIV/AIDS**	
Yes ○	No ○	Yes ○	No ○
Hypertension		**Tuberculosis**	
Yes ○	No ○	Yes ○	No ○
Other		**Other Pre-Existing Conditions (Click all that apply)**	
Yes ○	No ○		

Daily Medication Taken							
Blood Thinners		**HIV Medication**		**Opiates**		**Sedatives**	
Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
○	○	○	○	○	○	○	○
Blood Pressure Medication		**Beta-Blockers**					
Yes	**No**	**Yes**	**No**				
○	○	○	○				

Chief Complaint

* must provide value

- ○ Animal Bite
- ○ Assault
- ○ Burn Wound
- ○ Fall
- ○ Gunshot Wound
- ○ Head Injury
- ○ Limb Injury
- ○ Motor Vehicle Collision
- ○ Stab Wound
- ○ Wound
- ○ Miscellaneous / Other Injury

Injury Event Details

Injury Event Date D-M-Y	**Injury Event Time** UNK H:M **Unknown (UNK)**	**Using available information (e.g., injury severity, EMS times, hospital arrival times, dates and statements in the documentation), please indicate which window of time the injury likely occurred:** ○ Shortly prior to encounter (< 1 hour prior to initial encounter) ○ A few hours ago (1 to 3 hours prior to initial encounter) ○ In the morning (between 06:00 - 12 noon) ○ In the afternoon (between 12 noon - 18:00) ○ In the evening (between 18:00 - midnight) ○ During the night (between midnight - 06:00)
Incident Location		
Street Number	**Street Name**	**District**
Municipality	**City**	**Suburb** **4-Digit Code** 4 characters remaining
Activity when Injured ○ Work, including travel for work (e.g. truck driving) ○ Education, including school sports ○ Sports ○ Leisure/play ○ Travelling not elsewhere classified ○ Other	**Place of Injury** ○ Private house/home (including yard) ○ Residential institution ○ Medical service area ○ Street/highway/road ○ Railway line/station ○ Trade/service area ○ Industrial and construction area ○ Farm or place of primary production ○ Sea, lake, river, dam, borehole, well ○ Sports/athletic area ○ School, institution or educational area ○ Public administrative area ○ Open land, beach, forest, desert ○ Other	**Alcohol Use** ○ Suspected (by report or observation) ○ Confirmed by biological evidence ○ No use - by report or observation or biological evidence ○ No information available **Psychoactive drug/Substance Use** ○ Suspected (by report or observation) ○ Confirmed by biological evidence ○ No use - by report or observation or biological evidence ○ No information available

Dominant Mechanism of Injury

Mechanism

- ○ Firearm
- ○ Struck/hit
- ○ Stabbing or cut
- ○ Vehicular Injury
- ○ Fall
- ○ Thermal
- ○ Choking/hanging
- ○ Iatrogenic
- ○ Other

If Vehicular Injury:

Patient Mode of Transport

Road User

Patient Crashed into?

Intent

- ○ Unintentional (or accidental)
- ○ Intentional: self-harm or suicide
- ○ Intentional: assault/homicide
- ○ Legal intervention/war operations
- ○ Forces of Nature
- ○ Undetermined

Assault Relationship (If intentional assault selected)

Injury Force Type

Sexual Assault?

- ○ Yes
- ○ No

Body Injury Location

- ☐ Head
- ☐ Face
- ☐ Neck
- ☐ Thorax
- ☐ Abdomen
- ☐ Pelvis
- ☐ Spine
- ☐ Upper extremity
- ☐ Lower extremity
- ☐ External (skin)
- ☐ Other (e.g. vaginal, anal)

Protective Devices

- ☐ Seat belt
- ☐ Helmet
- ☐ Protective clothing
- ☐ Unrestrained vehicle driver/passenger
- ☐ None applicable

Description of Mechanism of Injury (Free text)

Additional Mechanisms of Injury

- ☐ None
- ☐ Firearm
- ☐ Struck/hit
- ☐ Stabbing or cut
- ☐ Vehicular Injury
- ☐ Fall
- ☐ Thermal
- ☐ Choking/hanging
- ☐ Iatrogenic
- ☐ Other

If Vehicular Injury:

Patient Mode of Transport

Road User

Patient Crashed into?

Severity Scoring

No. AIS	AIS Body Region	AIS Anatomical Structure	AIS Nature of Injury	AIS Level	AIS Severity
AIS 1					
AIS 2					
AIS 3					
AIS 4					
AIS 5					
AIS 6					
AIS 7					
AIS 8					
AIS 9					
AIS 10					

Form Last Updated by:

* must provide value

Mark an option when you completed your patient record review and data entry:

- [ ] EMS
- [ ] KHA
- [ ] TBH
- [ ] WOC
- [ ] CRS

Date and time of last form update:

* must provide value

D-M-Y H:M

Only mark this form as complete if all forms relevant to this patient's entire medical encounter are completed (EMS, all hospital encounters, FPS).

Please be sure to update transfer status when applicable.

Form Status

Complete? Incomplete

EMS

Record ID Field 4999

EMS Agency Details

EMS Case Ref. No (Year)	EMS Case Ref. No (Month)	EMS Case Ref. No (Day)	EMS Case Ref. No (4 Digit No)	EMS Case Ref. No (Letter)
			4 characters remaining	○ A ○ B ○ Other **Other:**

Upgrade	Type of Service Requested	Is the ePCR Documentation Missing?
	Private Interfacility Transfer	○ Yes ○ No

EMS Transportation Details

Injury Event Date	Injury Event Time	Dispatch Center Notification Date/Time
D-M-Y	H:M	D-M-Y H:M
Dispatch Unit En Route Time	**Arrived at A Time**	**Depart A Time**
H:M	H:M	H:M
Arrived at 1st B Date	**Arrived at 1st B Time**	**Sending facility if IFT**
D-M-Y	H:M	○ Ceres Hospital ○ Delft CHC ○ Khayelitsha Hospital ○ Site B CHC ○ Tygerberg Hospital ○ Worcester Hospital ○ Other
Receiving Facility/Unit	**Provider 1 Rank**	**Provider 2 Rank / HPCN**
Facility ○ Ceres Hospital ○ Delft ○ Khayelitsha Hospital ○ Site B CHC ○ Tygerberg Hospital ○ FPS Tygerberg ○ FPS Worcester ○ VULA site ○ Worcester Hospital **Unit** ○ Emergency Centre ○ Operating theatre ○ Ward ○ Intensive Care Unit ○ Other	○ BLS ○ ILS ○ ECT ○ ALS ○ ECP ○ Doctor **Health Profession Council Number**	○ BLS ○ ILS ○ ECT ○ ALS ○ ECP ○ Doctor **Health Profession Council Number**

EMS Triage and Vital Signs

EMS South African Triage Scale (SATS)

Time H:M

TEWS

SATS Colour
- ○ Red
- ○ Orange
- ○ Yellow
- ○ Green
- ○ Blue

Vital Signs

Type of vital signs
* must provide value
- ☐ First Vital Signs
- ☐ Second Vital Signs
- ☐ Third Vital Signs
- ☐ Last Vitals Signs
- ☐ None

Prehospital Procedures

Airway

Main airway Procedure Type
* must provide value
- ○ Chin lift / Jaw Thrust Maneuver
- ○ Oropharyngeal airway (OPA)
- ○ Nasopharyngeal airway
- ○ Supraglottic airway (Combitube)
- ○ Supraglottic airway (Laryngeal tube)
- ○ Supraglottic airway (Laryngeal mask airway (LMA))
- ○ Endotracheal tube (ETT)
- ○ Endotracheal tube (ETT) Insitu
- ○ Surgical Airway
- ○ Suction
- ○ None indicated (appropriate)
- ○ None performed although indicated (inappropriate)
- ○ Other

Breathing

Breathing Intervention
* must provide value
- ○ Yes
- ○ No

Circulation

Circulation Interventions
* must provide value
- ○ Yes
- ○ No

Disability

Disability Interventions
* must provide value
- ○ Yes
- ○ No

Exposure

Exposure Interventions
* must provide value
- ○ Yes
- ○ No

Prehospital Medication

Medication Administered

Medication Administered
* must provide value
- ○ Yes
- ○ No

IV Medication Infusions Continued

Medication Infusions Continued in Transport
* must provide value
- ○ Yes
- ○ No

EMS Case Outcome

Did patient die during EMS transport?
* must provide value

Date and Time EMS Form Completed?
* must provide value
D-M-Y H:M

Form Status

Complete? Incomplete

Delft Admission Details

Record ID Field	4999
Patient Transport and Transfer Information	
Receiving Facility * must provide value	○ Ceres Hospital ○ Delft CHC ○ Khayelitsha Hospital ○ Site B CHC ○ Tygerberg Hospital ○ Worcester Hospital
Facility Units of Care	
CHC Arrival Mode * must provide value	○ Western Cape EMS ○ Other EMS ○ Non-EMS
Phases of Care	
Phases of Care * must provide value	☐ Initial Resuscitation ☐ Intensive Care ☐ Non-Resuscitative EC Care
Form Status	
Complete?	Incomplete

REDCap

Delft Encounter

Record ID Field 4999

Entire Encounter at Facility

South African Triage Scale (SATS) Upon Facility Arrival	
Date D-M-Y	**Time** H:M
TEWS	**SATS Colour** ○ Red ○ Orange ○ Yellow ○ Green ○ Blue

Vital Signs

Select corresponding vital signs Recorded

* must provide value

- ☐ First Vital Signs
- ☐ Last Vital Signs
- ☐ Vital Sign Ranges (If three or more sets of vitals available)
- ☐ None

Laboratory Values

Complete Blood Count		**Chemistry**		**INR**		**Urinalysis**	
Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
○	○	○	○	○	○	○	○

Imaging

Imaging Modality and Body Part	**Imaging Results and Description**
X-Ray **None** ☐ **Head** ☐ **Face** ☐ **Neck** ☐ **Thorax** ☐ **Ab/P** ☐ **Spine** ☐ **UE** ☐ **LE** ☐ **Bony pelvis** ☐	▾ **Abnormality Description** 30 words remaining
General Ultrasound **None** ☐ **Head** ☐ **Face** ☐ **Neck** ☐ **Thorax** ☐ **Ab/P** ☐ **Spine** ☐ **UE** ☐ **LE** ☐ **Bony pelvis** ☐	▾ **Abnormality Description** 30 words remaining

Non-surgical Hospital Procedures

Non-surgical Hospital Procedures (check all that apply)

* must provide value

- [ ] Airway Management
- [ ] Backboard
- [ ] Bleeding Control (foley)
- [ ] Cardiocentesis
- [ ] Chest seal (vented or non-vented)
- [ ] CPR
- [ ] C-spine immobilization
- [ ] Embolization
- [ ] Extremity Splints
- [ ] Manual Pressure
- [ ] Needle decompression
- [ ] Oxygen Administration
- [ ] Pelvic Binder
- [ ] Positive Ventilation Initiated (CPAP or BiPAP only)
- [ ] Pressure dressing
- [ ] Reduction (for fracture)
- [ ] Reduction (for dislocation)
- [ ] Rewarming (e.g., warm IV fluids)
- [ ] Sedation (conscious or deep)
- [ ] Thoracostomy/Chest Tube
- [ ] Tourniquet
- [ ] Withdrawal From Life Support
- [ ] Wound Care
- [ ] None

Medication Administered

Fluids

Fluid Type

* must provide value

- [ ] None
- [ ] Normal Saline
- [ ] Dextrose 5%
- [ ] Dextrose 10%
- [ ] Dextrose 50%
- [ ] Ringers Lactate
- [ ] Hypertonic saline
- [ ] Other

Blood Products

Type of Blood Product Administered

* must provide value

- [ ] None given
- [ ] Cryoprecipitate
- [ ] Packed Red Blood Cells
- [ ] Plasma
- [ ] Platelets
- [ ] Whole Blood
- [ ] FD Plasma
- [ ] Other

Analgesia

Oral Analgesia given in first 24 hours (check all that apply)

* must provide value

- [ ] None
- [ ] Tramadol
- [ ] Paracetamol
- [ ] Ibuprofen
- [ ] Other

IV or IM Analgesia

* must provide value

- [ ] None
- [ ] Morphine
- [ ] Fentanyl
- [ ] Paracetamol
- [ ] Ketamine
- [ ] Other

Other Medication

Other Medication Administered

* must provide value

- [ ] None
- [ ] Inotropes
- [ ] Vasopressors
- [ ] Venous Thromboembolism Prophylaxis
- [ ] Venous Thromboembolism Treatment
- [ ] TXA
- [ ] Prophylactic antibiotics

Diagnosis

Category	Diagnosis
Airway and Breathing	☐ Airway obstruction ☐ Hemothorax ☐ Pneumothorax ☐ Pulmonary Contusion ☐ Airway and Breathing other ☐ None **Other:**
Circulation	☐ Shock ☐ Hemorrhagic hypovolemia ☐ Cardiac tamponade ☐ Tension pneumothorax ☐ Cardiac arrest ☐ Circulation other ☐ None **Other:**
Disability	☐ Mild Brain Injury ☐ Moderate Brain Injury ☐ Severe Brain Injury ☐ Intracranial Bleeding ☐ Hypoglycemia ☐ High Cervical Spine Cord Injury w/ Deficits ☐ Low Cervical Spine Cord Injury w/ Deficits ☐ Thoracic Spine Cord Injury w/ Deficits ☐ Lumbar Spine Cord Injury w/ Deficits ☐ Peripheral Nerve Injury ☐ Compartment Syndrome (Extremity) ☐ Disability Other ☐ None **Other:**
Environmental Exposure	☐ Hypothermia ☐ Hyperthermia ☐ Exposure other ☐ None **Other:**

Orthopedic	☐ Fracture of skull and facial bones ☐ Fracture of ribs, sternum, clavicles ☐ Fracture of cervical, thoracic, lumbar spine ☐ Fracture of pelvis (includes sacrum and coccyx) ☐ Fracture of upper extremity (includes scapula + humeral head to finger tips) ☐ Fracture of lower extremity (from femoral head to toes) ☐ Traumatic amputation of extremity ☐ Crush injury of extremity ☐ Tendon Injury ☐ Dislocation (closed) ☐ Dislocation (open) ☐ Other Orthopedic Diagnosis ☐ None **Other:**
Wounds/Burns	☐ Burn-first degree (partial thickness) ≥20% TBSA ☐ Burn-second degree (mid-thickness ≥10% TBSA ☐ Burn-third degree (deep) ≥5% TBSA ☐ Wounds/Burns other ☐ None **Other:**

Form Status

Complete? Incomplete

Delft Discharge

Record ID Field	4999

Hospital Summary/Disposition Items

Total GCS at discharge
* must provide value

Total Ventilator Days
* must provide value

Final CHC Disposition
* must provide value
You should only select TRANSFERRED or DECEASED

CHC Discharge Date
* must provide value
D-M-Y

CHC Discharge Time
* must provide value
H:M

Date and Time Case Completed (CHC Forms Only)
* must provide value
D-M-Y H:M

Case completed by:

Form Status

Complete? Incomplete

REDCap

Trauma Epidemiology and Outcomes Study (Version 3.1)
Record ID Field 4999

KHA Admission Details

Record ID Field	4999

Patient Transport and Transfer Information

Demo Form Injury Date/Time: _____ **at Unknown**

EMS Transfer Type: **Private Interfacility Transfer** **(If Primary, follow green prompts; If IFT, follow blue prompts)**

Dispatch Date/Time: _____ **at** _____

Scene/Hospital #1 Arrival Time: _____ **Scene/Hospital #1 Departure Time:** _____

Hospital (#1/#2) Arrival Date/Time: _____ **at** _____

EMS Transfer Type: _____

Dispatch Date/Time: _____ **at** _____**, left Hospital #1 at:** _____

Hospital #2 Arrival Date/Time: _____ **at** _____

Was this incoming arrival an Interfacility Transfer? * must provide value	○ Yes ○ No
Receiving Facility * must provide value	○ Ceres Hospital ○ Khayelitsha Hospital ○ Tygerberg Hospital ○ Worcester Hospital

Facility Units of Care

Facility Unit of Care * must provide value	☐ Emergency Centre ☐ Ward ☐ Operating Theatre ☐ ICU

Phases of Care

Phases of Care * must provide value	☐ Initial Resuscitation ☐ Damage Control Surgery ☐ Intensive Care ☐ Definitive Surgery ☐ Non-ICU (EG Ward, High Care) ☐ Non-Resuscitative EC Care

Time Points

Time Points * must provide value	☑ First 24 Hours ☑ 25-hours to 72 hours ☑ 73 hours to 7 days

Form Status

Complete?	Incomplete

First 24 Hours at KHA

Record ID Field 4999

First 24 Hours at Facility

South African Triage Scale (SATS) Upon Facility Arrival	
Date D-M-Y	**Time** H:M
TEWS	**SATS Colour** ○ Red ○ Orange ○ Yellow ○ Green ○ Blue
EC Resuscitation patient? ○ Yes ○ No	

Vital Signs (First 24-Hours)

Select corresponding vital signs Recorded

* must provide value

☐ First Vital Signs
☐ Last Vital Signs
☐ Vital Sign Ranges (If three or more sets of vitals available)
☐ None

Laboratory Values (First 24-Hour)

Arterial or Venous Blood Gas		**Complete Blood Count**		**Chemistry**		**INR**		**Urinalysis**	
Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
○	○	○	○	○	○	○	○	○	○

Imaging (First 24-Hour)

Imaging Modality and Body Part	**Imaging Results and Description**
X-Ray **None** ☐ **Head** ☐ **Face** ☐ **Neck** ☐ **Thorax** ☐ **Ab/P** ☐ **Spine** ☐ **UE** ☐ **LE** ☐ **Bony pelvis** ☐	 **Abnormality Description** 30 words remaining
CT non-contrasted **None** ☐ **Head** ☐ **Face** ☐ **Neck** ☐ **Thorax** ☐ **Ab/P** ☐ **Spine** ☐ **UE** ☐ **LE** ☐ **Bony pelvis** ☐	 **Abnormality Description** 30 words remaining

CT with contrast

None	Head	Face	Neck	Thorax	Ab/P	Spine	UE	LE	Bony pelvis
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Abnormality Description

30 words remaining

CT angio

None	Head	Face	Neck	Thorax	Ab/P	Spine	UE	LE	Bony pelvis
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Abnormality Description

30 words remaining

MRI

None	Head	Face	Neck	Thorax	Ab/P	Spine	UE	LE	Bony pelvis
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Abnormality Description

30 words remaining

FAST

None	Head	Face	Neck	Thorax	Ab/P	Spine	UE	LE	Bony pelvis
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Abnormality Description

30 words remaining

Ultrasound

None	Head	Face	Neck	Thorax	Ab/P	Spine	UE	LE	Bony pelvis
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Abnormality Description

30 words remaining

Lodox

None ○ Full-Body ○

Abnormality Description

30 words remaining

Non-surgical Hospital Procedures (First 24-Hour)

Non-surgical Hospital Procedures (check all that apply)

* must provide value

- ☐ Airway Management
- ☐ Backboard
- ☐ Bleeding Control (foley)
- ☐ Cardiocentesis
- ☐ Chest seal (vented or non-vented)
- ☐ CPR
- ☐ C-spine immobilization
- ☐ Embolization
- ☐ Extremity Splints
- ☐ Manual Pressure
- ☐ Needle decompression
- ☐ Oxygen Administration
- ☐ Pelvic Binder
- ☐ Positive Ventilation Initiated (CPAP or BiPAP only)
- ☐ Pressure dressing
- ☐ Reduction (for fracture)
- ☐ Reduction (for dislocation)
- ☐ Rewarming (e.g., warm IV fluids)
- ☐ Sedation (conscious or deep)
- ☐ Thoracostomy/Chest Tube
- ☐ Tourniquet
- ☐ Withdrawal From Life Support
- ☐ Wound Care
- ☐ None

Medication Administered (First 24-Hour)

Fluids

Fluid Type

* must provide value

- ☐ None
- ☐ Normal Saline
- ☐ Dextrose 5%
- ☐ Dextrose 10%
- ☐ Dextrose 50%
- ☐ Ringers Lactate
- ☐ Hypertonic saline
- ☐ Other

Blood Products

Type of Blood Product Administered

* must provide value

- ☐ None given
- ☐ Cryoprecipitate
- ☐ Packed Red Blood Cells
- ☐ Plasma
- ☐ Platelets
- ☐ Whole Blood
- ☐ FD Plasma
- ☐ Other

Analgesia

Oral Analgesia given in first 24 hours (check all that apply)
* must provide value

- [ ] None
- [ ] Tramadol
- [ ] Paracetamol
- [ ] Ibuprofen
- [ ] Other

IV or IM Analgesia
* must provide value

- [ ] None
- [ ] Morphine
- [ ] Fentanyl
- [ ] Paracetamol
- [ ] Ketamine
- [ ] Other

Other Medication

Other Medication Administered
* must provide value

- [ ] None
- [ ] Inotropes
- [ ] Vasopressors
- [ ] Venous Thromboembolism Prophylaxis
- [ ] Venous Thromboembolism Treatment
- [ ] TXA
- [ ] Prophylactic antibiotics

Surgical Procedures (First 24 hours)

Surgical Procedures				
Body Part	**Surgery Type**	**Surgery Date**	**Surgery Time**	**Surgery Success**
1. General	Wound - Debridement	08-(D-M-Y	08 H:M	Yes
2. General	Wound (Bleeding) - Packing	08-(D-M-Y	08 H:M	No
3. Face and Neck	Bleeding control procedures (not foley)	D-M-Y	H:M	
4.		D-M-Y	H:M	
5.		D-M-Y	H:M	
6.		D-M-Y	H:M	
7.		D-M-Y	H:M	
8.		D-M-Y	H:M	
9.		D-M-Y	H:M	
10.		D-M-Y	H:M	
11.		D-M-Y	H:M	
12.		D-M-Y	H:M	

Diagnosis (First 24 hours)

Category	**Diagnosis**
Airway and Breathing	☐ Airway obstruction ☐ Hemothorax ☐ Pneumothorax ☐ Pulmonary Contusion ☐ Airway and Breathing other ☐ None **Other:**

Circulation	☐ Shock ☐ Hemorrhagic hypovolemia ☐ Cardiac tamponade ☐ Tension pneumothorax ☐ Cardiac arrest ☐ Circulation other ☐ None **Other:**
Disability	☐ Mild Brain Injury ☐ Moderate Brain Injury ☐ Severe Brain Injury ☐ Intracranial Bleeding ☐ Hypoglycemia ☐ High Cervical Spine Cord Injury w/ Deficits ☐ Low Cervical Spine Cord Injury w/ Deficits ☐ Thoracic Spine Cord Injury w/ Deficits ☐ Lumbar Spine Cord Injury w/ Deficits ☐ Peripheral Nerve Injury ☐ Compartment Syndrome (Extremity) ☐ Disability Other ☐ None **Other:**
Environmental Exposure	☐ Hypothermia ☐ Hyperthermia ☐ Exposure other ☐ None **Other:**
Orthopedic	☐ Fracture of skull and facial bones ☐ Fracture of ribs, sternum, clavicles ☐ Fracture of cervical, thoracic, lumbar spine ☐ Fracture of pelvis (includes sacrum and coccyx) ☐ Fracture of upper extremity (includes scapula + humeral head to finger tips) ☐ Fracture of lower extremity (from femoral head to toes) ☐ Traumatic amputation of extremity ☐ Crush injury of extremity ☐ Tendon Injury ☐ Dislocation (closed) ☐ Dislocation (open) ☐ Other Orthopedic Diagnosis ☐ None **Other:**
Wounds/Burns	☐ Burn-first degree (partial thickness) ≥20% TBSA ☐ Burn-second degree (mid-thickness ≥10% TBSA ☐ Burn-third degree (deep) ≥5% TBSA ☐ Wounds/Burns other ☐ None **Other:**

SOFA Score (Day 1 or first 24 hours)?

○ Yes
○ No

Hospital Outcomes / Complications (First 24-Hours)

Infectious Complications/Outcomes

* must provide value

- ☐ Central Line-Associated Blood Stream Infection (CLABSI)
- ☐ Empyema
- ☐ Endocarditis
- ☐ Fungal Infection
- ☐ Intra-cranial infection
- ☐ Osteomyelitis
- ☐ Pneumonia (Non-Ventilator Associated)
- ☐ Pneumonia (Ventilator-Associated) (VAP)
- ☐ Sepsis (SIRS, septic shock, or severe sepsis)
- ☐ Surgical Site Infection - Deep
- ☐ Surgical Site Infection - Superficial
- ☐ Urinary Tract Infection (Catheter-Associated)
- ☐ Urinary Tract Infection (Non-Catheter Related)
- ☐ Wound Infection - Deep
- ☐ Wound Infection - Superficial
- ☐ Other Infectious Complication (but not listed above)
- ☐ None

Non-infectious Complications/Outcomes

* must provide value

- ☐ Abdominal Compartment Syndrome
- ☐ Acute Kidney Injury (insufficiency; ARF)
- ☐ Acute lung injury (ALI)
- ☐ Acute Respiratory Distress Syndrome (ARDS)
- ☐ Alcohol Withdrawal Syndrome
- ☐ Cardiac Arrest with return of spontaneous circulation
- ☐ Coagulopathy
- ☐ Crush Syndrome
- ☐ Deep Vein Thrombosis
- ☐ Delirium (altered mentation, not from head injury)
- ☐ Dialysis
- ☐ Liver Failure
- ☐ Multiple Organ Failure
- ☐ Myocardial Infarction
- ☐ Neurostorming - seizures
- ☐ Pancreatitis
- ☐ Pressure Ulcer
- ☐ Pulmonary Embolism (PE)
- ☐ Spinal Cord Injury progression
- ☐ Stroke/CVA
- ☐ TBI progression (including neurostorming, seizures)
- ☐ Other Non-infectious Complication (but not listed above)
- ☐ None

Form Status

Complete? Incomplete

25 to 72 Hours at KHA

Record ID Field 4999

Laboratory Values (25 to 72 Hours)

Arterial or Venous Blood Gas		Complete Blood Count		Chemistry		INR		Urinalysis	
Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
○	○	○	○	○	○	○	○	○	○

Imaging (25 to 72 Hours)

Imaging Modality and Body Part	Imaging Results and Description
X-Ray None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT non-contrasted None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT with contrast None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT angio None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining

MRI

None | Head | Face | Neck | Thorax | Ab/P | Spine | UE | LE | Bony pelvis

Abnormality Description

30 words remaining

FAST

None | Head | Face | Neck | Thorax | Ab/P | Spine | UE | LE | Bony pelvis

Abnormality Description

30 words remaining

Ultrasound

None | Head | Face | Neck | Thorax | Ab/P | Spine | UE | LE | Bony pelvis

Abnormality Description

30 words remaining

Lodox

None | Full-Body

Abnormality Description

30 words remaining

Non-surgical Hospital Procedures (25 to 72 Hours)

Non-surgical Hospital Procedures (check all that apply)

* must provide value

- [ ] Airway Management
- [ ] Backboard
- [ ] Bleeding Control (foley)
- [ ] Cardiocentesis
- [ ] Chest seal (vented or non-vented)
- [ ] CPR
- [ ] C-spine immobilization
- [ ] Embolization
- [ ] Extremity Splints
- [ ] Manual Pressure
- [ ] Needle decompression
- [ ] Oxygen Administration
- [ ] Pelvic Binder
- [ ] Positive Ventilation Initiated (CPAP or BiPAP only)
- [ ] Pressure dressing
- [ ] Reduction (for fracture)
- [ ] Reduction (for dislocation)
- [ ] Rewarming (e.g., warm IV fluids)
- [ ] Sedation (conscious or deep)
- [ ] Thoracostomy/Chest Tube
- [ ] Tourniquet
- [ ] Withdrawal From Life Support
- [ ] Wound Care
- [ ] None

Medication Administered (25 to 72 Hours)

Fluids

Fluid Type

* must provide value

- [ ] None
- [ ] Normal Saline
- [ ] Dextrose 5%
- [ ] Dextrose 10%
- [ ] Dextrose 50%
- [ ] Ringers Lactate
- [ ] Hypertonic saline
- [ ] Other

Blood Products

Type of Blood Product Administered

* must provide value

- [ ] None given
- [ ] Cryoprecipitate
- [ ] Packed Red Blood Cells
- [ ] Plasma
- [ ] Platelets
- [ ] Whole Blood
- [ ] FD Plasma
- [ ] Other

Analgesia

Oral Analgesia given between the 25 to 72 hours (check all that apply)

* must provide value

- [ ] None
- [ ] Tramadol
- [ ] Paracetamol
- [ ] Ibuprofen
- [ ] Other

IV or IM Analgesia

* must provide value

- [ ] None
- [ ] Morphine
- [ ] Fentanyl
- [ ] Paracetamol
- [ ] Ketamine
- [ ] Other

Other Medication

Other Medication Administered

* must provide value

- [ ] None
- [ ] Inotropes
- [ ] Vasopressors
- [ ] Venous Thromboembolism Prophylaxis
- [ ] Venous Thromboembolism Treatment
- [ ] TXA
- [ ] Prophylactic antibiotics

Surgical Procedures (25 to 72 hours)

Surgical Procedures				
Body Part	**Surgery Type**	**Surgery Date**	**Surgery Time**	**Surgery Success**
1.		D-M-Y	H:M	
2.		D-M-Y	H:M	
3.		D-M-Y	H:M	
4.		D-M-Y	H:M	
5.		D-M-Y	H:M	
6.		D-M-Y	H:M	
7.		D-M-Y	H:M	
8.		D-M-Y	H:M	
9.		D-M-Y	H:M	
10.		D-M-Y	H:M	
11.		D-M-Y	H:M	
12.		D-M-Y	H:M	

Diagnosis (25 to 72 hours)

Category	Diagnosis

Airway and Breathing	☐ Airway obstruction ☐ Hemothorax ☐ Pneumothorax ☐ Pulmonary Contusion ☐ Airway and Breathing other ☐ None **Other:**
Circulation	☐ Shock ☐ Hemorrhagic hypovolemia ☐ Cardiac tamponade ☐ Tension pneumothorax ☐ Cardiac arrest ☐ Circulation other ☐ None **Other:**
Disability	☐ Mild Brain Injury ☐ Moderate Brain Injury ☐ Severe Brain Injury ☐ Intracranial Bleeding ☐ Hypoglycemia ☐ High Cervical Spine Cord Injury w/ Deficits ☐ Low Cervical Spine Cord Injury w/ Deficits ☐ Thoracic Spine Cord Injury w/ Deficits ☐ Lumbar Spine Cord Injury w/ Deficits ☐ Peripheral Nerve Injury ☐ Compartment Syndrome (Extremity) ☐ Disability Other ☐ None **Other:**
Environmental Exposure	☐ Hypothermia ☐ Hyperthermia ☐ Exposure other ☐ None **Other:**
Orthopedic	☐ Fracture of skull and facial bones ☐ Fracture of ribs, sternum, clavicles ☐ Fracture of cervical, thoracic, lumbar spine ☐ Fracture of pelvis (includes sacrum and coccyx) ☐ Fracture of upper extremity (includes scapula + humeral head to finger tips) ☐ Fracture of lower extremity (from femoral head to toes) ☐ Traumatic amputation of extremity ☐ Crush injury of extremity ☐ Tendon Injury ☐ Dislocation (closed) ☐ Dislocation (open) ☐ Other Orthopedic Diagnosis ☐ None **Other:**
Wounds/Burns	☐ Burn-first degree (partial thickness) ?20% TBSA ☐ Burn-second degree (mid-thickness ?10% TBSA ☐ Burn-third degree (deep) ?5% TBSA ☐ Wounds/Burns other ☐ None **Other:**

SOFA Score (Day 2)?
- ○ Yes
- ○ No

SOFA Score (Day 3)?
- ○ Yes
- ○ No

Hospital Outcomes / Complications (25 to 72 Hourss)

Infectious Complications/Outcomes
* must provide value

- ☐ Central Line-Associated Blood Stream Infection (CLABSI)
- ☐ Empyema
- ☐ Endocarditis
- ☐ Fungal Infection
- ☐ Intra-cranial infection
- ☐ Osteomyelitis
- ☐ Pneumonia (Non-Ventilator Associated)
- ☐ Pneumonia (Ventilator-Associated) (VAP)
- ☐ Sepsis (SIRS, septic shock, or severe sepsis)
- ☐ Surgical Site Infection - Deep
- ☐ Surgical Site Infection - Superficial
- ☐ Urinary Tract Infection (Catheter-Associated)
- ☐ Urinary Tract Infection (Non-Catheter Related)
- ☐ Wound Infection - Deep
- ☐ Wound Infection - Superficial
- ☐ Other Infectious Complication (but not listed above)
- ☐ None

Non-infectious Complications/Outcomes
* must provide value

- ☐ Abdominal Compartment Syndrome
- ☐ Acute Kidney Injury (insufficiency; ARF)
- ☐ Acute lung injury (ALI)
- ☐ Acute Respiratory Distress Syndrome (ARDS)
- ☐ Alcohol Withdrawal Syndrome
- ☐ Cardiac Arrest with return of spontaneous circulation
- ☐ Coagulopathy
- ☐ Crush Syndrome
- ☐ Deep Vein Thrombosis
- ☐ Delirium (altered mentation, not from head injury)
- ☐ Dialysis
- ☐ Liver Failure
- ☐ Multiple Organ Failure
- ☐ Myocardial Infarction
- ☐ Neurostorming - seizures
- ☐ Pancreatitis
- ☐ Pressure Ulcer
- ☐ Pulmonary Embolism (PE)
- ☐ Spinal Cord Injury progression
- ☐ Stroke/CVA
- ☐ TBI progression (including neurostorming, seizures)
- ☐ Other Non-infectious Complication (but not listed above)
- ☐ None

Form Status

Complete? Incomplete

73 hours to 7 days at KHA

Record ID Field 4999

Laboratory Values (73 hours to 7 Days)

Arterial or Venous Blood Gas		Complete Blood Count		Chemistry		INR		Urinalysis	
Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
○	○	○	○	○	○	○	○	○	○

Imaging (73 hours to 7 Days)

Imaging Modality and Body Part	Imaging Results and Description
X-Ray None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT non-contrasted None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT with contrast None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT angio None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining

MRI

None | Head | Face | Neck | Thorax | Ab/P | Spine | UE | LE | Bony pelvis

Abnormality Description

30 words remaining

FAST

None | Head | Face | Neck | Thorax | Ab/P | Spine | UE | LE | Bony pelvis

Abnormality Description

30 words remaining

Ultrasound

None | Head | Face | Neck | Thorax | Ab/P | Spine | UE | LE | Bony pelvis

Abnormality Description

30 words remaining

Lodox

None | Full-Body

Abnormality Description

30 words remaining

Non-surgical Hospital Procedures (73 hours to 7 Days)

Non-surgical Hospital Procedures (check all that apply)

* must provide value

- [ ] Airway Management
- [ ] Backboard
- [ ] Bleeding Control (foley)
- [ ] Cardiocentesis
- [ ] Chest seal (vented or non-vented)
- [ ] CPR
- [ ] C-spine immobilization
- [ ] Embolization
- [ ] Extremity Splints
- [ ] Manual Pressure
- [ ] Needle decompression
- [ ] Oxygen Administration
- [ ] Pelvic Binder
- [ ] Positive Ventilation Initiated (CPAP or BiPAP only)
- [ ] Pressure dressing
- [ ] Reduction (for fracture)
- [ ] Reduction (for dislocation)
- [ ] Rewarming (e.g., warm IV fluids)
- [ ] Sedation (conscious or deep)
- [ ] Thoracostomy/Chest Tube
- [ ] Tourniquet
- [ ] Withdrawal From Life Support
- [ ] Wound Care
- [ ] None

Medication Administered (73 hours to 7 Days)

Fluids

Fluid Type

* must provide value

- [ ] None
- [ ] Normal Saline
- [ ] Dextrose 5%
- [ ] Dextrose 10%
- [ ] Dextrose 50%
- [ ] Ringers Lactate
- [ ] Hypertonic saline
- [ ] Other

Blood Products

Type of Blood Product Administered

* must provide value

- [ ] None given
- [ ] Cryoprecipitate
- [ ] Packed Red Blood Cells
- [ ] Plasma
- [ ] Platelets
- [ ] Whole Blood
- [ ] FD Plasma
- [ ] Other

Analgesia

Oral Analgesia given between 73 hours to 7 days (check all that apply)

* must provide value

- [ ] None
- [ ] Tramadol
- [ ] Paracetamol
- [ ] Ibuprofen
- [ ] Other

IV or IM Analgesia

* must provide value

- [ ] None
- [ ] Morphine
- [ ] Fentanyl
- [ ] Paracetamol
- [ ] Ketamine
- [ ] Other

Other Medication

Other Medication Administered

* must provide value

- [ ] None
- [ ] Inotropes
- [ ] Vasopressors
- [ ] Venous Thromboembolism Prophylaxis
- [ ] Venous Thromboembolism Treatment
- [ ] TXA
- [ ] Prophylactic antibiotics

Surgical Procedures (73 hours to 7 days)

Surgical Procedures				
Body Part	**Surgery Type**	**Surgery Date**	**Surgery Time**	**Surgery Success**
1.		D-M-Y	H:M	
2.		D-M-Y	H:M	
3.		D-M-Y	H:M	
4.		D-M-Y	H:M	
5.		D-M-Y	H:M	
6.		D-M-Y	H:M	
7.		D-M-Y	H:M	
8.		D-M-Y	H:M	
9.		D-M-Y	H:M	
10.		D-M-Y	H:M	
11.		D-M-Y	H:M	
12.		D-M-Y	H:M	

Diagnosis (73 hours to 7 days)

Category	Diagnosis

Airway and Breathing	☐ Airway obstruction ☐ Hemothorax ☐ Pneumothorax ☐ Pulmonary Contusion ☐ Airway and Breathing other ☐ None **Other:**
Circulation	☐ Shock ☐ Hemorrhagic hypovolemia ☐ Cardiac tamponade ☐ Tension pneumothorax ☐ Cardiac arrest ☐ Circulation other ☐ None **Other:**
Disability	☐ Mild Brain Injury ☐ Moderate Brain Injury ☐ Severe Brain Injury ☐ Intracranial Bleeding ☐ Hypoglycemia ☐ High Cervical Spine Cord Injury w/ Deficits ☐ Low Cervical Spine Cord Injury w/ Deficits ☐ Thoracic Spine Cord Injury w/ Deficits ☐ Lumbar Spine Cord Injury w/ Deficits ☐ Peripheral Nerve Injury ☐ Compartment Syndrome (Extremity) ☐ Disability Other ☐ None **Other:**
Environmental Exposure	☐ Hypothermia ☐ Hyperthermia ☐ Exposure other ☐ None **Other:**
Orthopedic	☐ Fracture of skull and facial bones ☐ Fracture of ribs, sternum, clavicles ☐ Fracture of cervical, thoracic, lumbar spine ☐ Fracture of pelvis (includes sacrum and coccyx) ☐ Fracture of upper extremity (includes scapula + humeral head to finger tips) ☐ Fracture of lower extremity (from femoral head to toes) ☐ Traumatic amputation of extremity ☐ Crush injury of extremity ☐ Tendon Injury ☐ Dislocation (closed) ☐ Dislocation (open) ☐ Other Orthopedic Diagnosis ☐ None **Other:**
Wounds/Burns	☐ Burn-first degree (partial thickness) ≥20% TBSA ☐ Burn-second degree (mid-thickness ≥10% TBSA ☐ Burn-third degree (deep) ≥5% TBSA ☐ Wounds/Burns other ☐ None **Other:**

SOFA Score (Day 4)?
- ○ Yes
- ○ No

SOFA Score (Day 5)?
- ○ Yes
- ○ No

SOFA Score (Day 6)?
- ○ Yes
- ○ No

SOFA Score (Day 7)?
- ○ Yes
- ○ No

Hospital Outcomes / Complications (73 Hours to 7 days)

Infectious Complications/Outcomes

* must provide value

- ☐ Central Line-Associated Blood Stream Infection (CLABSI)
- ☐ Empyema
- ☐ Endocarditis
- ☐ Fungal Infection
- ☐ Intra-cranial infection
- ☐ Osteomyelitis
- ☐ Pneumonia (Non-Ventilator Associated)
- ☐ Pneumonia (Ventilator-Associated) (VAP)
- ☐ Sepsis (SIRS, septic shock, or severe sepsis)
- ☐ Surgical Site Infection - Deep
- ☐ Surgical Site Infection - Superficial
- ☐ Urinary Tract Infection (Catheter-Associated)
- ☐ Urinary Tract Infection (Non-Catheter Related)
- ☐ Wound Infection - Deep
- ☐ Wound Infection - Superficial
- ☐ Other Infectious Complication (but not listed above)
- ☐ None

Non-infectious Complications/Outcomes

* must provide value

- ☐ Abdominal Compartment Syndrome
- ☐ Acute Kidney Injury (insufficiency; ARF)
- ☐ Acute lung injury (ALI)
- ☐ Acute Respiratory Distress Syndrome (ARDS)
- ☐ Alcohol Withdrawal Syndrome
- ☐ Cardiac Arrest with return of spontaneous circulation
- ☐ Coagulopathy
- ☐ Crush Syndrome
- ☐ Deep Vein Thrombosis
- ☐ Delirium (altered mentation, not from head injury)
- ☐ Dialysis
- ☐ Liver Failure
- ☐ Multiple Organ Failure
- ☐ Myocardial Infarction
- ☐ Neurostorming - seizures
- ☐ Pancreatitis
- ☐ Pressure Ulcer
- ☐ Pulmonary Embolism (PE)
- ☐ Spinal Cord Injury progression
- ☐ Stroke/CVA
- ☐ TBI progression (including neurostorming, seizures)
- ☐ Other Non-infectious Complication (but not listed above)
- ☐ None

Form Status

Complete? Incomplete

KHA Outcomes and Discharge

Record ID Field	4999

Hospital Summary/Disposition Items

Total GCS at discharge

Total Ventilator Days
* must provide value

Total length of stay in ICU
* must provide value
day(s)

Number of Operating Theatre Encounters
* must provide value

Final Hospital Disposition
* must provide value

Hospital Discharge Date
* must provide value
D-M-Y

Hospital Discharge Time
* must provide value
H:M

Date and Time Case Completed (Hospital Forms Only)
* must provide value
D-M-Y H:M

Case completed by:

Form Status

Complete? Incomplete

Site B Admission Details

Record ID Field	4999
Patient Transport and Transfer Information	
Receiving Facility * must provide value	○ Ceres Hospital ○ Delft CHC ○ Khayelitsha Hospital ○ Site B CHC ○ Tygerberg Hospital ○ Worcester Hospital
Facility Units of Care	
CHC Arrival Mode * must provide value	○ Western Cape EMS ○ Other EMS ○ Non-EMS
Phases of Care	
Phases of Care * must provide value	☐ Initial Resuscitation ☐ Intensive Care ☐ Non-Resuscitative EC Care
Form Status	
Complete?	Incomplete

Site B Encounter

Record ID Field 4999

Entire Encounter at Facility

South African Triage Scale (SATS) Upon Facility Arrival	
Date D-M-Y	**Time** H:M
TEWS	**SATS Colour** ○ Red ○ Orange ○ Yellow ○ Green ○ Blue

Vital Signs

Select corresponding vital signs Recorded

* must provide value

- ☐ First Vital Signs
- ☐ Last Vital Signs
- ☐ Vital Sign Ranges (If three or more sets of vitals available)
- ☐ None

Laboratory Values

Complete Blood Count		**Chemistry**		**INR**		**Urinalysis**	
Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
○	○	○	○	○	○	○	○

Imaging

Imaging Modality and Body Part	**Imaging Results and Description**
X-Ray **None** ☐ **Head** ☐ **Face** ☐ **Neck** ☐ **Thorax** ☐ **Ab/P** ☐ **Spine** ☐ **UE** ☐ **LE** ☐ **Bony pelvis** ☐	▾ **Abnormality Description** 30 words remaining
General Ultrasound **None** ☐ **Head** ☐ **Face** ☐ **Neck** ☐ **Thorax** ☐ **Ab/P** ☐ **Spine** ☐ **UE** ☐ **LE** ☐ **Bony pelvis** ☐	▾ **Abnormality Description** 30 words remaining

Non-surgical Hospital Procedures

Non-surgical Hospital Procedures (check all that apply)

* must provide value

- [ ] Airway Management
- [ ] Backboard
- [ ] Bleeding Control (foley)
- [ ] Cardiocentesis
- [ ] Chest seal (vented or non-vented)
- [ ] CPR
- [ ] C-spine immobilization
- [ ] Embolization
- [ ] Extremity Splints
- [ ] Manual Pressure
- [ ] Needle decompression
- [ ] Oxygen Administration
- [ ] Pelvic Binder
- [ ] Positive Ventilation Initiated (CPAP or BiPAP only)
- [ ] Pressure dressing
- [ ] Reduction (for fracture)
- [ ] Reduction (for dislocation)
- [ ] Rewarming (e.g., warm IV fluids)
- [ ] Sedation (conscious or deep)
- [ ] Thoracostomy/Chest Tube
- [ ] Tourniquet
- [ ] Withdrawal From Life Support
- [ ] Wound Care
- [ ] None

Medication Administered

Fluids

Fluid Type

* must provide value

- [ ] None
- [ ] Normal Saline
- [ ] Dextrose 5%
- [ ] Dextrose 10%
- [ ] Dextrose 50%
- [ ] Ringers Lactate
- [ ] Hypertonic saline
- [ ] Other

Blood Products

Type of Blood Product Administered

* must provide value

- [ ] None given
- [ ] Cryoprecipitate
- [ ] Packed Red Blood Cells
- [ ] Plasma
- [ ] Platelets
- [ ] Whole Blood
- [ ] FD Plasma
- [ ] Other

Analgesia

Oral Analgesia given in first 24 hours (check all that apply)

* must provide value

- [ ] None
- [ ] Tramadol
- [ ] Paracetamol
- [ ] Ibuprofen
- [ ] Other

IV or IM Analgesia

* must provide value

- [ ] None
- [ ] Morphine
- [ ] Fentanyl
- [ ] Paracetamol
- [ ] Ketamine
- [ ] Other

Other Medication

Other Medication Administered

* must provide value

- [ ] None
- [ ] Inotropes
- [ ] Vasopressors
- [ ] Venous Thromboembolism Prophylaxis
- [ ] Venous Thromboembolism Treatment
- [ ] TXA
- [ ] Prophylactic antibiotics

Diagnosis

Category	Diagnosis
Airway and Breathing	- [ ] Airway obstruction - [ ] Hemothorax - [ ] Pneumothorax - [ ] Pulmonary Contusion - [ ] Airway and Breathing other - [ ] None **Other:**
Circulation	- [ ] Shock - [ ] Hemorrhagic hypovolemia - [ ] Cardiac tamponade - [ ] Tension pneumothorax - [ ] Cardiac arrest - [ ] Circulation other - [ ] None **Other:**
Disability	- [ ] Mild Brain Injury - [ ] Moderate Brain Injury - [ ] Severe Brain Injury - [ ] Intracranial Bleeding - [ ] Hypoglycemia - [ ] High Cervical Spine Cord Injury w/ Deficits - [ ] Low Cervical Spine Cord Injury w/ Deficits - [ ] Thoracic Spine Cord Injury w/ Deficits - [ ] Lumbar Spine Cord Injury w/ Deficits - [ ] Peripheral Nerve Injury - [ ] Compartment Syndrome (Extremity) - [ ] Disability Other - [ ] None **Other:**
Environmental Exposure	- [ ] Hypothermia - [ ] Hyperthermia - [ ] Exposure other - [ ] None **Other:**

Orthopedic	☐ Fracture of skull and facial bones ☐ Fracture of ribs, sternum, clavicles ☐ Fracture of cervical, thoracic, lumbar spine ☐ Fracture of pelvis (includes sacrum and coccyx) ☐ Fracture of upper extremity (includes scapula + humeral head to finger tips) ☐ Fracture of lower extremity (from femoral head to toes) ☐ Traumatic amputation of extremity ☐ Crush injury of extremity ☐ Tendon Injury ☐ Dislocation (closed) ☐ Dislocation (open) ☐ Other Orthopedic Diagnosis ☐ None **Other:**
Wounds/Burns	☐ Burn-first degree (partial thickness) ≥20% TBSA ☐ Burn-second degree (mid-thickness ≥10% TBSA ☐ Burn-third degree (deep) ≥5% TBSA ☐ Wounds/Burns other ☐ None **Other:**

Form Status

Complete? Incomplete

Site B Discharge

Record ID Field	4999

Hospital Summary/Disposition Items

Total GCS at discharge
* must provide value

Total Ventilator Days
* must provide value

Final CHC Disposition
* must provide value
You should only select TRANSFERRED or DECEASED

CHC Discharge Date
* must provide value
D-M-Y

CHC Discharge Time
* must provide value
H:M

Date and Time Case Completed (CHC Form Only)
* must provide value
D-M-Y H:M

Case completed by:

Form Status

Complete? Incomplete

REDCap

Trauma Epidemiology and Outcomes Study (Version 3.1)
Record ID Field 4999

CRS Admission Details

Record ID Field	4999

Patient Transport and Transfer Information

Demo Form Injury Date/Time: _____ at Unknown

EMS Transfer Type: Private Interfacility Transfer (If Primary, follow green prompts; If IFT, follow blue prompts)

Dispatch Date/Time: _____ at _____

Scene/Hospital #1 Arrival Time: _____ Scene/Hospital #1 Departure Time: _____

Hospital (#1/#2) Arrival Date/Time: _____ at _____

EMS Transfer Type: _____

Dispatch Date/Time: _____ at _____, left Hospital #1 at: _____

Hospital #2 Arrival Date/Time: _____ at _____

Was this incoming arrival an Interfacility Transfer?
* must provide value

- ○ Yes
- ○ No

Receiving Facility
* must provide value

- ○ Ceres Hospital
- ○ Khayelitsha Hospital
- ○ Tygerberg Hospital
- ○ Worcester Hospital

Facility Units of Care

Facility Unit of Care
* must provide value

- ☐ Emergency Centre
- ☐ Ward
- ☐ Operating Theatre
- ☐ ICU

Phases of Care

Phases of Care
* must provide value

- ☐ Initial Resuscitation
- ☐ Damage Control Surgery
- ☐ Intensive Care
- ☐ Definitive Surgery
- ☐ Non-ICU (EG Ward, High Care)
- ☐ Non-Resuscitative EC Care

Time Points

Time Points
* must provide value

- ☑ First 24 Hours
- ☑ 25-hours to 72 hours
- ☑ 73 hours to 7 days

Form Status

Complete? Incomplete

First 24 Hours At CRS

Record ID Field 4999

First 24 Hours at Facility

South African Triage Scale (SATS) Upon Facility Arrival	
Date D-M-Y	**Time** H:M
TEWS	**SATS Colour** ○ Red ○ Orange ○ Yellow ○ Green ○ Blue

Vital Signs (First 24-Hours)

Select corresponding vital signs Recorded

* must provide value

- ☐ First Vital Signs
- ☐ Last Vital Signs
- ☐ Vital Sign Ranges (If three or more sets of vitals available)
- ☐ None

Laboratory Values (First 24-Hour)

Arterial or Venous Blood Gas		**Complete Blood Count**		**Chemistry**		**INR**		**Urinalysis**	
Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
○	○	○	○	○	○	○	○	○	○

Imaging (First 24-Hour)

Imaging Modality and Body Part	**Imaging Results and Description**
X-Ray **None** ☐ **Head** ☐ **Face** ☐ **Neck** ☐ **Thorax** ☐ **Ab/P** ☐ **Spine** ☐ **UE** ☐ **LE** ☐ **Bony pelvis** ☐	▾ **Abnormality Description** 30 words remaining
CT non-contrasted **None** ☐ **Head** ☐ **Face** ☐ **Neck** ☐ **Thorax** ☐ **Ab/P** ☐ **Spine** ☐ **UE** ☐ **LE** ☐ **Bony pelvis** ☐	▾ **Abnormality Description** 30 words remaining

CT with contrast

None	Head	Face	Neck	Thorax	Ab/P	Spine	UE	LE	Bony pelvis
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Abnormality Description

30 words remaining

CT angio

None	Head	Face	Neck	Thorax	Ab/P	Spine	UE	LE	Bony pelvis
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Abnormality Description

30 words remaining

MRI

None	Head	Face	Neck	Thorax	Ab/P	Spine	UE	LE	Bony pelvis
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Abnormality Description

30 words remaining

FAST

None	Head	Face	Neck	Thorax	Ab/P	Spine	UE	LE	Bony pelvis
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Abnormality Description

30 words remaining

Ultrasound

None	Head	Face	Neck	Thorax	Ab/P	Spine	UE	LE	Bony pelvis
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Abnormality Description

30 words remaining

Lodox

None ○ Full-Body ○

Abnormality Description

30 words remaining

Non-surgical Hospital Procedures (First 24-Hour)

Non-surgical Hospital Procedures (check all that apply)

* must provide value

- ☐ Airway Management
- ☐ Backboard
- ☐ Bleeding Control (foley)
- ☐ Cardiocentesis
- ☐ Chest seal (vented or non-vented)
- ☐ CPR
- ☐ C-spine immobilization
- ☐ Embolization
- ☐ Extremity Splints
- ☐ Manual Pressure
- ☐ Needle decompression
- ☐ Oxygen Administration
- ☐ Pelvic Binder
- ☐ Positive Ventilation Initiated (CPAP or BiPAP only)
- ☐ Pressure dressing
- ☐ Reduction (for fracture)
- ☐ Reduction (for dislocation)
- ☐ Rewarming (e.g., warm IV fluids)
- ☐ Sedation (conscious or deep)
- ☐ Thoracostomy/Chest Tube
- ☐ Tourniquet
- ☐ Withdrawal From Life Support
- ☐ Wound Care
- ☐ None

Medication Administered (First 24-Hour)

Fluids

Fluid Type

* must provide value

- ☐ None
- ☐ Normal Saline
- ☐ Dextrose 5%
- ☐ Dextrose 10%
- ☐ Dextrose 50%
- ☐ Ringers Lactate
- ☐ Hypertonic saline
- ☐ Other

Blood Products

Type of Blood Product Administered

* must provide value

- ☐ None given
- ☐ Cryoprecipitate
- ☐ Packed Red Blood Cells
- ☐ Plasma
- ☐ Platelets
- ☐ Whole Blood
- ☐ FD Plasma
- ☐ Other

Analgesia

Oral Analgesia given in first 24 hours (check all that apply)
* must provide value

- [ ] None
- [ ] Tramadol
- [ ] Paracetamol
- [ ] Ibuprofen
- [ ] Other

IV or IM Analgesia
* must provide value

- [ ] None
- [ ] Morphine
- [ ] Fentanyl
- [ ] Paracetamol
- [ ] Ketamine
- [ ] Other

Other Medication

Other Medication Administered
* must provide value

- [ ] None
- [ ] Inotropes
- [ ] Vasopressors
- [ ] Venous Thromboembolism Prophylaxis
- [ ] Venous Thromboembolism Treatment
- [ ] TXA
- [ ] Prophylactic antibiotics

Surgical Procedures (First 24 hours)

Surgical Procedures				
Body Part	**Surgery Type**	**Surgery Date**	**Surgery Time**	**Surgery Success**
1.		D-M-Y	H:M	
2.		D-M-Y	H:M	
3.		D-M-Y	H:M	
4.		D-M-Y	H:M	
5.		D-M-Y	H:M	
6.		D-M-Y	H:M	
7.		D-M-Y	H:M	
8.		D-M-Y	H:M	
9.		D-M-Y	H:M	
10.		D-M-Y	H:M	
11.		D-M-Y	H:M	
12.		D-M-Y	H:M	

Diagnosis (First 24 hours)

Category	Diagnosis
Airway and Breathing	☐ Airway obstruction ☐ Hemothorax ☐ Pneumothorax ☐ Pulmonary Contusion ☐ Airway and Breathing other ☐ None **Other:**

Circulation	☐ Shock ☐ Hemorrhagic hypovolemia ☐ Cardiac tamponade ☐ Tension pneumothorax ☐ Cardiac arrest ☐ Circulation other ☐ None **Other:**
Disability	☐ Mild Brain Injury ☐ Moderate Brain Injury ☐ Severe Brain Injury ☐ Intracranial Bleeding ☐ Hypoglycemia ☐ High Cervical Spine Cord Injury w/ Deficits ☐ Low Cervical Spine Cord Injury w/ Deficits ☐ Thoracic Spine Cord Injury w/ Deficits ☐ Lumbar Spine Cord Injury w/ Deficits ☐ Peripheral Nerve Injury ☐ Compartment Syndrome (Extremity) ☐ Disability Other ☐ None **Other:**
Environmental Exposure	☐ Hypothermia ☐ Hyperthermia ☐ Exposure other ☐ None **Other:**
Orthopedic	☐ Fracture of skull and facial bones ☐ Fracture of ribs, sternum, clavicles ☐ Fracture of cervical, thoracic, lumbar spine ☐ Fracture of pelvis (includes sacrum and coccyx) ☐ Fracture of upper extremity (includes scapula + humeral head to finger tips) ☐ Fracture of lower extremity (from femoral head to toes) ☐ Traumatic amputation of extremity ☐ Crush injury of extremity ☐ Tendon Injury ☐ Dislocation (closed) ☐ Dislocation (open) ☐ Other Orthopedic Diagnosis ☐ None **Other:**
Wounds/Burns	☐ Burn-first degree (partial thickness) ≥20% TBSA ☐ Burn-second degree (mid-thickness ≥10% TBSA ☐ Burn-third degree (deep) ≥5% TBSA ☐ Wounds/Burns other ☐ None **Other:**

SOFA Score (Day 1 or first 24 hours)?

○ Yes
○ No

Hospital Outcomes / Complications (First 24-Hours)

Infectious Complications/Outcomes

* must provide value

- ☐ Central Line-Associated Blood Stream Infection (CLABSI)
- ☐ Empyema
- ☐ Endocarditis
- ☐ Fungal Infection
- ☐ Intra-cranial infection
- ☐ Osteomyelitis
- ☐ Pneumonia (Non-Ventilator Associated)
- ☐ Pneumonia (Ventilator-Associated) (VAP)
- ☐ Sepsis (SIRS, septic shock, or severe sepsis)
- ☐ Surgical Site Infection - Deep
- ☐ Surgical Site Infection - Superficial
- ☐ Urinary Tract Infection (Catheter-Associated)
- ☐ Urinary Tract Infection (Non-Catheter Related)
- ☐ Wound Infection - Deep
- ☐ Wound Infection - Superficial
- ☐ Other Infectious Complication (but not listed above)
- ☐ None

Non-infectious Complications/Outcomes

* must provide value

- ☐ Abdominal Compartment Syndrome
- ☐ Acute Kidney Injury (insufficiency; ARF)
- ☐ Acute lung injury (ALI)
- ☐ Acute Respiratory Distress Syndrome (ARDS)
- ☐ Alcohol Withdrawal Syndrome
- ☐ Cardiac Arrest with return of spontaneous circulation
- ☐ Coagulopathy
- ☐ Crush Syndrome
- ☐ Deep Vein Thrombosis
- ☐ Delirium (altered mentation, not from head injury)
- ☐ Dialysis
- ☐ Liver Failure
- ☐ Multiple Organ Failure
- ☐ Myocardial Infarction
- ☐ Neurostorming - seizures
- ☐ Pancreatitis
- ☐ Pressure Ulcer
- ☐ Pulmonary Embolism (PE)
- ☐ Spinal Cord Injury progression
- ☐ Stroke/CVA
- ☐ TBI progression (including neurostorming, seizures)
- ☐ Other Non-infectious Complication (but not listed above)
- ☐ None

Form Status

Complete? Incomplete

25 to 72 Hours At CRS

Record ID Field 4999

Laboratory Values (25 to 72 hours)

Arterial or Venous Blood Gas		Complete Blood Count		Chemistry		INR		Urinalysis	
Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
○	○	○	○	○	○	○	○	○	○

Imaging (25 to 72 hours)

Imaging Modality and Body Part	Imaging Results and Description
X-Ray None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT non-contrasted None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT with contrast None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT angio None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining

MRI

None | Head | Face | Neck | Thorax | Ab/P | Spine | UE | LE | Bony pelvis

Abnormality Description

30 words remaining

FAST

None | Head | Face | Neck | Thorax | Ab/P | Spine | UE | LE | Bony pelvis

Abnormality Description

30 words remaining

Ultrasound

None | Head | Face | Neck | Thorax | Ab/P | Spine | UE | LE | Bony pelvis

Abnormality Description

30 words remaining

Lodox

None | Full-Body

Abnormality Description

30 words remaining

Non-surgical Hospital Procedures (25 to 72 hours)

Non-surgical Hospital Procedures (check all that apply)

* must provide value

- [ ] Airway Management
- [ ] Backboard
- [ ] Bleeding Control (foley)
- [ ] Cardiocentesis
- [ ] Chest seal (vented or non-vented)
- [ ] CPR
- [ ] C-spine immobilization
- [ ] Embolization
- [ ] Extremity Splints
- [ ] Manual Pressure
- [ ] Needle decompression
- [ ] Oxygen Administration
- [ ] Pelvic Binder
- [ ] Positive Ventilation Initiated (CPAP or BiPAP only)
- [ ] Pressure dressing
- [ ] Reduction (for fracture)
- [ ] Reduction (for dislocation)
- [ ] Rewarming (e.g., warm IV fluids)
- [ ] Sedation (conscious or deep)
- [ ] Thoracostomy/Chest Tube
- [ ] Tourniquet
- [ ] Withdrawal From Life Support
- [ ] Wound Care
- [ ] None

Medication Administered (25 to 72 hours)

Fluids

Fluid Type

* must provide value

- [ ] None
- [ ] Normal Saline
- [ ] Dextrose 5%
- [ ] Dextrose 10%
- [ ] Dextrose 50%
- [ ] Ringers Lactate
- [ ] Hypertonic saline
- [ ] Other

Blood Products

Type of Blood Product Administered

* must provide value

- [ ] None given
- [ ] Cryoprecipitate
- [ ] Packed Red Blood Cells
- [ ] Plasma
- [ ] Platelets
- [ ] Whole Blood
- [ ] FD Plasma
- [ ] Other

Analgesia

Oral Analgesia given between 25 hours to 72 hours (check all that apply)

* must provide value

- [ ] None
- [ ] Tramadol
- [ ] Paracetamol
- [ ] Ibuprofen
- [ ] Other

IV or IM Analgesia

* must provide value

- [ ] None
- [ ] Morphine
- [ ] Fentanyl
- [ ] Paracetamol
- [ ] Ketamine
- [ ] Other

Other Medication

Other Medication Administered

* must provide value

- [ ] None
- [ ] Inotropes
- [ ] Vasopressors
- [ ] Venous Thromboembolism Prophylaxis
- [ ] Venous Thromboembolism Treatment
- [ ] TXA
- [ ] Prophylactic antibiotics

Surgical Procedures (25 to 72 hours)

Surgical Procedures				
Body Part	**Surgery Type**	**Surgery Date**	**Surgery Time**	**Surgery Success**
1.		D-M-Y	H:M	
2.		D-M-Y	H:M	
3.		D-M-Y	H:M	
4.		D-M-Y	H:M	
5.		D-M-Y	H:M	
6.		D-M-Y	H:M	
7.		D-M-Y	H:M	
8.		D-M-Y	H:M	
9.		D-M-Y	H:M	
10.		D-M-Y	H:M	
11.		D-M-Y	H:M	
12.		D-M-Y	H:M	

Diagnosis (25 to 72 hours)

Category	Diagnosis

Airway and Breathing	☐ Airway obstruction ☐ Hemothorax ☐ Pneumothorax ☐ Pulmonary Contusion ☐ Airway and Breathing other ☐ None **Other:**
Circulation	☐ Shock ☐ Hemorrhagic hypovolemia ☐ Cardiac tamponade ☐ Tension pneumothorax ☐ Cardiac arrest ☐ Circulation other ☐ None **Other:**
Disability	☐ Mild Brain Injury ☐ Moderate Brain Injury ☐ Severe Brain Injury ☐ Intracranial Bleeding ☐ Hypoglycemia ☐ High Cervical Spine Cord Injury w/ Deficits ☐ Low Cervical Spine Cord Injury w/ Deficits ☐ Thoracic Spine Cord Injury w/ Deficits ☐ Lumbar Spine Cord Injury w/ Deficits ☐ Peripheral Nerve Injury ☐ Compartment Syndrome (Extremity) ☐ Disability Other ☐ None **Other:**
Environmental Exposure	☐ Hypothermia ☐ Hyperthermia ☐ Exposure other ☐ None **Other:**
Orthopedic	☐ Fracture of skull and facial bones ☐ Fracture of ribs, sternum, clavicles ☐ Fracture of cervical, thoracic, lumbar spine ☐ Fracture of pelvis (includes sacrum and coccyx) ☐ Fracture of upper extremity (includes scapula + humeral head to finger tips) ☐ Fracture of lower extremity (from femoral head to toes) ☐ Traumatic amputation of extremity ☐ Crush injury of extremity ☐ Tendon Injury ☐ Dislocation (closed) ☐ Dislocation (open) ☐ Other Orthopedic Diagnosis ☐ None **Other:**
Wounds/Burns	☐ Burn-first degree (partial thickness) ≥20% TBSA ☐ Burn-second degree (mid-thickness ≥10% TBSA ☐ Burn-third degree (deep) ≥5% TBSA ☐ Wounds/Burns other ☐ None **Other:**

SOFA Score (Day 2)?
- ○ Yes
- ○ No

SOFA Score (Day 3)?
- ○ Yes
- ○ No

Hospital Outcomes / Complications (25-72-hours)

Infectious Complications/Outcomes
* must provide value

- ☐ Central Line-Associated Blood Stream Infection (CLABSI)
- ☐ Empyema
- ☐ Endocarditis
- ☐ Fungal Infection
- ☐ Intra-cranial infection
- ☐ Osteomyelitis
- ☐ Pneumonia (Non-Ventilator Associated)
- ☐ Pneumonia (Ventilator-Associated) (VAP)
- ☐ Sepsis (SIRS, septic shock, or severe sepsis)
- ☐ Surgical Site Infection - Deep
- ☐ Surgical Site Infection - Superficial
- ☐ Urinary Tract Infection (Catheter-Associated)
- ☐ Urinary Tract Infection (Non-Catheter Related)
- ☐ Wound Infection - Deep
- ☐ Wound Infection - Superficial
- ☐ Other Infectious Complication (but not listed above)
- ☐ None

Non-infectious Complications/Outcomes
* must provide value

- ☐ Abdominal Compartment Syndrome
- ☐ Acute Kidney Injury (insufficiency; ARF)
- ☐ Acute lung injury (ALI)
- ☐ Acute Respiratory Distress Syndrome (ARDS)
- ☐ Alcohol Withdrawal Syndrome
- ☐ Cardiac Arrest with return of spontaneous circulation
- ☐ Coagulopathy
- ☐ Crush Syndrome
- ☐ Deep Vein Thrombosis
- ☐ Delirium (altered mentation, not from head injury)
- ☐ Dialysis
- ☐ Liver Failure
- ☐ Multiple Organ Failure
- ☐ Myocardial Infarction
- ☐ Neurostorming - seizures
- ☐ Pancreatitis
- ☐ Pressure Ulcer
- ☐ Pulmonary Embolism (PE)
- ☐ Spinal Cord Injury progression
- ☐ Stroke/CVA
- ☐ TBI progression (including neurostorming, seizures)
- ☐ Other Non-infectious Complication (but not listed above)
- ☐ None

Form Status

Complete? Incomplete

73 Hours To 7 Days At CRS

Record ID Field 4999

Laboratory Values (73 hours to 7 days)

Arterial or Venous Blood Gas		Complete Blood Count		Chemistry		INR		Urinalysis	
Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
○	○	○	○	○	○	○	○	○	○

Imaging (73 hours to 7 days)

Imaging Modality and Body Part	Imaging Results and Description
X-Ray None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT non-contrasted None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT with contrast None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT angio None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining

MRI

None | Head | Face | Neck | Thorax | Ab/P | Spine | UE | LE | Bony pelvis

Abnormality Description

30 words remaining

FAST

None | Head | Face | Neck | Thorax | Ab/P | Spine | UE | LE | Bony pelvis

Abnormality Description

30 words remaining

Ultrasound

None | Head | Face | Neck | Thorax | Ab/P | Spine | UE | LE | Bony pelvis

Abnormality Description

30 words remaining

Lodox

None | Full-Body

Abnormality Description

30 words remaining

Non-surgical Hospital Procedures (73 hours to 7 days)

Non-surgical Hospital Procedures (check all that apply)

* must provide value

- [ ] Airway Management
- [ ] Backboard
- [ ] Bleeding Control (foley)
- [ ] Cardiocentesis
- [ ] Chest seal (vented or non-vented)
- [ ] CPR
- [ ] C-spine immobilization
- [ ] Embolization
- [ ] Extremity Splints
- [ ] Manual Pressure
- [ ] Needle decompression
- [ ] Oxygen Administration
- [ ] Pelvic Binder
- [ ] Positive Ventilation Initiated (CPAP or BiPAP only)
- [ ] Pressure dressing
- [ ] Reduction (for fracture)
- [ ] Reduction (for dislocation)
- [ ] Rewarming (e.g., warm IV fluids)
- [ ] Sedation (conscious or deep)
- [ ] Thoracostomy/Chest Tube
- [ ] Tourniquet
- [ ] Withdrawal From Life Support
- [ ] Wound Care
- [ ] None

Medication Administered (73 hours to 7 days)

Fluids

Fluid Type

* must provide value

- [ ] None
- [ ] Normal Saline
- [ ] Dextrose 5%
- [ ] Dextrose 10%
- [ ] Dextrose 50%
- [ ] Ringers Lactate
- [ ] Hypertonic saline
- [ ] Other

Blood Products

Type of Blood Product Administered

* must provide value

- [ ] None given
- [ ] Cryoprecipitate
- [ ] Packed Red Blood Cells
- [ ] Plasma
- [ ] Platelets
- [ ] Whole Blood
- [ ] FD Plasma
- [ ] Other

Analgesia

Oral Analgesia given in between 73 hours and 7 days (check all that apply)

* must provide value

- [ ] None
- [ ] Tramadol
- [ ] Paracetamol
- [ ] Ibuprofen
- [ ] Other

IV or IM Analgesia

* must provide value

- [ ] None
- [ ] Morphine
- [ ] Fentanyl
- [ ] Paracetamol
- [ ] Ketamine
- [ ] Other

Other Medication

Other Medication Administered

* must provide value

- [ ] None
- [ ] Inotropes
- [ ] Vasopressors
- [ ] Venous Thromboembolism Prophylaxis
- [ ] Venous Thromboembolism Treatment
- [ ] TXA
- [ ] Prophylactic antibiotics

Surgical Procedures (73 hours to 7 days)

Surgical Procedures				
Body Part	**Surgery Type**	**Surgery Date**	**Surgery Time**	**Surgery Success**
1.		D-M-Y	H:M	
2.		D-M-Y	H:M	
3.		D-M-Y	H:M	
4.		D-M-Y	H:M	
5.		D-M-Y	H:M	
6.		D-M-Y	H:M	
7.		D-M-Y	H:M	
8.		D-M-Y	H:M	
9.		D-M-Y	H:M	
10.		D-M-Y	H:M	
11.		D-M-Y	H:M	
12.		D-M-Y	H:M	

Diagnosis (73 hours to 7 days)

Category	Diagnosis

Airway and Breathing	☐ Airway obstruction ☐ Hemothorax ☐ Pneumothorax ☐ Pulmonary Contusion ☐ Airway and Breathing other ☐ None **Other:**
Circulation	☐ Shock ☐ Hemorrhagic hypovolemia ☐ Cardiac tamponade ☐ Tension pneumothorax ☐ Cardiac arrest ☐ Circulation other ☐ None **Other:**
Disability	☐ Mild Brain Injury ☐ Moderate Brain Injury ☐ Severe Brain Injury ☐ Intracranial Bleeding ☐ Hypoglycemia ☐ High Cervical Spine Cord Injury w/ Deficits ☐ Low Cervical Spine Cord Injury w/ Deficits ☐ Thoracic Spine Cord Injury w/ Deficits ☐ Lumbar Spine Cord Injury w/ Deficits ☐ Peripheral Nerve Injury ☐ Compartment Syndrome (Extremity) ☐ Disability Other ☐ None **Other:**
Environmental Exposure	☐ Hypothermia ☐ Hyperthermia ☐ Exposure other ☐ None **Other:**
Orthopedic	☐ Fracture of skull and facial bones ☐ Fracture of ribs, sternum, clavicles ☐ Fracture of cervical, thoracic, lumbar spine ☐ Fracture of pelvis (includes sacrum and coccyx) ☐ Fracture of upper extremity (includes scapula + humeral head to finger tips) ☐ Fracture of lower extremity (from femoral head to toes) ☐ Traumatic amputation of extremity ☐ Crush injury of extremity ☐ Tendon Injury ☐ Dislocation (closed) ☐ Dislocation (open) ☐ Other Orthopedic Diagnosis ☐ None **Other:**
Wounds/Burns	☐ Burn-first degree (partial thickness) ≥20% TBSA ☐ Burn-second degree (mid-thickness ≥10% TBSA ☐ Burn-third degree (deep) ≥5% TBSA ☐ Wounds/Burns other ☐ None **Other:**

SOFA Score (Day 4)?
- ○ Yes
- ○ No

SOFA Score (Day 5)?
- ○ Yes
- ○ No

SOFA Score (Day 6)?
- ○ Yes
- ○ No

SOFA Score (Day 7)?
- ○ Yes
- ○ No

Hospital Outcomes / Complications (73 hours to 7 Days)

Infectious Complications/Outcomes
* must provide value

- ☐ Central Line-Associated Blood Stream Infection (CLABSI)
- ☐ Empyema
- ☐ Endocarditis
- ☐ Fungal Infection
- ☐ Intra-cranial infection
- ☐ Osteomyelitis
- ☐ Pneumonia (Non-Ventilator Associated)
- ☐ Pneumonia (Ventilator-Associated) (VAP)
- ☐ Sepsis (SIRS, septic shock, or severe sepsis)
- ☐ Surgical Site Infection - Deep
- ☐ Surgical Site Infection - Superficial
- ☐ Urinary Tract Infection (Catheter-Associated)
- ☐ Urinary Tract Infection (Non-Catheter Related)
- ☐ Wound Infection - Deep
- ☐ Wound Infection - Superficial
- ☐ Other Infectious Complication (but not listed above)
- ☐ None

Non-infectious Complications/Outcomes
* must provide value

- ☐ Abdominal Compartment Syndrome
- ☐ Acute Kidney Injury (insufficiency; ARF)
- ☐ Acute lung injury (ALI)
- ☐ Acute Respiratory Distress Syndrome (ARDS)
- ☐ Alcohol Withdrawal Syndrome
- ☐ Cardiac Arrest with return of spontaneous circulation
- ☐ Coagulopathy
- ☐ Crush Syndrome
- ☐ Deep Vein Thrombosis
- ☐ Delirium (altered mentation, not from head injury)
- ☐ Dialysis
- ☐ Liver Failure
- ☐ Multiple Organ Failure
- ☐ Myocardial Infarction
- ☐ Neurostorming - seizures
- ☐ Pancreatitis
- ☐ Pressure Ulcer
- ☐ Pulmonary Embolism (PE)
- ☐ Spinal Cord Injury progression
- ☐ Stroke/CVA
- ☐ TBI progression (including neurostorming, seizures)
- ☐ Other Non-infectious Complication (but not listed above)
- ☐ None

Form Status

Complete? Incomplete

CRS Outcomes and Discharge

Record ID Field	4999

Hospital Summary/Disposition Items

Total GCS at discharge
* must provide value

Total Ventilator Days
* must provide value

Total length of stay in ICU
* must provide value
day(s)

Number of Operating Theatre Encounters
* must provide value

Final Hospital Disposition
* must provide value

Hospital Discharge Date
* must provide value
D-M-Y

Hospital Discharge Time
* must provide value
H:M

Date and Time Case Completed (Hospital Forms Only)
* must provide value
D-M-Y H:M

Case completed by:

Form Status

Complete? Incomplete

TBH Admission Details

Record ID Field	4999

Patient Transport and Transfer Information

Demo Form Injury Date/Time: _____ at Unknown

EMS Transfer Type: Private Interfacility Transfer (If Primary, follow green prompts; If IFT, follow blue prompts)

Dispatch Date/Time: _____ at _____

Scene/Hospital #1 Arrival Time: _____ Scene/Hospital #1 Departure Time: _____

Hospital (#1/#2) Arrival Date/Time: _____ at _____

EMS Transfer Type: _____

Dispatch Date/Time: _____ at _____, left Hospital #1 at: _____

Hospital #2 Arrival Date/Time: _____ at _____

Was this incoming arrival an Interfacility Transfer?
* must provide value

- ○ Yes
- ○ No

Receiving Facility
* must provide value

- ○ Ceres Hospital
- ○ Khayelitsha Hospital
- ○ Tygerberg Hospital
- ○ Worcester Hospital

Facility Units of Care

Facility Unit of Care
* must provide value

- ☐ Emergency Centre
- ☐ Ward
- ☐ Operating Theatre
- ☐ ICU

Phases of Care

Phases of Care
* must provide value

- ☐ Initial Resuscitation
- ☐ Damage Control Surgery
- ☐ Intensive Care
- ☐ Definitive Surgery
- ☐ Non-ICU (EG Ward, High Care)
- ☐ Non-Resuscitative EC Care

Time Points

Time Points
* must provide value

- ☐ First 24 Hours
- ☐ 25-hours to 72 hours
- ☐ 73 hours to 7 days

Form Status

Complete? Incomplete

First 24 Hours at TBH

Record ID Field 4999

Imaging (First 24-Hour)

Imaging Modality and Body Part	Imaging Results and Description
X-Ray None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT non-contrasted None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT with contrast None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT angio None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining

MRI

None	Head	Face	Neck	Thorax	Ab/P	Spine	UE	LE	Bony pelvis
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

30 words remaining

FAST

None	Head	Face	Neck	Thorax	Ab/P	Spine	UE	LE	Bony pelvis
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Abnormality Description

30 words remaining

Ultrasound

None	Head	Face	Neck	Thorax	Ab/P	Spine	UE	LE	Bony pelvis
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Abnormality Description

30 words remaining

Lodox

None	Full-Body
○	○

Abnormality Description

30 words remaining

Surgical Procedures (First 24 hours)

Surgical Procedures				
Body Part	**Surgery Type**	**Surgery Date**	**Surgery Time**	**Surgery Success**
1.		D-M-Y	H:M	
2.		D-M-Y	H:M	

3.		D-M-Y	H:M	
4.		D-M-Y	H:M	
5.		D-M-Y	H:M	
6.		D-M-Y	H:M	
7.		D-M-Y	H:M	
8.		D-M-Y	H:M	
9.		D-M-Y	H:M	
10.		D-M-Y	H:M	
11.		D-M-Y	H:M	

12.		D-M-Y	H:M	

Form Status

Complete? Incomplete

25 to 72 Hours at TBH

Record ID Field 4999

Imaging (25 to 72 hours)

Imaging Modality and Body Part	Imaging Results and Description
X-Ray None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT non-contrasted None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT with contrast None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT angio None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining

MRI

None | Head | Face | Neck | Thorax | Ab/P | Spine | UE | LE | Bony pelvis

Abnormality Description

30 words remaining

FAST

None | Head | Face | Neck | Thorax | Ab/P | Spine | UE | LE | Bony pelvis

Abnormality Description

30 words remaining

Ultrasound

None | Head | Face | Neck | Thorax | Ab/P | Spine | UE | LE | Bony pelvis

Abnormality Description

30 words remaining

Lodox

None | Full-Body

Abnormality Description

30 words remaining

Surgical Procedures (25 to 72 hours)

Surgical Procedures				
Body Part	**Surgery Type**	**Surgery Date**	**Surgery Time**	**Surgery Success**
1.		D-M-Y	H:M	
2.		D-M-Y	H:M	
3.		D-M-Y	H:M	
4.		D-M-Y	H:M	
5.		D-M-Y	H:M	
6.		D-M-Y	H:M	
7.		D-M-Y	H:M	
8.		D-M-Y	H:M	
9.		D-M-Y	H:M	
10.		D-M-Y	H:M	
11.		D-M-Y	H:M	
12.		D-M-Y	H:M	

Form Status

Complete? Incomplete

73 hours to 7 days at TBH

Record ID Field	4999

Imaging (73 hours to 7 days)

Imaging Modality and Body Part	**Imaging Results and Description**
X-Ray None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT non-contrasted None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT with contrast None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT angio None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining

MRI

None | Head | Face | Neck | Thorax | Ab/P | Spine | UE | LE | Bony pelvis

Abnormality Description

30 words remaining

FAST

None | Head | Face | Neck | Thorax | Ab/P | Spine | UE | LE | Bony pelvis

Abnormality Description

30 words remaining

Ultrasound

None | Head | Face | Neck | Thorax | Ab/P | Spine | UE | LE | Bony pelvis

Abnormality Description

30 words remaining

Lodox

None | Full-Body

Abnormality Description

30 words remaining

Surgical Procedures (73 hours to 7 days)

Surgical Procedures				
Body Part	**Surgery Type**	**Surgery Date**	**Surgery Time**	**Surgery Success**
1.		D-M-Y	H:M	
2.		D-M-Y	H:M	
3.		D-M-Y	H:M	
4.		D-M-Y	H:M	
5.		D-M-Y	H:M	
6.		D-M-Y	H:M	
7.		D-M-Y	H:M	
8.		D-M-Y	H:M	
9.		D-M-Y	H:M	
10.		D-M-Y	H:M	
11.		D-M-Y	H:M	
12.		D-M-Y	H:M	

Form Status

Complete? Incomplete

TBH Outcomes and Discharge

Record ID Field	4999

Hospital Summary/Disposition Items

Total GCS at discharge
* must provide value

Total Ventilator Days
* must provide value

Total length of stay in ICU
* must provide value
day(s)

Number of Operating Theatre Encounters
* must provide value

Final Hospital Disposition
* must provide value

Hospital Discharge Date
* must provide value
D-M-Y

Hospital Discharge Time
* must provide value
H:M

Date and Time Case Completed (Hospital Forms Only)
* must provide value
D-M-Y H:M

Case completed by:

Form Status

Complete? Incomplete

WOC Admission Details

Record ID Field	4999

Patient Transport and Transfer Information

Demo Form Injury Date/Time: _____ **at Unknown**

EMS Transfer Type: **Private Interfacility Transfer** **(If Primary, follow green prompts; If IFT, follow blue prompts)**

Dispatch Date/Time: _____ **at** _____

Scene/Hospital #1 Arrival Time: _____ **Scene/Hospital #1 Departure Time:** _____

Hospital (#1/#2) Arrival Date/Time: _____ **at** _____

EMS Transfer Type: _____

Dispatch Date/Time: _____ **at** _____, **left Hospital #1 at:** _____

Hospital #2 Arrival Date/Time: _____ **at** _____

Was this incoming arrival an Interfacility Transfer?
* must provide value

- ○ Yes
- ○ No

Receiving Facility
* must provide value

- ○ Ceres Hospital
- ○ Khayelitsha Hospital
- ○ Tygerberg Hospital
- ○ Worcester Hospital

Facility Units of Care

Facility Unit of Care
* must provide value

- ☐ Emergency Centre
- ☐ Ward
- ☐ Operating Theatre
- ☐ ICU

Phases of Care

Phases of Care
* must provide value

- ☐ Initial Resuscitation
- ☐ Damage Control Surgery
- ☐ Intensive Care
- ☐ Definitive Surgery
- ☐ Non-ICU (EG Ward, High Care)
- ☐ Non-Resuscitative EC Care

Time Points

Time Points
* must provide value

- ☑ First 24 Hours
- ☑ 25-hours to 72 hours
- ☑ 73 hours to 7 days

Form Status

Complete? Incomplete

First 24 Hours At WOC

Record ID Field 4999

First 24 Hours at Facility

South African Triage Scale (SATS) Upon Facility Arrival	
Date D-M-Y	**Time** H:M
TEWS	**SATS Colour** ○ Red ○ Orange ○ Yellow ○ Green ○ Blue

Vital Signs (First 24-Hours)

Select corresponding vital signs Recorded

* must provide value

- ☐ First Vital Signs
- ☐ Last Vital Signs
- ☐ Vital Sign Ranges (If three or more sets of vitals available)
- ☐ None

Laboratory Values (First 24-Hour)

Arterial or Venous Blood Gas		**Complete Blood Count**		**Chemistry**		**INR**		**Urinalysis**	
Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
○	○	○	○	○	○	○	○	○	○

Imaging (First 24-Hour)

Imaging Modality and Body Part	**Imaging Results and Description**
X-Ray **None** ☐ **Head** ☐ **Face** ☐ **Neck** ☐ **Thorax** ☐ **Ab/P** ☐ **Spine** ☐ **UE** ☐ **LE** ☐ **Bony pelvis** ☐	▾ **Abnormality Description** 30 words remaining
CT non-contrasted **None** ☐ **Head** ☐ **Face** ☐ **Neck** ☐ **Thorax** ☐ **Ab/P** ☐ **Spine** ☐ **UE** ☐ **LE** ☐ **Bony pelvis** ☐	▾ **Abnormality Description** 30 words remaining

CT with contrast

None	Head	Face	Neck	Thorax	Ab/P	Spine	UE	LE	Bony pelvis
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Abnormality Description

30 words remaining

CT angio

None	Head	Face	Neck	Thorax	Ab/P	Spine	UE	LE	Bony pelvis
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Abnormality Description

30 words remaining

MRI

None	Head	Face	Neck	Thorax	Ab/P	Spine	UE	LE	Bony pelvis
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Abnormality Description

30 words remaining

FAST

None	Head	Face	Neck	Thorax	Ab/P	Spine	UE	LE	Bony pelvis
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Abnormality Description

30 words remaining

Ultrasound

None	Head	Face	Neck	Thorax	Ab/P	Spine	UE	LE	Bony pelvis
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Abnormality Description

30 words remaining

Lodox

None ○ Full-Body ○

Abnormality Description

30 words remaining

Non-surgical Hospital Procedures (First 24-Hour)

Non-surgical Hospital Procedures (check all that apply)

* must provide value

- ☐ Airway Management
- ☐ Backboard
- ☐ Bleeding Control (foley)
- ☐ Cardiocentesis
- ☐ Chest seal (vented or non-vented)
- ☐ CPR
- ☐ C-spine immobilization
- ☐ Embolization
- ☐ Extremity Splints
- ☐ Manual Pressure
- ☐ Needle decompression
- ☐ Oxygen Administration
- ☐ Pelvic Binder
- ☐ Positive Ventilation Initiated (CPAP or BiPAP only)
- ☐ Pressure dressing
- ☐ Reduction (for fracture)
- ☐ Reduction (for dislocation)
- ☐ Rewarming (e.g., warm IV fluids)
- ☐ Sedation (conscious or deep)
- ☐ Thoracostomy/Chest Tube
- ☐ Tourniquet
- ☐ Withdrawal From Life Support
- ☐ Wound Care
- ☐ None

Medication Administered (First 24-Hour)

Fluids

Fluid Type

* must provide value

- ☐ None
- ☐ Normal Saline
- ☐ Dextrose 5%
- ☐ Dextrose 10%
- ☐ Dextrose 50%
- ☐ Ringers Lactate
- ☐ Hypertonic saline
- ☐ Other

Blood Products

Type of Blood Product Administered

* must provide value

- ☐ None given
- ☐ Cryoprecipitate
- ☐ Packed Red Blood Cells
- ☐ Plasma
- ☐ Platelets
- ☐ Whole Blood
- ☐ FD Plasma
- ☐ Other

Analgesia

Oral Analgesia given in first 24 hours (check all that apply)
* must provide value

- [ ] None
- [ ] Tramadol
- [ ] Paracetamol
- [ ] Ibuprofen
- [ ] Other

IV or IM Analgesia
* must provide value

- [ ] None
- [ ] Morphine
- [ ] Fentanyl
- [ ] Paracetamol
- [ ] Ketamine
- [ ] Other

Other Medication

Other Medication Administered
* must provide value

- [ ] None
- [ ] Inotropes
- [ ] Vasopressors
- [ ] Venous Thromboembolism Prophylaxis
- [ ] Venous Thromboembolism Treatment
- [ ] TXA
- [ ] Prophylactic antibiotics

Surgical Procedures (First 24 hours)

Surgical Procedures				
Body Part	**Surgery Type**	**Surgery Date**	**Surgery Time**	**Surgery Success**
1.		D-M-Y	H:M	
2.		D-M-Y	H:M	
3.		D-M-Y	H:M	
4.		D-M-Y	H:M	
5.		D-M-Y	H:M	
6.		D-M-Y	H:M	
7.		D-M-Y	H:M	
8.		D-M-Y	H:M	
9.		D-M-Y	H:M	
10.		D-M-Y	H:M	
11.		D-M-Y	H:M	
12.		D-M-Y	H:M	

Diagnosis (First 24 hours)

Category	Diagnosis
Airway and Breathing	☐ Airway obstruction ☐ Hemothorax ☐ Pneumothorax ☐ Pulmonary Contusion ☐ Airway and Breathing other ☐ None **Other:**

Circulation	☐ Shock ☐ Hemorrhagic hypovolemia ☐ Cardiac tamponade ☐ Tension pneumothorax ☐ Cardiac arrest ☐ Circulation other ☐ None **Other:**
Disability	☐ Mild Brain Injury ☐ Moderate Brain Injury ☐ Severe Brain Injury ☐ Intracranial Bleeding ☐ Hypoglycemia ☐ High Cervical Spine Cord Injury w/ Deficits ☐ Low Cervical Spine Cord Injury w/ Deficits ☐ Thoracic Spine Cord Injury w/ Deficits ☐ Lumbar Spine Cord Injury w/ Deficits ☐ Peripheral Nerve Injury ☐ Compartment Syndrome (Extremity) ☐ Disability Other ☐ None **Other:**
Environmental Exposure	☐ Hypothermia ☐ Hyperthermia ☐ Exposure other ☐ None **Other:**
Orthopedic	☐ Fracture of skull and facial bones ☐ Fracture of ribs, sternum, clavicles ☐ Fracture of cervical, thoracic, lumbar spine ☐ Fracture of pelvis (includes sacrum and coccyx) ☐ Fracture of upper extremity (includes scapula + humeral head to finger tips) ☐ Fracture of lower extremity (from femoral head to toes) ☐ Traumatic amputation of extremity ☐ Crush injury of extremity ☐ Tendon Injury ☐ Dislocation (closed) ☐ Dislocation (open) ☐ Other Orthopedic Diagnosis ☐ None **Other:**
Wounds/Burns	☐ Burn-first degree (partial thickness) ≥20% TBSA ☐ Burn-second degree (mid-thickness ≥10% TBSA ☐ Burn-third degree (deep) ≥5% TBSA ☐ Wounds/Burns other ☐ None **Other:**

SOFA Score (Day 1 or first 24 hours)?

○ Yes
○ No

Hospital Outcomes / Complications (First 24-Hours)

Infectious Complications/Outcomes

* must provide value

- ☐ Central Line-Associated Blood Stream Infection (CLABSI)
- ☐ Empyema
- ☐ Endocarditis
- ☐ Fungal Infection
- ☐ Intra-cranial infection
- ☐ Osteomyelitis
- ☐ Pneumonia (Non-Ventilator Associated)
- ☐ Pneumonia (Ventilator-Associated) (VAP)
- ☐ Sepsis (SIRS, septic shock, or severe sepsis)
- ☐ Surgical Site Infection - Deep
- ☐ Surgical Site Infection - Superficial
- ☐ Urinary Tract Infection (Catheter-Associated)
- ☐ Urinary Tract Infection (Non-Catheter Related)
- ☐ Wound Infection - Deep
- ☐ Wound Infection - Superficial
- ☐ Other Infectious Complication (but not listed above)
- ☐ None

Non-infectious Complications/Outcomes

* must provide value

- ☐ Abdominal Compartment Syndrome
- ☐ Acute Kidney Injury (insufficiency; ARF)
- ☐ Acute lung injury (ALI)
- ☐ Acute Respiratory Distress Syndrome (ARDS)
- ☐ Alcohol Withdrawal Syndrome
- ☐ Cardiac Arrest with return of spontaneous circulation
- ☐ Coagulopathy
- ☐ Crush Syndrome
- ☐ Deep Vein Thrombosis
- ☐ Delirium (altered mentation, not from head injury)
- ☐ Dialysis
- ☐ Liver Failure
- ☐ Multiple Organ Failure
- ☐ Myocardial Infarction
- ☐ Neurostorming - seizures
- ☐ Pancreatitis
- ☐ Pressure Ulcer
- ☐ Pulmonary Embolism (PE)
- ☐ Spinal Cord Injury progression
- ☐ Stroke/CVA
- ☐ TBI progression (including neurostorming, seizures)
- ☐ Other Non-infectious Complication (but not listed above)
- ☐ None

Form Status

Complete? Incomplete

25 To 72 Hours At WOC

Record ID Field 4999

Laboratory Values (25 to 72 hours)

Arterial or Venous Blood Gas		Complete Blood Count		Chemistry		INR		Urinalysis	
Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
○	○	○	○	○	○	○	○	○	○

Imaging (25 to 72 hours)

Imaging Modality and Body Part	Imaging Results and Description
X-Ray None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT non-contrasted None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT with contrast None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT angio None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining

MRI

None | Head | Face | Neck | Thorax | Ab/P | Spine | UE | LE | Bony pelvis

Abnormality Description

30 words remaining

FAST

None | Head | Face | Neck | Thorax | Ab/P | Spine | UE | LE | Bony pelvis

Abnormality Description

30 words remaining

Ultrasound

None | Head | Face | Neck | Thorax | Ab/P | Spine | UE | LE | Bony pelvis

Abnormality Description

30 words remaining

Lodox

None | Full-Body

Abnormality Description

30 words remaining

Non-surgical Hospital Procedures (25 to 72 hours)

Non-surgical Hospital Procedures (check all that apply)

* must provide value

- [ ] Airway Management
- [ ] Backboard
- [ ] Bleeding Control (foley)
- [ ] Cardiocentesis
- [ ] Chest seal (vented or non-vented)
- [ ] CPR
- [ ] C-spine immobilization
- [ ] Embolization
- [ ] Extremity Splints
- [ ] Manual Pressure
- [ ] Needle decompression
- [ ] Oxygen Administration
- [ ] Pelvic Binder
- [ ] Positive Ventilation Initiated (CPAP or BiPAP only)
- [ ] Pressure dressing
- [ ] Reduction (for fracture)
- [ ] Reduction (for dislocation)
- [ ] Rewarming (e.g., warm IV fluids)
- [ ] Sedation (conscious or deep)
- [ ] Thoracostomy/Chest Tube
- [ ] Tourniquet
- [ ] Withdrawal From Life Support
- [ ] Wound Care
- [ ] None

Medication Administered (25 to 72 hours)

Fluids

Fluid Type

* must provide value

- [ ] None
- [ ] Normal Saline
- [ ] Dextrose 5%
- [ ] Dextrose 10%
- [ ] Dextrose 50%
- [ ] Ringers Lactate
- [ ] Hypertonic saline
- [ ] Other

Blood Products

Type of Blood Product Administered

* must provide value

- [ ] None given
- [ ] Cryoprecipitate
- [ ] Packed Red Blood Cells
- [ ] Plasma
- [ ] Platelets
- [ ] Whole Blood
- [ ] FD Plasma
- [ ] Other

Analgesia

Oral Analgesia given between 25 hours to 72 hours (check all that apply)

* must provide value

- [ ] None
- [ ] Tramadol
- [ ] Paracetamol
- [ ] Ibuprofen
- [ ] Other

IV or IM Analgesia

* must provide value

- [ ] None
- [ ] Morphine
- [ ] Fentanyl
- [ ] Paracetamol
- [ ] Ketamine
- [ ] Other

Other Medication

Other Medication Administered

* must provide value

- [ ] None
- [ ] Inotropes
- [ ] Vasopressors
- [ ] Venous Thromboembolism Prophylaxis
- [ ] Venous Thromboembolism Treatment
- [ ] TXA
- [ ] Prophylactic antibiotics

Surgical Procedures (25 to 72 hours)

Surgical Procedures				
Body Part	**Surgery Type**	**Surgery Date**	**Surgery Time**	**Surgery Success**
1.		D-M-Y	H:M	
2.		D-M-Y	H:M	
3.		D-M-Y	H:M	
4.		D-M-Y	H:M	
5.		D-M-Y	H:M	
6.		D-M-Y	H:M	
7.		D-M-Y	H:M	
8.		D-M-Y	H:M	
9.		D-M-Y	H:M	
10.		D-M-Y	H:M	
11.		D-M-Y	H:M	
12.		D-M-Y	H:M	

Diagnosis (25 to 72 hours)

Category	Diagnosis

Airway and Breathing	☐ Airway obstruction ☐ Hemothorax ☐ Pneumothorax ☐ Pulmonary Contusion ☐ Airway and Breathing other ☐ None **Other:**
Circulation	☐ Shock ☐ Hemorrhagic hypovolemia ☐ Cardiac tamponade ☐ Tension pneumothorax ☐ Cardiac arrest ☐ Circulation other ☐ None **Other:**
Disability	☐ Mild Brain Injury ☐ Moderate Brain Injury ☐ Severe Brain Injury ☐ Intracranial Bleeding ☐ Hypoglycemia ☐ High Cervical Spine Cord Injury w/ Deficits ☐ Low Cervical Spine Cord Injury w/ Deficits ☐ Thoracic Spine Cord Injury w/ Deficits ☐ Lumbar Spine Cord Injury w/ Deficits ☐ Peripheral Nerve Injury ☐ Compartment Syndrome (Extremity) ☐ Disability Other ☐ None **Other:**
Environmental Exposure	☐ Hypothermia ☐ Hyperthermia ☐ Exposure other ☐ None **Other:**
Orthopedic	☐ Fracture of skull and facial bones ☐ Fracture of ribs, sternum, clavicles ☐ Fracture of cervical, thoracic, lumbar spine ☐ Fracture of pelvis (includes sacrum and coccyx) ☐ Fracture of upper extremity (includes scapula + humeral head to finger tips) ☐ Fracture of lower extremity (from femoral head to toes) ☐ Traumatic amputation of extremity ☐ Crush injury of extremity ☐ Tendon Injury ☐ Dislocation (closed) ☐ Dislocation (open) ☐ Other Orthopedic Diagnosis ☐ None **Other:**
Wounds/Burns	☐ Burn-first degree (partial thickness) ≥20% TBSA ☐ Burn-second degree (mid-thickness ≥10% TBSA ☐ Burn-third degree (deep) ≥5% TBSA ☐ Wounds/Burns other ☐ None **Other:**

SOFA Score (Day 2)?
- ○ Yes
- ○ No

SOFA Score (Day 3)?
- ○ Yes
- ○ No

Hospital Outcomes / Complications (25-72-hours)

Infectious Complications/Outcomes
* must provide value

- ☐ Central Line-Associated Blood Stream Infection (CLABSI)
- ☐ Empyema
- ☐ Endocarditis
- ☐ Fungal Infection
- ☐ Intra-cranial infection
- ☐ Osteomyelitis
- ☐ Pneumonia (Non-Ventilator Associated)
- ☐ Pneumonia (Ventilator-Associated) (VAP)
- ☐ Sepsis (SIRS, septic shock, or severe sepsis)
- ☐ Surgical Site Infection - Deep
- ☐ Surgical Site Infection - Superficial
- ☐ Urinary Tract Infection (Catheter-Associated)
- ☐ Urinary Tract Infection (Non-Catheter Related)
- ☐ Wound Infection - Deep
- ☐ Wound Infection - Superficial
- ☐ Other Infectious Complication (but not listed above)
- ☐ None

Non-infectious Complications/Outcomes
* must provide value

- ☐ Abdominal Compartment Syndrome
- ☐ Acute Kidney Injury (insufficiency; ARF)
- ☐ Acute lung injury (ALI)
- ☐ Acute Respiratory Distress Syndrome (ARDS)
- ☐ Alcohol Withdrawal Syndrome
- ☐ Cardiac Arrest with return of spontaneous circulation
- ☐ Coagulopathy
- ☐ Crush Syndrome
- ☐ Deep Vein Thrombosis
- ☐ Delirium (altered mentation, not from head injury)
- ☐ Dialysis
- ☐ Liver Failure
- ☐ Multiple Organ Failure
- ☐ Myocardial Infarction
- ☐ Neurostorming - seizures
- ☐ Pancreatitis
- ☐ Pressure Ulcer
- ☐ Pulmonary Embolism (PE)
- ☐ Spinal Cord Injury progression
- ☐ Stroke/CVA
- ☐ TBI progression (including neurostorming, seizures)
- ☐ Other Non-infectious Complication (but not listed above)
- ☐ None

Form Status

Complete? Incomplete

73 hours to 7 Days at WOC

Record ID Field 4999

Laboratory Values (73 hours to 7 days)

Arterial or Venous Blood Gas		Complete Blood Count		Chemistry		INR		Urinalysis	
Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
○	○	○	○	○	○	○	○	○	○

Imaging (73 hours to 7 days)

Imaging Modality and Body Part	Imaging Results and Description
X-Ray None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT non-contrasted None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT with contrast None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining
CT angio None ☐ Head ☐ Face ☐ Neck ☐ Thorax ☐ Ab/P ☐ Spine ☐ UE ☐ LE ☐ Bony pelvis ☐	▾ **Abnormality Description** 30 words remaining

MRI

None | Head | Face | Neck | Thorax | Ab/P | Spine | UE | LE | Bony pelvis

Abnormality Description

30 words remaining

FAST

None | Head | Face | Neck | Thorax | Ab/P | Spine | UE | LE | Bony pelvis

Abnormality Description

30 words remaining

Ultrasound

None | Head | Face | Neck | Thorax | Ab/P | Spine | UE | LE | Bony pelvis

Abnormality Description

30 words remaining

Lodox

None | Full-Body

Abnormality Description

30 words remaining

Non-surgical Hospital Procedures (73 hours to 7 days)

Non-surgical Hospital Procedures (check all that apply)

* must provide value

- [ ] Airway Management
- [ ] Backboard
- [ ] Bleeding Control (foley)
- [ ] Cardiocentesis
- [ ] Chest seal (vented or non-vented)
- [ ] CPR
- [ ] C-spine immobilization
- [ ] Embolization
- [ ] Extremity Splints
- [ ] Manual Pressure
- [ ] Needle decompression
- [ ] Oxygen Administration
- [ ] Pelvic Binder
- [ ] Positive Ventilation Initiated (CPAP or BiPAP only)
- [ ] Pressure dressing
- [ ] Reduction (for fracture)
- [ ] Reduction (for dislocation)
- [ ] Rewarming (e.g., warm IV fluids)
- [ ] Sedation (conscious or deep)
- [ ] Thoracostomy/Chest Tube
- [ ] Tourniquet
- [ ] Withdrawal From Life Support
- [ ] Wound Care
- [ ] None

Medication Administered (73 hours to 7 days)

Fluids

Fluid Type

* must provide value

- [ ] None
- [ ] Normal Saline
- [ ] Dextrose 5%
- [ ] Dextrose 10%
- [ ] Dextrose 50%
- [ ] Ringers Lactate
- [ ] Hypertonic saline
- [ ] Other

Blood Products

Type of Blood Product Administered

* must provide value

- [ ] None given
- [ ] Cryoprecipitate
- [ ] Packed Red Blood Cells
- [ ] Plasma
- [ ] Platelets
- [ ] Whole Blood
- [ ] FD Plasma
- [ ] Other

Analgesia

Oral Analgesia given in between 73 hours and 7 days (check all that apply)

* must provide value

- [ ] None
- [ ] Tramadol
- [ ] Paracetamol
- [ ] Ibuprofen
- [ ] Other

IV or IM Analgesia

* must provide value

- [ ] None
- [ ] Morphine
- [ ] Fentanyl
- [ ] Paracetamol
- [ ] Ketamine
- [ ] Other

Other Medication

Other Medication Administered

* must provide value

- [ ] None
- [ ] Inotropes
- [ ] Vasopressors
- [ ] Venous Thromboembolism Prophylaxis
- [ ] Venous Thromboembolism Treatment
- [ ] TXA
- [ ] Prophylactic antibiotics

Surgical Procedures (73 hours to 7 days)

Surgical Procedures				
Body Part	**Surgery Type**	**Surgery Date**	**Surgery Time**	**Surgery Success**
1.		D-M-Y	H:M	
2.		D-M-Y	H:M	
3.		D-M-Y	H:M	
4.		D-M-Y	H:M	
5.		D-M-Y	H:M	
6.		D-M-Y	H:M	
7.		D-M-Y	H:M	

8.		D-M-Y	H:M	
9.		D-M-Y	H:M	
10.		D-M-Y	H:M	
11.		D-M-Y	H:M	
12.		D-M-Y	H:M	

Diagnosis (73 hours to 7 days)

Category	Diagnosis
Airway and Breathing	☐ Airway obstruction ☐ Hemothorax ☐ Pneumothorax ☐ Pulmonary Contusion ☐ Airway and Breathing other ☐ None **Other:**
Circulation	☐ Shock ☐ Hemorrhagic hypovolemia ☐ Cardiac tamponade ☐ Tension pneumothorax ☐ Cardiac arrest ☐ Circulation other ☐ None **Other:**

Disability	☐ Mild Brain Injury ☐ Moderate Brain Injury ☐ Severe Brain Injury ☐ Intracranial Bleeding ☐ Hypoglycemia ☐ High Cervical Spine Cord Injury w/ Deficits ☐ Low Cervical Spine Cord Injury w/ Deficits ☐ Thoracic Spine Cord Injury w/ Deficits ☐ Lumbar Spine Cord Injury w/ Deficits ☐ Peripheral Nerve Injury ☐ Compartment Syndrome (Extremity) ☐ Disability Other ☐ None **Other:**
Environmental Exposure	☐ Hypothermia ☐ Hyperthermia ☐ Exposure other ☐ None **Other:**
Orthopedic	☐ Fracture of skull and facial bones ☐ Fracture of ribs, sternum, clavicles ☐ Fracture of cervical, thoracic, lumbar spine ☐ Fracture of pelvis (includes sacrum and coccyx) ☐ Fracture of upper extremity (includes scapula + humeral head to finger tips) ☐ Fracture of lower extremity (from femoral head to toes) ☐ Traumatic amputation of extremity ☐ Crush injury of extremity ☐ Tendon Injury ☐ Dislocation (closed) ☐ Dislocation (open) ☐ Other Orthopedic Diagnosis ☐ None **Other:**
Wounds/Burns	☐ Burn-first degree (partial thickness) ≥20% TBSA ☐ Burn-second degree (mid-thickness ≥10% TBSA ☐ Burn-third degree (deep) ≥5% TBSA ☐ Wounds/Burns other ☐ None **Other:**

SOFA Score (Day 4)? ○ Yes ○ No

SOFA Score (Day 5)? ○ Yes ○ No

SOFA Score (Day 6)? ○ Yes ○ No

SOFA Score (Day 7)? ○ Yes ○ No

Hospital Outcomes / Complications (73 hours to 7 Days)

Infectious Complications/Outcomes

* must provide value

- ☐ Central Line-Associated Blood Stream Infection (CLABSI)
- ☐ Empyema
- ☐ Endocarditis
- ☐ Fungal Infection
- ☐ Intra-cranial infection
- ☐ Osteomyelitis
- ☐ Pneumonia (Non-Ventilator Associated)
- ☐ Pneumonia (Ventilator-Associated) (VAP)
- ☐ Sepsis (SIRS, septic shock, or severe sepsis)
- ☐ Surgical Site Infection - Deep
- ☐ Surgical Site Infection - Superficial
- ☐ Urinary Tract Infection (Catheter-Associated)
- ☐ Urinary Tract Infection (Non-Catheter Related)
- ☐ Wound Infection - Deep
- ☐ Wound Infection - Superficial
- ☐ Other Infectious Complication (but not listed above)
- ☐ None

Non-infectious Complications/Outcomes

* must provide value

- ☐ Abdominal Compartment Syndrome
- ☐ Acute Kidney Injury (insufficiency; ARF)
- ☐ Acute lung injury (ALI)
- ☐ Acute Respiratory Distress Syndrome (ARDS)
- ☐ Alcohol Withdrawal Syndrome
- ☐ Cardiac Arrest with return of spontaneous circulation
- ☐ Coagulopathy
- ☐ Crush Syndrome
- ☐ Deep Vein Thrombosis
- ☐ Delirium (altered mentation, not from head injury)
- ☐ Dialysis
- ☐ Liver Failure
- ☐ Multiple Organ Failure
- ☐ Myocardial Infarction
- ☐ Neurostorming - seizures
- ☐ Pancreatitis
- ☐ Pressure Ulcer
- ☐ Pulmonary Embolism (PE)
- ☐ Spinal Cord Injury progression
- ☐ Stroke/CVA
- ☐ TBI progression (including neurostorming, seizures)
- ☐ Other Non-infectious Complication (but not listed above)
- ☐ None

Form Status

Complete? Incomplete

WOC Outcomes and Discharge

Record ID Field	4999

Hospital Summary/Disposition Items

Total GCS at discharge
* must provide value

Total Ventilator Days
* must provide value

Total length of stay in ICU
* must provide value
day(s)

Number of Operating Theatre Encounters
* must provide value

Final Hospital Disposition
* must provide value

Hospital Discharge Date
* must provide value
D-M-Y

Hospital Discharge Time
* must provide value
H:M

Date and Time Case Completed (Hospital Forms Only)
* must provide value
D-M-Y H:M

Case completed by:

Form Status

Complete? Incomplete

Forensics and Pathology Service

Record ID Field 4999

PM Report Status	FPS Facility Name	Date of Death	Time of Death
○ Available ○ Has been requested ○ PM Report Missing		D-M-Y	H:M
	Death Register (WC) Number		
		☐ FPS did not dissect body (due to COVID or other reasons)	

Primary Mechanism of Death (MOD)	Primary MOD Subcategory
	Central Nervous System: **Hemorrhage:** **Multiple Organ Failure + Sepsis** **Comorbidities:** **Other:** **Catastrophic Tissue Destruction:**
Secondary Mechanism of Death (MOD)	**Secondary MOD Subcategory**
	Central Nervous System: **Hemorrhage:** **Multiple Organ Failure + Sepsis** **Comorbidities:** **Other:** **Catastrophic Tissue Destruction:**

Cause of Death	Mechanism of Injury

Did you verify AIS injuries in Demographic and injury information?

* must provide value

○ Yes
○ No

	Abbreviated Injury Scale Summary	AIS Cause of Death
AIS 1	_____ - _____ - _____ - _____ . _____	
AIS 2	_____ - _____ - _____ - _____ . _____	
AIS 3	_____ - _____ - _____ - _____ . _____	
AIS 4	_____ - _____ - _____ - _____ . _____	
AIS 5	_____ - _____ - _____ - _____ . _____	
AIS 6	_____ - _____ - _____ - _____ . _____	
AIS 7	_____ - _____ - _____ - _____ . _____	
AIS 8	_____ - _____ - _____ _____ . _____	
AIS 9	_____ - _____ - _____ - _____ . _____	
AIS 10	_____ - _____ - _____ - _____. _____	

Form Status

Complete? Incomplete

Cape-Colorado-Combat (C3) Global Trauma Network: A Prolonged Civilian Casualty Care Research Platform

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Disclaimer and Disclosures

- Disclaimer:
  - Views do not reflect the official policy of the U.S. Army Medical Department, U.S. Department of the Army, U.S. Department of Defense, or the U.S. Government.
- Conflicts of Interest:
  - none
- Commercial Relationships:
  - none

CU Center for COmbat Medicine and BATtlefield (COMBAT) Research

University of Colorado
Anschutz Medical Campus

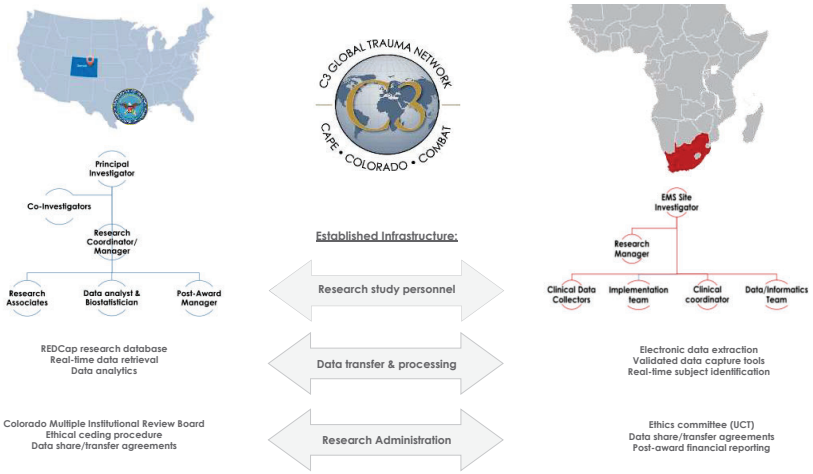
Mission - To solve the US military's **toughest** clinical challenges through **innovation**, **research**, and **advanced development** for the future battlespace

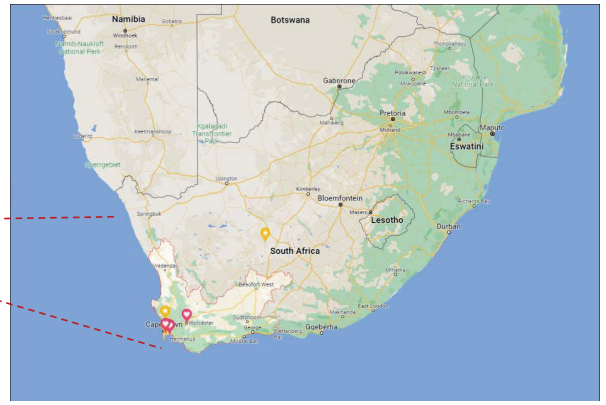
Prolonged Casualty Care is one of those tough challenges

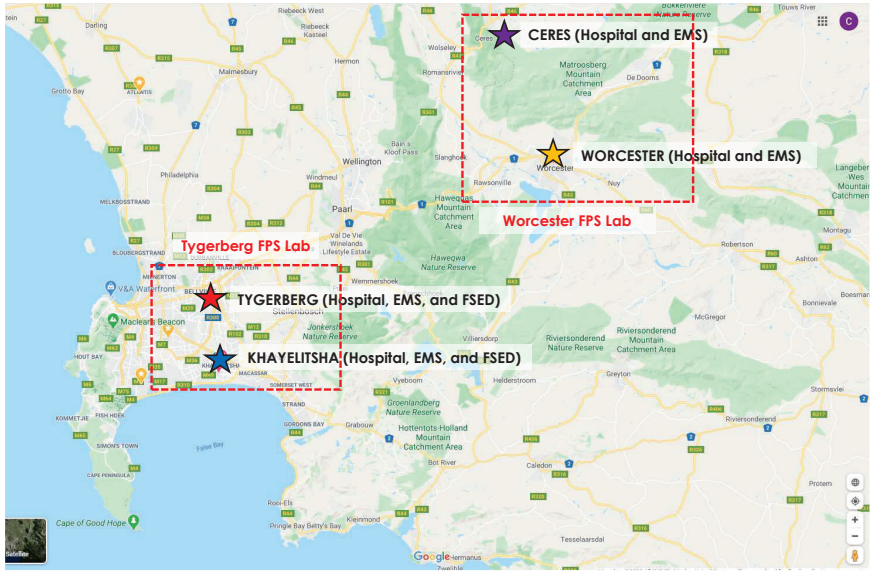
PFC & PCC

- Combat casualty outcomes worse in PFC/PCC
- PFC/PCC are a major research focus of the U.S. military
- Representative data is limited on this topic
- Relevance to Israel and IDF

Cape-Colorado-Combat (C3) Global Trauma Network

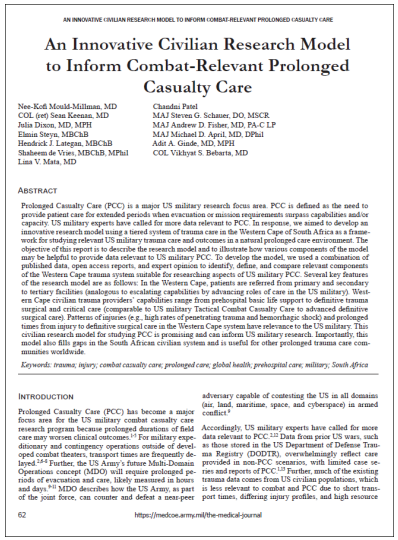






Features of the C3 Network

- Population:
  - Highest trauma (& mortality) rates in world
  - Approx. 100,000 EMS trauma cases per year
  - We enroll >5,000 major trauma cases/year
  - Penetrating injury ~45-50% (compare 5-10% in USA)
  - High frequency of prolonged care
    - Median time = 10.5-hrs
  - We have completed 10 prior funded studies
    - Including an EMS hemorrhagic shock trial
    - Over 20 publications from our collaborations



AN INNOVATIVE CIVILIAN RESEARCH MODEL TO INFORM COMBAT-RELEVANT PROLONGED CASUALTY CARE

An Innovative Civilian Research Model to Inform Combat-Relevant Prolonged Casualty Care

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COL Vikhyat S. Bebarta, MD

ABSTRACT

Prolonged Casualty Care (PCC) is a major US military research focus area. PCC is defined as the need to provide patient care for extended periods when evacuation or mission requirements surpass capabilities and/or capacity. US military experts have called for more data relevant to PCC. In response, we aimed to develop an innovative research model using a tiered system of trauma care in the Western Cape of South Africa as a framework for studying relevant US military trauma care and outcomes in a natural prolonged care environment. The objective of this report is to describe the research model and to illustrate how various components of the model may be helpful to provide data relevant to US military PCC. To develop the model, we used a combination of published data, open access reports, and expert opinion to identify, define, and compare relevant components of the Western Cape trauma system suitable for researching aspects of US military PCC. Several key features of the research model are as follows: In the Western Cape, patients are referred from primary and secondary to tertiary facilities (analogous to escalating capabilities by advancing roles of care in the US military). Western Cape civilian trauma providers' capabilities range from prehospital basic life support to definitive trauma surgical and critical care (comparable to US military Tactical Combat Casualty Care to advanced definitive surgical care). Patterns of injuries (e.g., high rates of penetrating trauma and hemorrhagic shock) and prolonged times from injury to definitive surgical care in the Western Cape system have relevance to the US military. This civilian research model for studying PCC is promising and can inform US military research. Importantly, this model also fills gaps in the South African civilian system and is useful for other prolonged trauma care communities worldwide.

Keywords: trauma; injury; combat casualty care; prolonged care; global health; prehospital care; military; South Africa

INTRODUCTION

Prolonged Casualty Care (PCC) has become a major focus area for the US military combat casualty care research program because prolonged durations of field care may worsen clinical outcomes.[1,2] For military expeditionary and contingency operations outside of developed combat theaters, transport times are frequently delayed.[2,3] Further, the US Army's future Multi-Domain Operations concept (MDO) will require prolonged periods of evacuation and care, likely measured in hours and days.[4-6] MDO describes how the US Army, as part of the joint force, can counter and defeat a near-peer adversary capable of contesting the US in all domains (air, land, maritime, space, and cyberspace) in armed conflict.[4]

Accordingly, US military experts have called for more data relevant to PCC.[2,3] Data from prior US wars, such as those stored in the US Department of Defense Trauma Registry (DODTR), overwhelmingly reflect care provided in non-PCC scenarios, with limited case series and reports of PCC.[2,3] Further, much of the existing trauma data comes from US civilian populations, which is less relevant to combat and PCC due to short transport times, differing injury profiles, and high resource

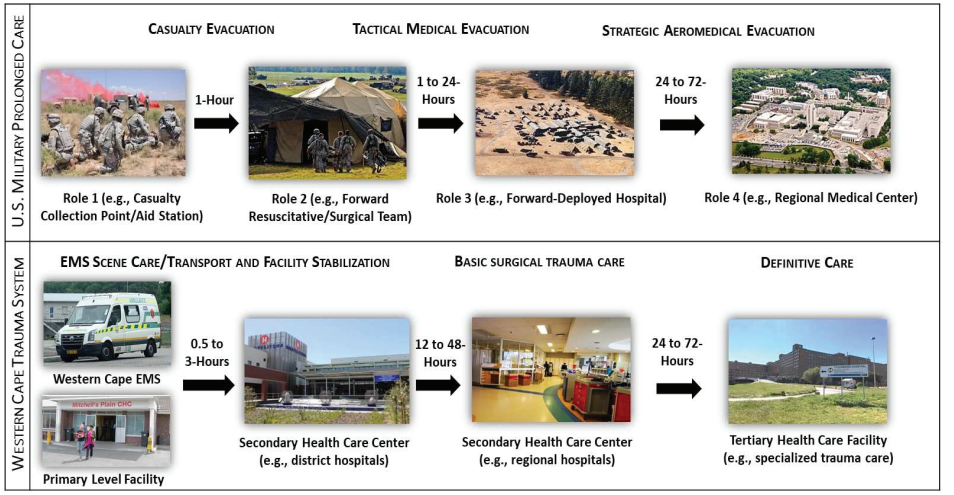
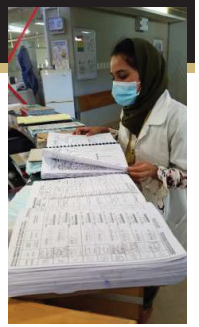
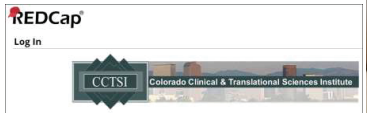


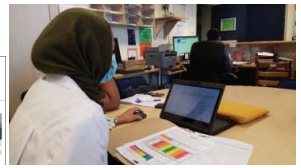
Figure from: Mould-Millman NK, Keenan S; et al. An Innovative Civilian Research Model to Inform Combat-Relevant Prolonged Casualty Care. Medical Journal, US Army Medical Center of Excellence (MEDCoE). 2022 Apr 1.

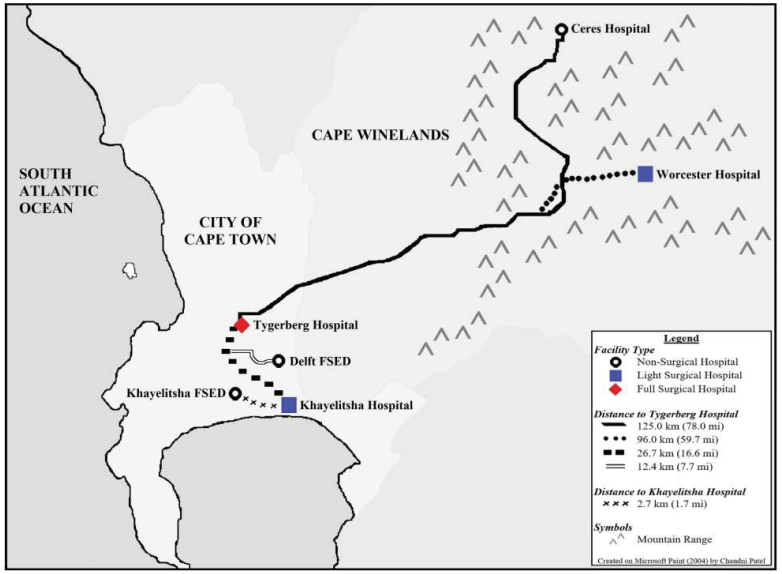
Features of the C3 Network

- Data collection platform:
  - Collect >5-million data points per year
  - Trained teams of data collectors and staff
  - Electronic data capture at point-of-care
  - We are embedded within facilities/organizations
  - Data linking of EMS + hospital + pathology data
  - Transmittal to UCD REDCap database







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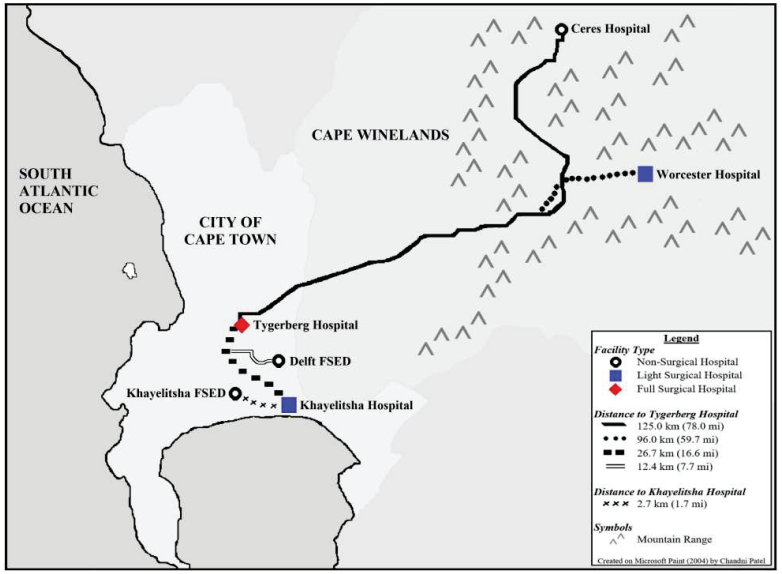
Ceres Hospital
CAPE WINELANDS
SOUTH ATLANTIC OCEAN
Worcester Hospital
CITY OF CAPE TOWN
Tygerberg Hospital
Delft FSED
Khayelitsha FSED
Khayelitsha Hospital
Legend
Facility Type
Non-Surgical Hospital
Light Surgical Hospital
Full Surgical Hospital
Distance to Tygerberg Hospital
125.0 km (78.0 mi)
96.0 km (59.7 mi)
26.7 km (16.6 mi)
12.4 km (7.7 mi)
Distance to Khayelitsha Hospital
2.7 km (1.7 mi)
Symbols
Mountain Range
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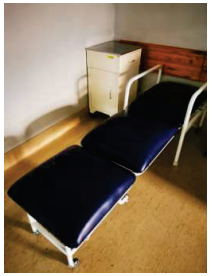

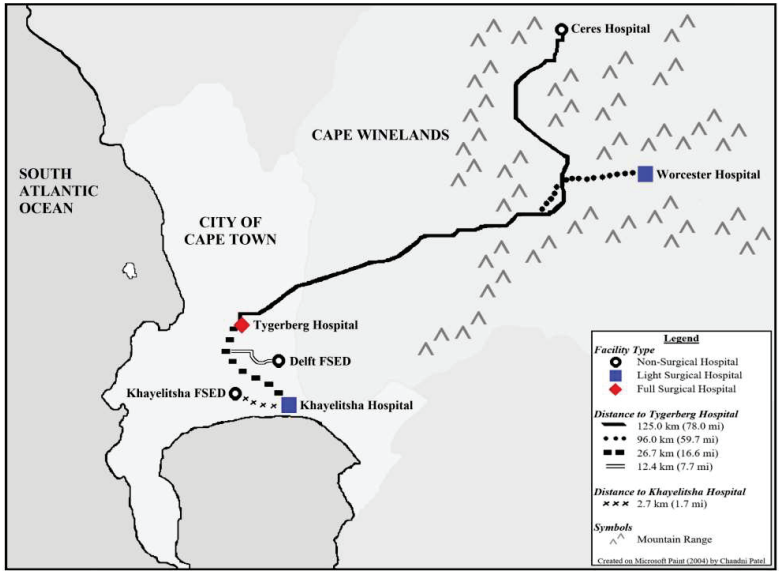
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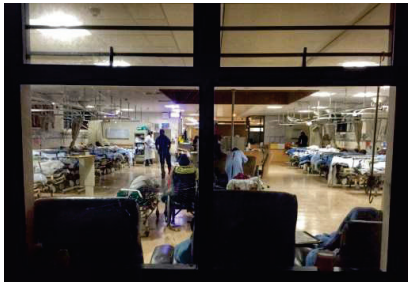

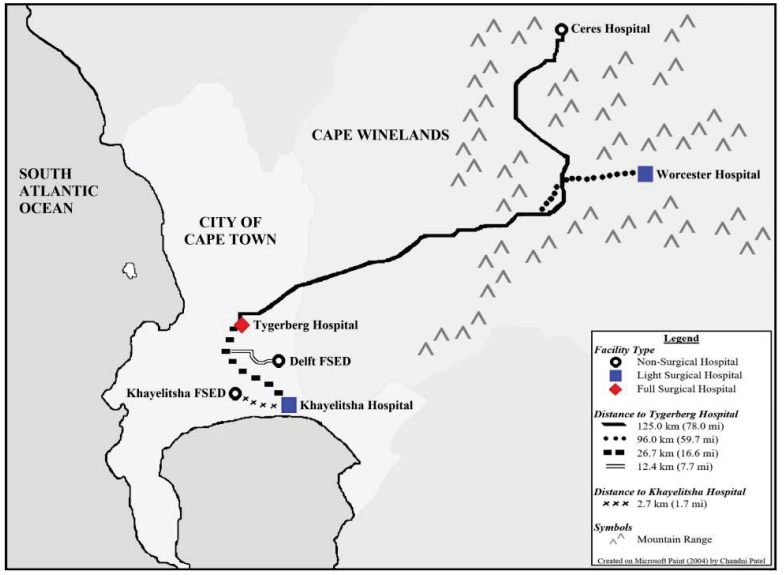
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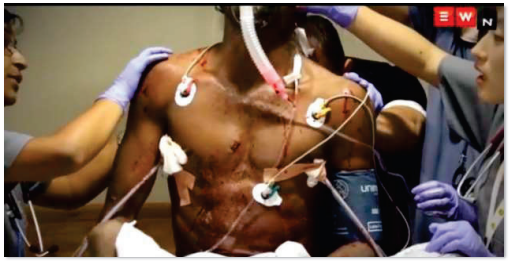
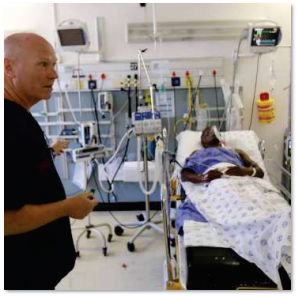




C3 Network Focus Areas

- EpiC study
  - PFC & PCC
- TXA
  - Prehospital TXA
  - Hospital TXA
- Blood products
  - Whole blood vs component
- Crush Syndrome
  - Prediction/scoring tool
- Preventable mortality
  - Expert panel review

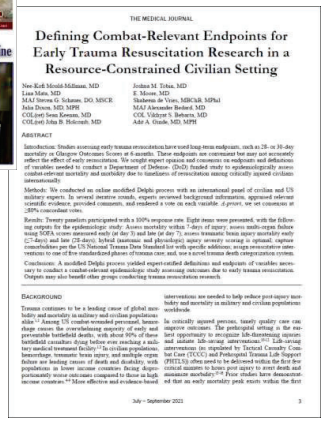
Epidemiology and Outcomes of Prolonged Trauma Care:
a Multi-center Prospective Observational Study in
the Western Cape of South Africa.

DOD Award #s: W81XWH20-2-0042 (30-Sep-2020 to 29-Sep-2024);
W81XWH19-2-0055 (30-Sep-2019 to 29-Sep-2022).
Stellenbosch University HREC: Project ID 14866; Ethics Reference Number N20/03/036

EpiC

- Goal:
  - Epidemiologic study to prospectively assesses the effect of time to definitive care and the effect of critical prehospital and hospital interventions on morbidity and mortality…
- Outcomes:
  - Mortality (24-hr, 7-day, 30-day)
  - Multiple organ failure scores
  - Infection rates
- Timeline:
  - Sep 2021 to Sep 2024
- MIL-CIV input:
  - Steering committee (SOF, tri-service, clinical input)
  - Technical experts (US mil, US civ, South Africa civ)

EpiC



THE MEDICAL JOURNAL

Defining Combat-Relevant Endpoints for Early Trauma Resuscitation Research in a Resource-Constrained Civilian Setting

Nee-Kofi Mould-Millman, MD · Joshua M. Tobin, MD · Lisa Mata, MD · E. Moore, MD · MAJ Steven G. Schauer, DO, MSCR · Shaheem de Vries, MBChB, MPhil · Julia Dixon, MD, MPH · MAJ Alexander Borland, MD · COL(ret) Sean Keenan, MD · COL Viktyor S. Bebarta, MD · COL(ret) John B. Holcomb, MD · Adit A. Ginde, MD, MPH

ABSTRACT

Introduction: Studies assessing early trauma resuscitation have used long-term endpoints, such as 28- or 30-day mortality or Glasgow Outcomes Scores at 6 months. These endpoints are convenient but may not accurately reflect the effect of early resuscitation. We sought expert opinion and consensus on endpoints and definitions of variables needed to conduct a Department of Defense- (DoD) funded study to epidemiologically assess combat-relevant mortality and morbidity due to timeliness of resuscitation among critically injured civilians internationally.

Methods: We conducted an online modified Delphi process with an international panel of civilian and US military experts. In several iterative rounds, experts reviewed background information, appraised relevant scientific evidence, provided comments, and rendered a vote on each variable. *A priori*, we set consensus at ≥80% coincidant votes.

Results: Twenty panelists participated with a 100% response rate. Eight items were presented, with the following outputs for the epidemiologic study: Assess mortality within 7 days of injury; assess multi-organ failure using SOFA scores measured early (at day 3) and late (at day 7); assess traumatic brain injury mortality early (≤7-days) and late (28-days); hybrid (anatomic and physiologic) injury severity scoring is optimal; capture comorbidities per the US National Trauma Data Standard list with specific additions; assign resuscitative interventions to one of five standardized phases of trauma care, and, use a novel trauma death categorization system.

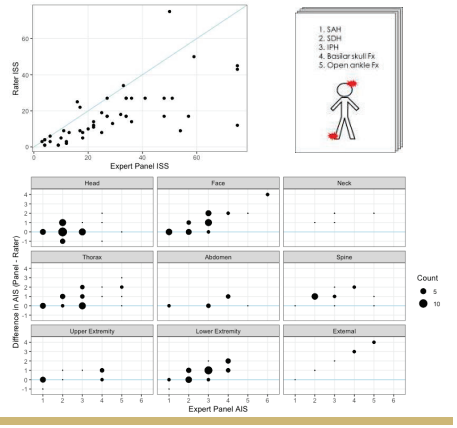
Conclusions: A modified Delphi process yielded expert-certified definitions and endpoints of variables necessary to conduct a combat-relevant epidemiologic study assessing outcomes due to early trauma resuscitation. Outputs may also benefit other groups conducting trauma resuscitation research.

BACKGROUND:

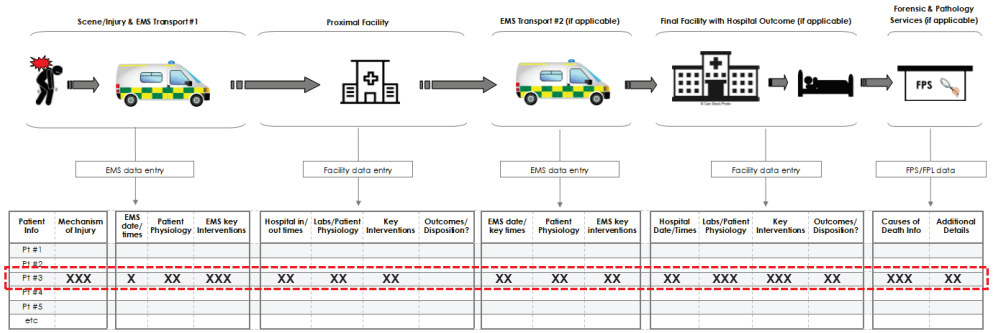
Trauma continues to be a leading cause of global mortality and morbidity in military and civilian populations alike.[1,2] Among US combat-wounded personnel, hemorrhage causes the overwhelming majority of early and preventable battlefield deaths, with about 90% of these battlefield casualties dying before ever reaching a military medical treatment facility.[3,4] In civilian populations, hemorrhage, traumatic brain injury, and multiple organ failure are leading causes of death and disability, with populations in lower income countries facing disproportionately worse outcomes compared to those in high-income countries.[5,6] More effective and evidence-based interventions are needed to help reduce post-injury morbidity and mortality in military and civilian populations worldwide.

In critically injured persons, timely quality care can improve outcomes. The prehospital setting is the earliest opportunity to recognize life-threatening injuries and initiate life-saving interventions.[6,7] Life-saving interventions (as stipulated by Tactical Casualty Combat Care (TCCC) and Prehospital Trauma Life Support (PHTLS)) often need to be delivered within the first few critical minutes to hours post injury to avert death and minimize morbidity.[6–8] Prior studies have demonstrated that an early mortality peak occurs within the first

July – September 2021 3



EpiC



The Journal of Trauma and Acute Care Surgery®

J Trauma Acute Care Surg, 2022.
Volume 93, Number 2, Supplement
DOI: 10.1097/TA.0000000000003675

*Pilot study during COVID

ORIGINAL ARTICLE

OPEN

Prolonged casualty care: Extrapolating civilian data to the military context

Nee-Kofi Mould-Millman, MD, MSCS, Navneet Kaur Baidwan, PhD, Brenda Beaty, MSPH, Krithika Suresh, PhD, Julia M. Dixon, MD, MPH, Chandni Patel, BPH, Shaheem de Vries, MBChB, Hendrick J. Lategan, MBChB, Elmin Steyn, MBChB, Janette Verster, MBChB, Maj Steven G. Schauer, DO, MS, Col Tyson E. Becker, MD, MPH, Cord Cunningham, MD, MHA, MPH, Sean Keenan, MD, Ernest E. Moore, MD, Lee A. Wallis, MBChB, PhD, Adit A. Ginde, MD, MPH, *and* Col Vikhyat S. Bebarta, MD, *Aurora, Colorado*

BACKGROUND: Civilian and military populations alike are increasingly faced with undesirable situations in which prehospital and definitive care times will be delayed. The Western Cape of South Africa has some similarities in capabilities, injury profiles, resource limitations, and system configuration to US military prolonged casualty care (PCC) settings. This study provides an initial description of civilians in the Western Cape who experience PCC and compares the PCC and non-PCC populations.

METHODS: We conducted a 6-month analysis of an ongoing, prospective, large-scale epidemiologic study of prolonged trauma care in the Western Cape (Epidemiology and Outcomes of Prolonged Trauma Care [EpiC]). We define PCC as ≥10 hours from injury to arrival at definitive care. We describe patient characteristics, critical interventions, key times, and outcomes as they may relate to military PCC and compare these using χ^2 and Wilcoxon tests. We estimated the associations between PCC status and the primary and secondary outcomes using logistic regression models.

RESULTS: Of 995 patients, 146 experienced PCC. The PCC group, compared with non-PCC, were more critically injured (66% vs. 51%), received more critical interventions (36% vs. 29%), and had a greater proportionate mortality (5% vs. 3%), longer hospital stays (3 vs. 1 day), and higher Sequential Organ Failure Assessment scores (5 vs. 3). The odds of 7-day mortality and a Sequential Organ Failure Assessment score of ≥5 were 1.6 (odds ratio, 1.59; 95% confidence interval, 0.68–3.74) and 3.6 (odds ratio, 3.69; 95% confidence interval, 2.11–6.42) times higher, respectively, in PCC versus non-PCC patients.

CONCLUSION: The EpiC study enrolled critically injured patients with PCC who received resuscitative interventions. Prolonged casualty care patients had worse outcomes than non-PCC. The EpiC study will be a useful platform to provide ongoing data for PCC relevant analyses, for future PCC-focused interventional studies, and to develop PCC protocols and algorithms. Findings will be relevant to the Western Cape, South Africa, other LMICs, and military populations experiencing prolonged care. (*J Trauma Acute Care Surg.* 2022;93: S78–S85.)

LEVEL OF EVIDENCE: Therapeutic/care management; Level IV
KEY WORDS: Trauma; prolonged care; mortality; morbidity.

There are important parallels between prolonged civilian and combat casualty care in which the common aim is to bring effective care closer to the wounded and to provide sustained care for prolonged durations using limited resources.[1,2] In civilian populations living in low- and middle-income countries specifically, prehospital delays more than 60 minutes contribute up to 20% excess mortality.[3,4] Since 2008, medical evacuation in the US military has been designed to occur in less than 60 minutes ("golden hour"), thus contributing to the lowest combat mortality rate in history.[5] However, in near future multidomain operations, delayed evacuations on the order of hours to days are anticipated; hence, there is a need to

TABLE 1. Baseline Patient Characteristics for the Entire EpiC Study Population, and by Non-PCC Versus PCC (≥10 Hours) Subgroups

	All N = 995	Non-PCC n = 849 (85%)	PCC n = 146 (15%)	p
Patient characteristics				
Age (median, Q1–Q3)	31.5 (25.7–40.0)	31.7 (25.5–40.0)	30.7 (26.0–39.7)	0.64
Sex: male	700 (70%)	595 (70%)	105 (72%)	0.65
Injury characteristics				
Penetrating injury	455 (46%)	399 (47%)	56 (38%)	0.053
Dominant mechanism of injury:				
Firearm	94 (9%)	81 (10%)	13 (9%)	
Struck/hit (i.e., blunt)	196 (20%)	168 (20%)	28 (19%)	
Stabbing or cut	312 (31%)	273 (32%)	39 (27%)	
Vehicular	217 (22%)	185 (22%)	32 (22%)	
Fall/thermal/other	160 (16%)	130 (15%)	30 (21%)	
Unknown	16 (2%)	12 (1%)	4 (3%)	0.45
Severity measures				
TEWS score ≥ 7	137 (14%)	103 (12%)	34 (23%)	0.0003
SATS: Red	384 (39%)	304 (36%)	80 (54%)	<0.0001
NISS ≥15	138 (14%)	93 (11%)	45 (31%)	<0.0001
AIS severity ≥ severe	63 (6%)	47 (6%)	16 (11%)	0.01
GCS score ≤12	78 (8%)	57 (7%)	21 (15%)	0.001
Shock index ≥1	226 (23%)	197 (23%)	29 (20%)	0.35
Critical patient (meets any of the above severity measures)	533 (54%)	437 (51%)	96 (66%)	0.001
AIS body regions with AIS severity score >1				
Head	256 (26%)	158 (24%)	98 (33%)	
Face	54 (6%)	36 (5%)	18 (6%)	
Neck	14 (1%)	12 (2%)	2 (1%)	
Thorax	189 (20%)	157 (23%)	32 (11%)	
Abdomen	106 (11%)	81 (12%)	25 (8%)	
Spine	28 (3%)	20 (9%)	8 (3%)	
Upper extremity	102 (11%)	67 (10%)	35 (12%)	
Lower extremity	206 (21%)	133 (20%)	73 (25%)	
External	13 (1%)	8 (1%)	5 (2%)	0.0001
Total	968 (100%)	672 (69%)	296 (31%)	
Median (Q1–Q3) severity score	3 (2–3)	3 (2–3)	3 (2–3)	0.80
Critical interventions received*				
Received any intervention during EMSs or at hospital, within 24 h of injury	299 (30%)	246 (29%)	53 (36%)	0.07

*Defined in Supplementary Tables 1.4 and 1.8.
AIS, Abbreviated Injury Scale; GCS, Glasgow Coma Scale; NISS, New Injury Severity Score; SATS, South African Triage Scale; TEWS, Trauma Early Warning Score.

15% had PCC ≥10 hours
24% had PCC ≥4 hours

Age 31.5 years
70% male

46% penetrating
10% firearm injuries

23% in hemorrhagic shock
54% considered critical
(PCC=66% vs 51% non-PCC)

26% head injuries
15% GCS ≤12
31% thoracic injuries

Median AIS=3 (severe)
30% receive LSI's

TABLE 3. Frequencies and Proportions of All EpiC Mortality and Morbidity-Related Outcomes Within 7 Days Postinjury, by Subgroups

Outcomes	All N = 995	Non-PCC n = 849 (85%)	PCC n = 146 (15%)	*p*
1^{O} – Death in ambulance or within 7 d of injury, n (%)*	33 (3.3%)	26 (3.1%)	7 (4.8%)	0.28
2^{O} – Death in ambulance or within 30 d of injury, n (%)*	37 (3.7%)	29 (3.4%)	8 (5.5%)	0.22
2^{O} – Total hospital LOS (emergency department and in-patients)	1 (1–3)	1 (1–2)	3 (2–9)	<0.0001
2^{O} – LOS (in-patients only)**	5 (3–11)	4 (3–9)	7 (3–12)	0.003
2^{O} – Worst SOFA score†	4 (1–7)	3 (1–7)	5 (2–7)	0.13

*Two non-PCC patients died during EMSs transport and were missing a mortality outcome.
**A total of 273 were admitted as in-patients (189 non-PCC and 83 with PCC).
†Of the patients, 86% were noncritical and appropriately missing a SOFA score, so medians are based on 141 individuals (100 non-PCC and 41 PCC).
1^{O}, Primary outcome; 2^{O}, secondary outcome; LOS, length of stay.

PCC patients:

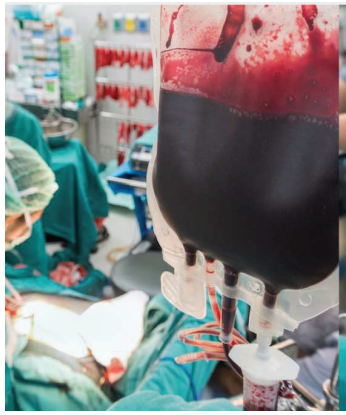
- 2 days longer hospital length of stay (p < 0.001)
- Higher median SOFA score (5 vs. 3, p = 0.13)
- 3.7 greater odds of having organ failure (OR, 3.69; 95% CI, 2.11–6.42; p < 0.001)

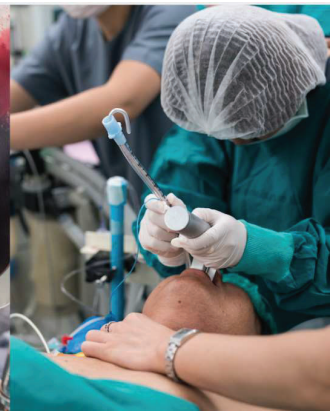
PCC patients:

59% higher 7-day mortality (4.8% versus 3.1%)

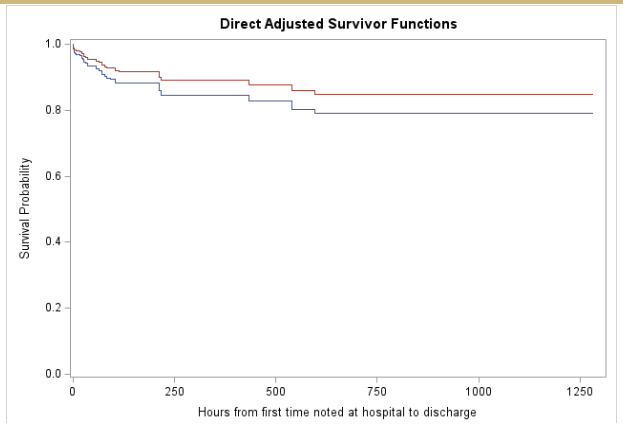
(OR 1.59; 95% CI, 0.68–3.74; p = 0.28)

TXA & Blood Products





TXA

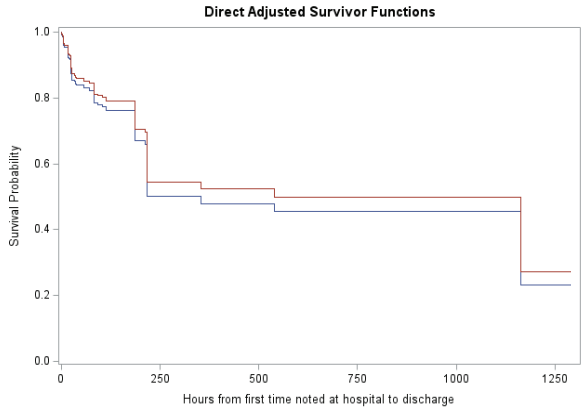


TXA group has ~10% higher likelihood of survival (extends beyond 30-days)

The effect appears larger among those with PFC/PCC

Inverse Probability Weighted (age, TEWS, blood products) and adjusted for comorbidities, other critical interventions, injury force type

Blood



Blood products group has better survival probability (limited to first 24 hours)

Inverse Probability Weighted (age, TEWS, other LSI) and adjusted for comorbidities, injury force type

Mortality

- Preventable Mortality
  - 150 cases; ~40% relevant to PFC
  - 50 on-scene deaths; 100 EMS or facility deaths
  - 1 in 3 deaths due to hemorrhage, and 1 in 3 due to TBI


Other Areas of Interest

- Device studies/wearables
- Predictive algorithms
- Traumatic brain injury
- Early broad spectrum antibiotics
- Vasopressors for prolonged shock
- Training and educational interventions

Thank You.

- CCCRP
- USAMRAA
- CDMRP




Questions?

C3 GLOBAL TRAUMA NETWORK
C3
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University of Colorado
Anschutz Medical Campus

CENTER FOR COMBAT RESEARCH
CU ANSCHUTZ

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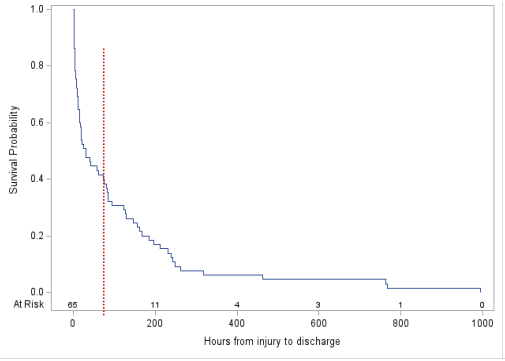
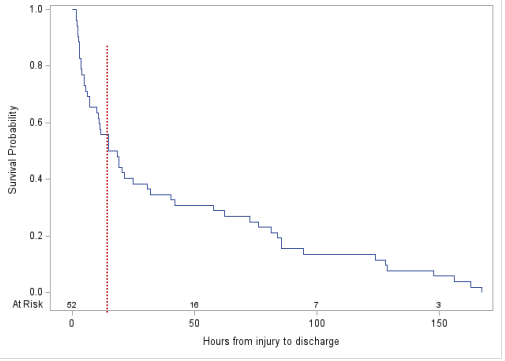
LinkedIn – the-center-for-combat-research
Website – combatresearch.org

Mortality

30-day mortality:
50% survival probability at 25 hours



7-day mortality:
50% survival probability at 15 hours



Appendix 9 - Mortality Panel Case Summary

Case: 155069024

Sites Encountered (EMS->CRS->TBH)
To be presented by Prof Elmin Steyn

Case Summary & Timeline

04/05/21 05:45	**51 yo male Multiple gunshot wounds.**
06:10	CRS EC triage PR 85 BP 111/76 T35 alert 100% RED Hb 14 GSW left upper arm, abdomen, left upper leg Affected extremities NVI
	XR extremities without fractures, CXR clear, no free air in abdomen 2 large bore IVs, IV fluids Discussed with TBH for transfer
09:20	Loaded by EMS for transfer to TBH Abdomen distended and pt complaining of pain
10:40	Arrived at TBH, distended abdomen with guarding, +free ait
21:45	Awaiting CT

Case Summary & Timeline

05/05/21 06:00	Exlap, left leg exploration and femoral artery repair Findings: # distal ileum 4x perforations 10cm from ileocecal valvue- done ileocectomy and brought out ileostomy and mucous fistula. # 2x mesenterium defects, adjacent small bowel viable. # transverse mesocolon hematoma and defect, no colon injury. - closed defect. # posterior stomach wall at antrum big perforation - debrided edges and closed vicryl and omentum patch.
HD 1-3	ICU care in resus, TPN started
Hospital Day 3	Transferred to ICU, on TPN
Hospital Day 5 9/05/21	Extubated, Temp 38.2, patient continues to be restless and confused
HD 7 and HD9	IR placement of pigtail catheter for intra-abdominal fluid collection
HD 12	Wound dehiscence and high output ileostomy

Case Summary & Timeline

HD13	I&D, removal of bullet from left flank
HD 26-28	AKI Cr 635 Urea 42 enteroatmospheric fistula, R femoral CVC placed Worsening AKI
HD 31-42	In resus, dialysis for AKI, on 40% face mask, confused, NG, wound vac on fistula, concern for sepsis, new pigtail for paracolic gutter fluid collection
HD 42-52	Back in ward, patient continued on TPN, frequently refuses Physio throughout hospital course
HD 52	14:28, patient weak and sleepy, PR 146 BP127/76 96-98%HGT 6.9, Hb 5.9, Dr. informed, no interventions at this time
HD53 00:00	BP 106/63 PR122 T37.6 100% Hb 4.9 HGT 10.9 3 units of emergency blood given, given dextrose
27/06/21 HD54 17:35	**Time of death** Pt became unresponsive and pulseless. CPR and adrenaline x3

FPS Post Mortem Findings

Date & time of death:	**27/06/21 @ 17:37**
Major Injuries (per PM report):	1) Frozen abdomen with intestinal fibrin adhesions, no overt peritoneal sepsis, small fluid collection return mixed flora, post mortem flora 2) Left upper lobe purulence 3) Left pulmonary artery PE 4) Well organized thrombus in left deep femoral vein (2 weeks old)
Cause of Death:	• *Sequela of injury*

Death Summary

Mechanism of Death:	• Main category: other
	• Sub-category pulmonary embolism? Vs sequela of injury?

Preventability	• Preventable (or Definitely Survivable) • Potentially Preventable (or potentially survivable) • Non-Preventable (or non-survivable) • Non-preventable (but with care that could have been improved) • Indeterminate*
	• ** If indeterminate, indicate what piece(s) of information would have helped you to render a decision.*

See preventability definitions on slide #4 of the instructions.

Categorizing Deficiencies

Level of Deficiency	Communication & Documentation	Clinical Care	Resources	Policy, Guidelines, or Protocols
System				
Facility/ Organization		Delay to emergency surgery		
Unit(s)		Requesting a CT scan should not delay surgery when there is a clear indication for surgery.	Insufficient emergency theatre time and staff resources.	
People (providers)		Early antibiotic dose?		
People				

Indicate 2-3 top issues.

Strategies for Improvement

Level of Deficiency	Communication & Documentation	Clinical Care	Resources	Policy, Guidelines, or Protocols
System				
Facility/ Organization				
Unit(s)		Avoid delays due to CT through team training sessions	Require more emergency surgery lists	
People (providers)				
People (community)				

Identify 1 (or 2) strategies for each deficiency listed in the previous slide.

Case Discussion (entire panel)

- Questions or comments from panel
- Questions or comments from audience

- Consensus scoring on preventability:
  - Preventable (or Definitely Survivable)
  - Potentially Preventable (or potentially survivable)
  - Non-Preventable (or non-survivable)
  - Non-preventable (but with care that could have been improved)
  - Indeterminate*

Appendix 11.1 TXA poster, SOMA

Outcomes From Tranexamic Acid (TXA) in Traumatic Hemorrhage: A Prospective Cohort Study in a High Trauma, Austere, Prolonged Care Setting

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BACKGROUND

- Trauma-induced hemorrhage is a leading cause of death.
- ~30% have early coagulopathy (bleeding disorder), resulting in a four-fold increased risk of mortality.
- TXA may be important to slow bleeding and prolong survival
- This has implications for prolonged care on the battlefield.
- TXA use extended to civilian and military settings;
- However, several studies have not shown benefit, use in real-world prolonged care settings remains under-researched.

OBJECTIVES

- To gain additional evidence regarding the potential mortality benefit of TXA in adult traumatic hemorrhage in a 'real-world' high-trauma, military-relevant civilian setting.

METHODS

- 'EpiC' is a multicenter, prospective, observational study
- Location: Western Cape Province of South Africa
  - Resource-limited health setting
  - Military-relevant mechanisms and severities
  - Patients frequently experience prolonged care
- Period: March 23 to August 27, 2021.
- Eligibility criteria:
  - Adults ≥ 18 years
  - Blunt or penetrating injuries
  - Shock index ≥0.7 or systolic blood pressure ≤100mmHg
- Models were inverse probability weighted (propensity score based) by South Africa Triage Scale acuity scores, age, and any blood product administration in first 24 hours.
- The final models were multivariable adjusted for comorbidities, injury force type, and administration of other critical interventions.

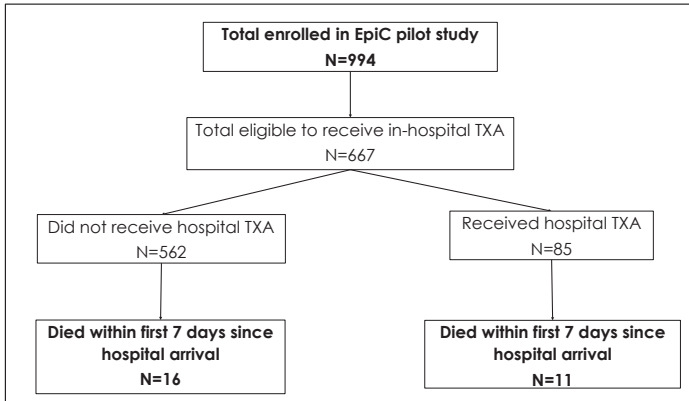

Figure 1: Patient Flow Chart

= 52% mortality reduction at 24-hours
(p-value: 0.272)

= 61% mortality reduction at 7-days
(p-value: 0.101)

Figure 2: Association between TXA administration and mortality

LIMITATIONS

- Time from injury was not incorporated in pilot data analyses.
- Hemorrhagic (likely candidates for TXA administration) and non-hemorrhagic deaths were analyzed together
- We did not incorporate time to event analysis.

RESULTS

Table 1: Descriptive statistics means (SD) and frequencies (percentages) for key study characteristics by TXA administration

Characteristics	TXA eligible (n=647)	
	No TXA (n=562) Mean (SD), n (%)	TXA (n=85) Mean (SD), n (%)
Age	32.8 (10.9)	33.3 (10.6)
Triage Early Warning Score	4.7 (1.9)	6.8 (2.5)
New Injury Severity Score	6.0 (9.4)	18.0 (15.6)
Sex		
Male	371 (66.0)	71 (83.5)
Female	191 (34.0)	14 (16.5)
Injury force		
Blunt	256 (45.6)	28 (32.9)
Penetrating	244 (43.4)	50 (58.8)
Burn	19 (3.4)	0 (0.0)
Two or more/other	41 (7.3)	7 (8.2)
Injury mechanism		
Stabbing or cut	206 (36.7)	37 (43.5)
Vehicular Injury	91 (16.2)	15 (17.7)
Firearm	42 (7.5)	18 (21.2)
Other	210 (37.4)	14 (16.5)
Injury intent		
Intentional/legal/war	399 (71.0)	68 (80.0)
Unintentional (or accidental)	163 (29.0)	17 (20.0)
Blood products received within 24 hours since arrival		
No	526 (93.6)	46 (54.1)
Yes	36 (6.4)	39 (45.9)
Died within 24 hours since arrival		
No	553 (98.4)	77 (90.6)
Yes	9 (1.6)	8 (9.4)
Died within 7 days since arrival		
No	546 (97.2)	74 (87.1)
Yes	16 (2.9)	11 (12.9)

Table 2: Analysis of the association between TXA administration and mortality

Outcome	Risk Ratio	95% Confidence Interval	p-value
24-hour mortality	0.48	(0.13, 1.78)	0.272
7-day mortality	0.39	(0.13, 1.20)	0.101

CONCLUSIONS

- Preliminary evidence suggests that TXA administration in early trauma is associated with lower mortality risk. However, the results were not significant.
- This effort advances the U.S. Army's future operations in which battlefield evacuation time and care may be prolonged.
- These findings will directly benefit South African patients and the Western Cape trauma system.
- On-going research is needed on this topic.

Funding Information: U.S. Department of Defense (DHA award #s: W81XWH-20-2-0042 [2019-2022] and W81XWH-19-2-0055 [2020-2024]; PI: Mould-Millman)

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Disclaimer: Views are of the authors and not the U.S. Department of Defense

Authors have no conflicts of interest.

Appendix 11.2 Blood Products poster, SOMA

SURVIVABILITY OF TRAUMA PATIENTS RECEIVING BLOOD PRODUCTS IN A HIGH-TRAUMA, INTERNATIONAL SETTING

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BACKGROUND

- Hemorrhage is the leading cause of preventable deaths amongst injured patients.
- Most deaths occur within the first 24 hours of injury.
- South Africa has among the highest injury mortality rates worldwide.
- Further evidence can guide policy and inform more effective interventions, such as blood products.
- EpiC is a longitudinal study of trauma outcomes due to early resuscitation in the Western Cape of South Africa.

OBJECTIVES

- To evaluate the effects of early blood product transfusions on mortality in this high-trauma setting.

METHODS

- DESIGN: Prospective, observational, cohort study design
- PERIOD: March 23 to August 27, 2021
- SETTING: 4 hospitals in the **Western Cape of South Africa.**
- INCLUSIONS: Adults ≥18 yrs with at least one transfusion criteria:
  - Systolic Blood Pressure < 100mmHg or shock index > 0.9
  - penetrating or blunt injury
- EXPOSURE: Blood product transfusion (whole blood, red cells, plasma, cryoprecipitate, and/or platelets) within the first 24-hours of admission
- OUTCOMES: All-cause 24-hour and 7-day in-hospital mortality
- ANALYSIS: Multivariable adjusted generalized linear models
  - Propensity scores: Inverse probability weights using triage scores (TEWS), age, and tranexamic acid (TXA) administration
  - Adjustments: Injury force type, comorbidities, and life-saving interventions.

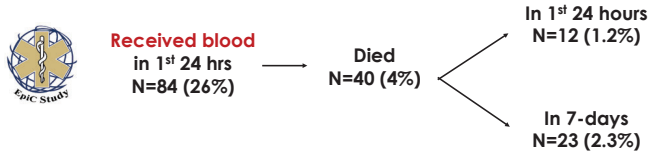

Figure 1: Patient Flow Chart (total enrolled, N=994)

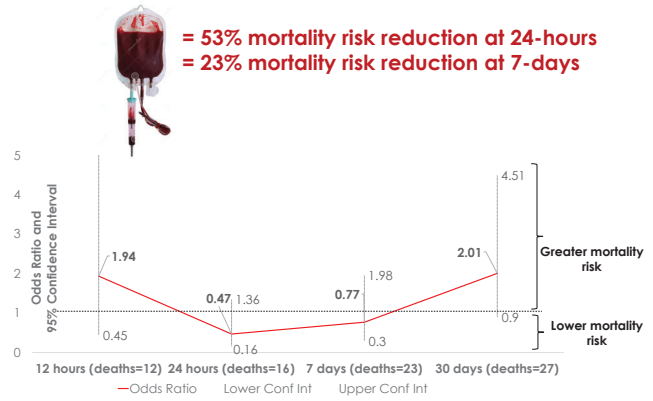

Figure 2: Association between early (first 24 hours since hospital arrival) blood product administration and mortality

LIMITATIONS

- Hemorrhagic and non-hemorrhagic deaths were combined.
- Blood product components or ratios were not assessed.
- Exposures and outcomes from injury time were not ascertained.
- Trauma capabilities and injury mechanisms in this civilian system differ slightly from U.S. military injuries and capabilities.

RESULTS

Table 1: Characteristics of Blood Product Eligible Patients

Characteristic	All	Did not receive blood	Received blood
	Median, Mean (SD), n (%)	Median, Mean (SD), n (%)	Median, Mean (SD), n (%)
Age	29.3, 31.8 (10.2)	28.9, 31.0 (9.3)	30.8, 34.3 (12.3)
Triage Early Warning Score	5.0, 5.6 (2.2)	4.0, 5.0 (1.8)	7.0, 7.4 (2.5)
New Injury Severity Score	3.0, 10.6 (13.7)	3.0, 5.7 (8.6)	26.0, 24.8 (15.8)
Sex			
Male	217 (66.2)	151 (61.9)	66 (78.6)
Female	111 (33.8)	93 (38.1)	18 (21.4)
Injury force			
Blunt	120 (36.6)	93 (38.1)	27 (32.1)
Penetrating	166 (50.6)	118 (48.4)	48 (57.1)
Burn	11 (3.4)	9 (3.7)	2 (2.4)
Two or more/other	28 (8.8)	22 (9.0)	7 (8.3)
Injury mechanism			
Firearm	35 (10.7)	14 (5.7)	21 (25.0)
Other	102 (31.1)	88 (36.1)	14 (16.7)
Stabbing or cut	141 (43.0)	110 (45.1)	31 (37.0)
Vehicular Injury	41 (12.5)	24 (9.8)	17 (20.2)
Injury intent			
Intentional/legal/war	260 (79.3)	195 (79.9)	65 (77.4)
Unintentional	68 (20.7)	49 (20.1)	19 (22.6)
Received TXA within 24 hours since arrival			
No	275 (83.8)	230 (94.3)	45 (53.6)
Yes	53 (16.2)	14 (5.7)	39 (46.4)
Died within 24 hours since arrival			
No	312 (95.1)	240 (98.4)	72 (85.7)
Yes	16 (4.9)	4 (1.6)	12 (14.3)
Died within 7 days since arrival			
No	305 (93.0)	239 (97.9)	66 (78.6)
Yes	23 (7.0)	5 (2.1)	18 (21.4)
Died within 30 days since arrival			
No	301 (91.8)	239 (98.0)	62 (73.8)
Yes	27 (8.2)	5 (2.1)	22 (26.2)

CONCLUSIONS

- This preliminary analysis suggests that blood product administration may be protective against 7-day mortality, although the effect size was non-statistically significant.
- The EpiC study continues to enroll patients to enable a more robust analysis.
- Additional evidence can help direct the use of valuable resources in this resource-limited South African setting.

Funding Information: U.S. Department of Defense (DHA award #s: W81XWH-20-2-0042 [2019-2022] and W81XWH-19-2-0055 [2020-2024]; PI: Mould-Millman)

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Disclaimer: Views are of the authors and not the U.S. Department of Defense

Authors have no conflicts of interest.

Appendix 11.3 Civilian Research Model poster, SOMA

An Innovative Civilian Research Model to Inform Combat-Relevant Prolonged Casualty Care

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6. 40th Forward Resuscitative Surgical Detachment, 627th Hospital Ctr, Fort Carson, CO - USA

BACKGROUND

- Prolonged Casualty Care (PCC)is the need to provide patient care for extended periods when evacuation is not an immediate capability.
- PCC is expected as part of the U.S. Army's preparations for future Multi-Domain Operations.
- Current data reflects care in non-PCC scenarios; more relevant data is needed to improve trauma outcomes and inform military preparations.
- Using South Africa's Western Cape (WC) tiered trauma care system as a framework, an innovative research model has been developed for studying trauma outcomes in a PCC environment.

OBJECTIVES

- To describe a research model for PCC and illustrate its relevance to U.S. Military operations

METHODS

- The Epidemiology and Outcomes of Prolonged Trauma Care (EpiC) study is a multicenter, prehospital, observational study in the Western Cape of South Africa.
- EpiC study findings from Mar 23, 2021 to Aug 27, 2021 help to illustrate patient flow through the trauma system, and reveal similarities to U.S. combat care and trajectories.
- Published data, reports, and expert opinions were used to identify, define, and compare the Western Cape trauma system to U.S. military roles.
- Findings were consolidated to develop a final research model.

	Far forward (lowest capabilities/resources) → → → Definitive care (highest capabilities/resources)						
	Transport and Evacuation	Stabilization and initial care	Damage Control Resuscitation	Damage Control Surgery	Definitive surgery	Convalescent Care	Rehabilitative Care
U.S. mil – role 1	X	X	X				
WC – EMS (scene)		X	X				
WC – EMS (IFT)		X					
WC – 1^{0} level			X				
WC – 2^{0} level (district)			X				
U.S. military – role 2			X	X			
WC – 2^{0} level (regional)			X	X			
U.S. military – role 3			X	X	X	X	
WC – 3^{0} level				X	X	X	X
U.S. military – role 4					X	X	X

Figure 1. Conceptual model for comparison of U.S. military roles of care with Western Cape civilian trauma tiered system. The Western Cape system experiences high rates of inter-personal violence and penetrating injuries, prolonged times from injury to first facility, and lengthy times to Role 4 (trauma center), which are all relevant to U.S. military PCC.

LIMITATIONS

- U.S. military sees more blast injuries than Western Cape civilians.
- Western Cape EMS providers have ATLS as baseline trauma training, whereas U.S. military medical personnel have TCCC.
- Capabilities are more standardized in the U.S. mil system compared to Western Cape civilian hospitals (each with differing resources).

RESULTS

Table 1: Comparing settings and goals of trauma care in Western Cape civilian and U.S. military PCC.

	Setting	Goals of Care	Prolonged Care Situation
U.S. military	PCC will occur in remote and austere settings, removed from definitive care due to the combat environment.	100% survival of all patients with survivable and potentially survivable injuries to arrival at Military Treatment Facility.	In PCC, patient's needs exceed expected care capabilities. Timeframe is hours to days.
WC civilian	Trauma care is escalated by patient progression through a tiered health system that is geographically dispersed and resource-constrained.	To provide equitable, timely, and judicious use of limited resources for an entire civilian population.	Routinely, patient needs exceed facility resources necessitating a transfer ('referral') to a higher level of care. This can contribute delays of hours to 1-2 days.

Table 2: U.S. military roles of care and Western Cape civilian equivalence.

U.S. Mil Role	U.S. Mil Characteristics	U.S. Mil Types of Treatment and Resources	Western Cape equivalent*
1	Immediate lifesaving measures; Combat and operational stress preventive measures; Patient location and acquisition (collection)	Bleeding control of massive hemorrhage; managing airway, respiration, and circulation and preventing or treating hypothermia and shock; protecting wounds; immobilizing fractures; forward resuscitation, not including surgical care.[27]	EMS Primary level
2	Advanced trauma management; Emergency medical treatment; Combat and operational stress control	Fresh whole blood and/or blood products (packed red blood cells, frozen plasma, cryoprecipitate), intravenous fluids, limited X-ray, limited laboratory, dental support, advanced trauma management, emergency surgery, and resuscitative care.[27]	Secondary level
3	Expansion of advanced trauma management; Patient holding capability; Ancillary services	Advanced resuscitation; Initial wound surgery; Postoperative treatment; emergency and specialty surgery, intensive care, medical specialty care.[27]	Secondary level (regional only) Tertiary level
4	Most definitive medical care	Specialized surgery and the full range of preventive, acute, restorative, curative, rehabilitative, and convalescent care found in United States base hospitals and robust overseas facilities.[27]	Tertiary level

CONCLUSIONS

- The Western Cape civilian and U.S. military settings are similar in that patients are frequently critically injured and receive resource-limited care, in escalating tiers, for prolonged durations.
- The research model developed here shows much potential for studying PCC and informing U.S. military combat care.

Funding Information: U.S. Department of Defense (DHA award #s: W81XWH-20-2-0042 [2019-2022] and W81XWH-19-2-0055 [2020-2024]; PI: Mould-Millman)

Questions? Nee-Kofi.Mould-Millman@UCDenver.edu

Disclaimer: Views are of the authors and not the U.S. Department of Defense

Authors have no conflicts of interest.

Appendix 11.4 - Blood Products poster, SAEM

SURVIVABILITY OF TRAUMA PATIENTS RECEIVING BLOOD PRODUCTS IN A HIGH-TRAUMA, INTERNATIONAL SETTING

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4. U.S. Department of Defense
5. Denver Health Medical Center, Denver CO - USA

BACKGROUND

- Hemorrhage is the leading cause of preventable deaths amongst injured patients.
- Most deaths occur within the first 24 hours from injury.
- South Africa has among the highest injury and mortality rates worldwide
- Additional evidence can guide policy and inform more effective interventions, such as blood products.
- EpiC is a longitudinal study of trauma outcomes due to early resuscitation in the Western Cape of South Africa.

OBJECTIVES

- We aim to evaluate the effects of early blood product transfusions on mortality in this high-trauma setting.

METHODS

- DESIGN: Prospective, observational, cohort study design.
- PERIOD: March 23 to August 27, 2021
- SETTING: 4 hospitals in the **Western Cape of South Africa.**
- INCLUSIONS: Adults ≥18 yrs with at least one transfusion criteria:
  - SBP <100mmHg or shock index >0.9, and
  - penetrating or blunt injury.
- EXPOSURE: Blood product transfusion (whole blood, red cells, plasma, cryoprecipitate, and/or platelets) within the first 24-hours since admission.
- OUTCOMES: All-cause 24-hour and 7-day in-hospital mortality.
- ANALYSIS: Multivariable adjusted generalized linear models
  - Propensity scores: Inverse probability weights using triage scores (TEWS), age, and TXA
  - Adjustments: Injury force type, comorbidities, and life-saving interventions.

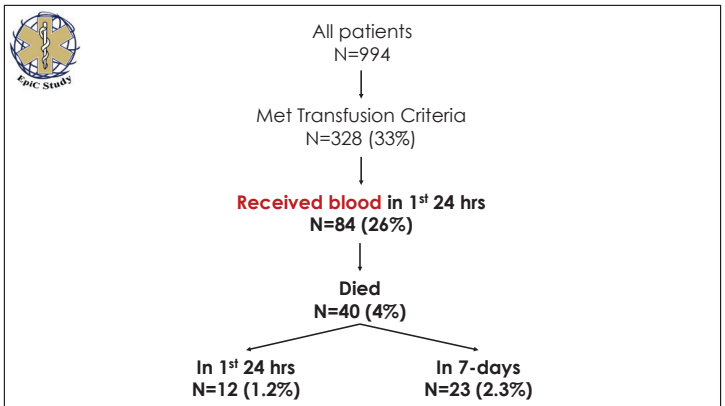
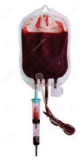


Figure 1: Patient Flow Chart



= 53% mortality risk reduction at 24-hrs
= 23% mortality risk reduction at 7-days

OR (24 hour)=0.47 (0.16, 1.36; p-value: 0.16)
OR (7 days)=0.77 (0.30, 1.98; p-value: 0.17)

Figure 2: Patient Outcomes

LIMITATIONS

- We used pilot data from the EpiC study (i.e., small sample).
- We included hemorrhagic and non-hemorrhagic deaths.
- We did not assess various components of blood products separately.

RESULTS

Table 1: Characteristics of Blood Product Eligible Patients

Characteristic	All n (%)	No Blood n (%)	Yes Blood n (%)
Sex			
Male	217 (66.2)	151 (61.9)	66 (78.6)
Female	111 (33.8)	93 (38.1)	18 (21.4)
Injury force			
Blunt	120 (36.6)	93 (38.1)	27 (32.1)
Penetrating	166 (50.6)	118 (48.4)	48 (57.1)
Burn	11 (3.4)	9 (3.7)	2 (2.4)
Two or more/other	28 (8.8)	22 (9.0)	7 (8.3)
Injury mechanism			
Firearm	35 (10.7)	14 (5.7)	21 (25.0)
Other	102 (31.1)	88 (36.1)	14 (16.7)
Stabbing or cut	141 (43.0)	110 (45.1)	31 (37.0)
Vehicular Injury	41 (12.5)	24 (9.8)	17 (20.2)
Injury intent			
Intentional/legal/war	260 (79.3)	195 (79.9)	65 (77.4)
Unintentional (or accidental)	68 (20.7)	49 (20.1)	19 (22.6)
Received TXA within 24 hours since arrival			
No	275 (83.8)	230 (94.3)	45 (53.6)
Yes	53 (16.2)	14 (5.7)	39 (46.4)
Died within 24 hours since arrival			
No	312 (95.1)	240 (98.4)	72 (85.7)
Yes	16 (4.9)	4 (1.6)	12 (14.3)
Died within 7 days since arrival			
No	305 (93.0)	239 (97.9)	66 (78.6)
Yes	23 (7.0)	5 (2.1)	18 (21.4)

Table 2: Characteristics of All vs Blood vs No Blood Patients

Group	Variable	N	Mean	Std Dev	Min	Max
All	**Triage Score**	328	5.6	2.2	3	14
	Age (years)	323	31.8	10.2	18.1	77.8
	Injury Severity Score	326	10.6	13.7	1	59
No blood	**Triage Score**	244	4.95	1.75	3	12
	Age (years)	243	31.0	9.34	18.1	77.8
	Injury Severity Score	242	5.7	8.55	1	50
Yes blood	**Triage Score**	84	7.4	2.53	4	14
	Age (years)	80	34.3	12.3	18.3	73.2
	Injury Severity Score	84	24.8	15.8	1	59

CONCLUSIONS

- This preliminary analysis suggests that blood product administration may be protective against 24-hour mortality.
- Although the effect size was non-statistically significant.
- The EpiC study continues to enroll patients to enable a more robust analysis.
- Additional evidence can help direct use of valuable resources in this resource-limited South African setting.

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Questions? Nee-Kofi.Mould-Millman@ucdenver.edu

Disclaimer: Views are of the authors and not the U.S. Department of Defense

Authors have no conflicts of interest.

Appendix 11.5 TXA Presentation, SAEM

Tranexamic Acid (TXA) in Traumatic Hemorrhage: A Prospective Cohort Study in a High Trauma Setting.

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  - none
- Commercial Relationships:
  - none
- Grant funding:
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  - Mould-Millman, PI, NIH NHLBI, LRP award
- Disclaimer:
  - Views do not reflect the official policy of the U.S. DOD

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3

Background

- Trauma-induced hemorrhage is a leading cause of deaths globally.
- 25-35% of severe trauma patients have early coagulopathy
- Coagulopathy imparts a four-fold increased risk of mortality.
- Tranexamic Acid (TXA), an anti-fibrinolytic drug, has demonstrated clinical equipoise in prior trauma studies.

4

Objectives

- To assess the mortality benefit of TXA in adult traumatic hemorrhage in a high-trauma setting internationally.

5

Methods

- Design: Multicenter, prospective, observational study
- Period: March 23 to August 27, 2021 (pilot phase)
- Setting: Western Cape province of South Africa
- Sites: 4 hospitals, 4 EMS bases, 2 forensic/pathology labs
- Eligibility criteria:
  - Adults (≥18 years of age)
  - blunt and penetrating injuries
  - systolic blood pressure <100-mmHg or shock index >0.7
- Analysis:
  - Exposure: TXA (<24-hours post-injury)
  - 1° outcome: 30-day hospital mortality
  - Multivariable generalized linear models
    - Adjusted for: life-saving interventions, injury force type, comorbidities
    - Propensity matched by: age, triage early warning score, blood products

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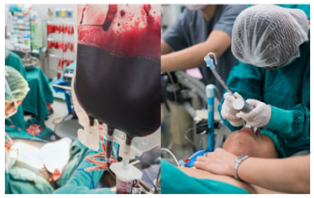
Results

- Enrolled population:
  - Eligible patients = 647
  - Median age = 33 years
  - Males = 442 (68%)
  - Intentional = 467 (72%)
  - Mean ISS = 7.3 (SD ±11)
  - Torso = 30%; Head = 18%
  - Mortality:
    - 24-hours = 22 (3.4%)
    - 7-days = 36 (5.5%)
    - 30-days = 46 (7.1%)
  - 13% received TXA
    - 46% also received blood products



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Results

	Adjusted RR	95% CI	p-value
Died within 30 days vs alive	0.72	0.27, 1.92	P=0.51
Died within 7 days vs alive	0.39	0.13, 1.20	P=0.10
Died within 24 hrs vs alive	0.48	0.13, 1.78	p=0.27

* adjusted for life-saving interventions, injury force type, comorbidities
** weighted by age, triage early warning score, blood products

8

Limitations

- Lower power
  - Due to small sample size (TXA n=85)
- True effect size likely 'diluted'
  - We did not limit TXA to first 3-hours
  - Mix of hemorrhage and non-hemorrhage deaths

9

Conclusions

- Per our preliminary evidence:
  - 28% reduction in 30-day mortality
  - 61% reduction in 7-day mortality
  - The effect sizes were non-statistically significant
- Next steps:
  - To enroll larger sample sizes
  - To select a more homogeneous population

10

Thank you.

- <u>Refs:</u>

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11

The Injury Severity Score Under-estimates True Injury Severity in a Low Resource Setting

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Conflicts of Interest

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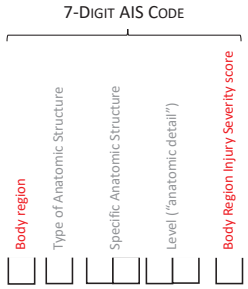
Background

- 90% of trauma-related deaths occur in low- and middle-income countries (LMIC)
- No consensus on which injury severity rating tools perform best in these contexts
- Injury Severity Score (ISS) has served as the de-facto gold standard

Experts concerned that ISS may underpredict true trauma severity in LMICs

Background

- ISS = Sum of squares of three highest AIS
- ISS range 3 - 75



Body Region Injury Severity Score	Description
1	Minor
2	Moderate
3	Serious
4	Severe
5	Critical
6	Maximal

Study Question

How does ISS perform in LMICs compared to gold standard?

Objectives

- Calculate the difference in ISS overall scores assigned by independent AIS rater vs. expert panel in LMIC setting
- Compare mean body region injury severity scores between AIS rater vs. expert panel by anatomic region

Methods

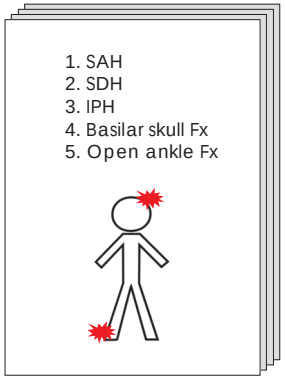
- Design: Retrospective chart review
- Setting: Western Cape, South Africa
- Population: High trauma, high mortality
- Participants: AIS rater + Panel of 5 local trauma physicians
- Study Period: Patients from 3 – 8/2021. Panel in 10/2021.
- Analysis: Mixed effects logistic regression
- Ethics: Approval in South Africa and Colorado

Methods

AIS Rater

#	AIS Code	AIS-BRISS Severity (1-6)
1	1-4-##-##	3
2	1-4-##-##	**5**
3	1-4-##-##	2
4	1-5-##-##	**3**
5	8-5-##-##	**3**
	*Overall ISS (3-75)=	**43**

* add the squared values of top 3 severities



Expert Panel

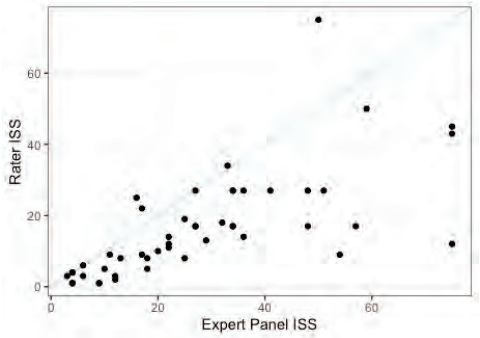
#	Description of organ injury	E-BRISS Severity (1-6)
1	SAH	3
2	SDH	**4**
3	IPH	**5**
4	Basilar skull Fx	3
5	Open ankle Fx	**4**
	#Overall severity (3-75)=	**57**

add the squared values of top 3 severities

Results: Demographics

Total patients	49	
Age	33	26-44
Sex		
Female	11	22%
Male	38	78%
Average # of AIS scores	3	2-5
Injury Force Type		
Blunt	26	53%
Penetrating	23	47%
Dominant Mechanism of Injury		
Fall or Struck/hit	12	24%
Firearm	13	27%
Stabbing or cut	9	18%
Vehicular Injury	15	31%
Mortality	4	8.2%

Results: Injury Severity Scores

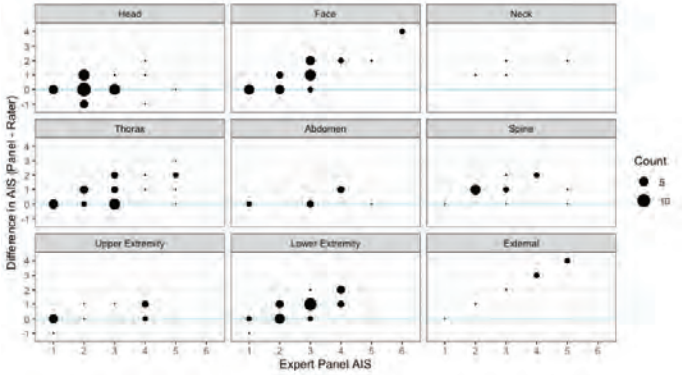


Expert ISS Mean: 28 (SD 20)

AIS Rater ISS Mean: 16 (SD 15)

Average -11.2 point difference
(95% CI: -15.2, -7.3; p<0.001)

Results: AIS Body Region Severity Scores



Results: AIS Body Region Severity Scores

Body region	# AIS codes available for both rater and panel	Mean absolute difference |panel – rater| (95% CI)	p-value
External	7	2.43 (1.83, 3.03)	<0.001
Neck	4	1.50 (0.70, 2.30)	<0.001
Face	33	1.03 (0.75, 1.31)	<0.001
Spine	15	1.00 (0.59, 1.41)	<0.001
Lower extremity	32	0.84 (0.56, 1.13)	<0.001
Thorax	31	0.77 (0.49, 1.06)	<0.001
Upper extremity	14	0.43 (0.002, 0.85)	0.05
Head	39	0.41 (0.15, 0.67)	0.002
Abdomen	9	0.33 (-0.20, 0.86)	0.22

Conclusions

- ISS underestimates injury severity in South Africa
- Consider a corrective weighting system in *EPIC*
- Studies with larger cohorts required to verify these findings

Thank you. Questions?

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Extrapolating Civilian Prolonged Casualty Care Data to the Military Context

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15 SEP 2022

Human/Animal Statement/DoD Disclaimer Requirement

This study was conducted under a protocol reviewed and approved by the US Army Medical Research and Development Command Institutional Review Board and in accordance with the approved protocol.

The views expressed in this presentation are those of the author(s) and do not reflect the official policy or position of the U.S. Army Medical Department, Department of the Army, DoD, or the U.S. Government.

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none

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Background

- Civilian and military populations are often faced with suboptimal operational conditions and increasing volumes which lead to longer times from prehospital to definitive care
- Parallels exist between prolonged civilian and combat casualty care with common aims of bringing effective care closer to the point of injury while conserving limited resources
- U.S. military expects delayed evacuations in future large scale combat operations, creating the need to study prehospital care during transport times longer than most US-based trauma systems
- The Western Cape (WC) of South Africa is uniquely similar to U.S. prolonged casualty care (PCC) settings among injury profiles, capabilities, system configurations, and resource limitations
  - Because of these similarities, the WC is a prime location for PCC research among civilians
  - DOD has already made several longitudinal investments in PCC research in this region

Objectives

- Provide an initial description of civilians who experience PCC in the Western Cape
- Compare PCC and non-PCC populations
- Demonstrate usefulness of an international civilian population for U.S. military-relevant PCC study

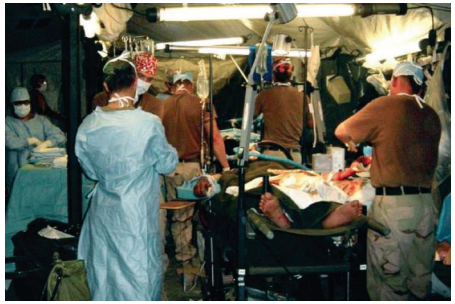
Methods

- Design: Multicenter, prospective, observational study
- Period: March 23 to August 27, 2021 (6-month **pilot phase**)
- Setting: Western Cape province of South Africa
- Sites: 4 hospitals, 4 EMS bases, 2 forensic/pathology labs
- Eligibility criteria:
  - Adults (≥18 years of age) enrolled in EpiC
  - PCC defined as ≥10 hours from injury to definitive care facility
- Analysis:
  - Primary outcome: 7-day mortality
  - Secondary outcomes: Hospital length of stay and SOFA score (organ failure)
  - Description of patient characteristics, critical interventions, key times, outcomes relevant to military PCC
    - Characteristic comparisons between PCC and non-PCC groups
    - Sensitivity analysis using PCC ≥ 4 hours from injury to surgical facility
    - Associations between PCC and non-PCC groups using logistic regression models

Results

Enrolled population:

- Eligible patients = 146 (15%) of 995 trauma patients
- Median age = 31.5 years
- Males = 70%
- PCC [≥10hours] = 15% (N=146)
- Non-PCC = 85% (N=849)



Results: Baseline Patient Characteristics

TABLE 1. Baseline Patient Characteristics for the Entire EpiC Study Population, and by Non-PCC Versus PCC (≥10 Hours) Subgroups

	All N = 995	Non-PCC n = 849 (85%)	PCC n = 146 (15%)	*p*
Patient characteristics				
Age (median, Q1–Q3)	31.5 (25.7–40.0)	31.7 (25.5–40.0)	30.7 (26.0–39.7)	0.64
Sex: male	700 (70%)	595 (70%)	105 (72%)	0.65
Injury characteristics				
Penetrating injury	455 (46%)	399 (47%)	56 (38%)	0.053
Dominant mechanism of injury:				
Firearm	94 (9%)	81 (10%)	13 (9%)	
Struck/hit (i.e., blunt)	196 (20%)	168 (20%)	28 (19%)	
Stabbing or cut	312 (31%)	273 (32%)	39 (27%)	
Vehicular	217 (22%)	185 (22%)	32 (22%)	
Fall/thermal/other	160 (16%)	130 (15%)	30 (21%)	
Unknown	16 (2%)	12 (1%)	4 (3%)	0.45
Severity measures				
TEWS score ≥ 7	137 (14%)	103 (12%)	34 (23%)	0.0003
SATS: Red	384 (39%)	304 (36%)	80 (54%)	<0.0001
NISS ≥15	138 (14%)	93 (11%)	45 (31%)	<0.0001
AIS severity ≥ severe	63 (6%)	47 (6%)	16 (11%)	0.01
GCS score ≤12	78 (8%)	57 (7%)	21 (15%)	0.001
Shock index ≥1	226 (23%)	197 (23%)	29 (20%)	0.35
Critical patient (meets any of the above severity measures)	533 (54%)	437 (51%)	96 (66%)	0.001

Results: Baseline Patient Characteristics (continued)

TABLE 1. Baseline Patient Characteristics for the Entire EpiC Study Population, and by Non-PCC Versus PCC (≥10 Hours) Subgroups

	All N = 995	Non-PCC n = 849 (85%)	PCC n = 146 (15%)	*p*
AIS body regions with AIS severity score >1				
Head	256 (26%)	158 (24%)	98 (33%)	
Face	54 (6%)	36 (5%)	18 (6%)	
Neck	14 (1%)	12 (2%)	2 (1%)	
Thorax	189 (20%)	157 (23%)	32 (11%)	
Abdomen	106 (11%)	81 (12%)	25 (8%)	
Spine	28 (3%)	20 (9%)	8 (3%)	
Upper extremity	102 (11%)	67 (10%)	35 (12%)	
Lower extremity	206 (21%)	133 (20%)	73 (25%)	
External	13 (1%)	8 (1%)	5 (2%)	0.0001
Total	968 (100%)	672 (69%)	296 (31%)	
Median (Q1–Q3) severity score	3 (2–3)	3 (2–3)	3 (2–3)	0.80
Critical interventions received				
Received any intervention during EMSs or at hospital, within 24 h of injury	299 (30%)	246 (29%)	53 (36%)	0.07

AIS, Abbreviated Injury Scale; GCS, Glasgow Coma Scale; NISS, New Injury Severity Score; SATS, South African Triage Scale; TEWS, Trauma Early Warning Score.

Results

TABLE 2. Frequencies and Proportions of All EpiC Mortality and Morbidity-Related Outcomes Within 7 Days Postinjury, by Subgroups

Outcomes	All N = 995	Non-PCC n = 849 (85%)	PCC n = 146 (15%)	*p*
1^{O} – Death in ambulance or within 7 d of injury, n (%)*	33 (3.3%)	26 (3.1%)	7 (4.8%)	0.28
2^{O} – Death in ambulance or within 30 d of injury, n (%)*	37 (3.7%)	29 (3.4%)	8 (5.5%)	0.22
2^{O} – Total hospital LOS (emergency department and in-patients)	1 (1–3)	1 (1–2)	3 (2–9)	<0.0001
2^{O} – LOS (in-patients only)**	5 (3–11)	4 (3–9)	7 (3–12)	0.003
2^{O} – Worst SOFA score†	4 (1–7)	3 (1–7)	5 (2–7)	0.13

*Two non-PCC patients died during EMSs transport and were missing a mortality outcome.
**A total of 273 were admitted as in-patients (189 non-PCC and 83 with PCC).
†Of the patients, 86% were noncritical and appropriately missing a SOFA score, so medians are based on 141 individuals (100 non-PCC and 41 PCC).
1^{O}, Primary outcome; 2^{O}, secondary outcome; LOS, length of stay.

Results

- The PCC>10 cohort had more critical interventions (42% vs 36%)
- 40 deaths overall (4%): 2 prehospital and 38 in-hospital, occurring at median time of 10.1 (3.1-56.2) hours post injury
- Odds of 7-day mortality were 1.6 (OR: 1.59; 0.68, 3.74) times higher in PCC vs non-PCC
- Odds of SOFA score > 5 were 3.6 (OR: 3.69; 2.11, 6.42) times higher in PCC vs non-PCC
- Patients with PCC > 4 hours (N=260, 24%) had similar distributions and trends of patient characteristics, injury characteristics, and severity measures as those with >10 hour cut off

Limitations

- Some mechanisms of injury differ between WC and military populations (ex: blast injuries)
- Western Cape EMS providers have ATLS as baseline trauma training, whereas U.S. military medical personnel have TCCC.
- Capabilities are more standardized in the U.S. military system compared to Western Cape civilian hospitals (each with differing resources).

Conclusions

- 15-25% of the enrolled Western Cape civilian population appears suitable for studying PCC-relevant to civilians and U.S. military
  - This population is frequently critically injured, receives a diversity of critical and operative interventions, and experiences a relatively low mortality rate (3-5%)
- Casualties with longer durations of PCC have relatively worse mortality and organ failure comparted to shorter durations

Next Steps

- The EpiC study will provide ongoing data for PCC observational studies:
  - Inform future interventional trials
  - Develop PCC protocols and algorithms
  - Demonstrate on-going relevancy to WC populations and other low- and middle-income countries, and combat-wounded facing prolonged evacuation

The End

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Questions?

Tranexamic Acid (TXA) in Traumatic Hemorrhage: A Prospective Cohort Study in a High Trauma Setting

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SCHOOL OF MEDICINE
UNIVERSITY OF COLORADO **ANSCHUTZ MEDICAL CAMPUS**

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7. Ernest E. Moore Shock Trauma Center, Denver, CO - USA

BACKGROUND

- Trauma-induced hemorrhage is a leading cause of death.
- ~30% of severely injured patients have early coagulopathy (bleeding disorder), resulting in a four-fold increased risk of mortality.
- TXA has been widely studied and expanded to control bleeding among civilian and military populations
- Future multidomain military operations anticipate limited resources and prolonged durations of care; TXA may be used to prolong survival in these situations
- The Western Cape Province of South Africa offers military-relevant context for studying TXA and severe injuries

OBJECTIVES

- To gain additional evidence regarding the mortality benefit of TXA in adult traumatic hemorrhage in a 'real-world' high-trauma, military-relevant civilian setting.

METHODS

- 'EpiC' is a multicenter, prospective, observational study
- Four participating medical facilities in the Western Cape Province of South Africa (trauma levels 1-3)
  - Resource-limited health setting
  - Military-relevant mechanisms and severities
  - Patients frequently experience prolonged care
- Period: March 23 to August 27, 2021.
- Eligibility criteria:
  - Adults ≥ 18 years
  - Blunt or penetrating injuries
  - Shock index ≥0.7 or systolic blood pressure ≤100mmHg
- Analysis: association between TXA (yes/no) and 30-day hospital mortality rate using Cox Hazard Models
  - Models were inverse probability weighted by triage acuity scores, age, and any blood products given
  - Models were multivariable adjusted for comorbidities and administration of other critical interventions

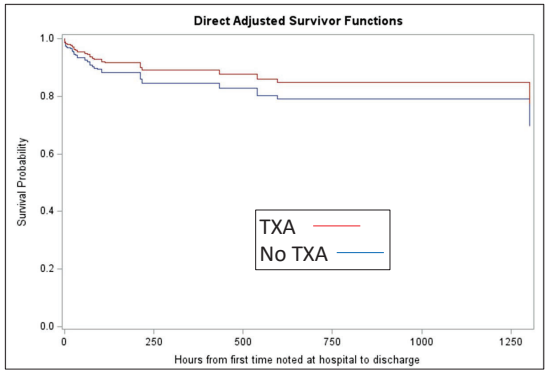

Figure 1: Cox Proportional Hazard models analyzing the association between TXA administration and mortality

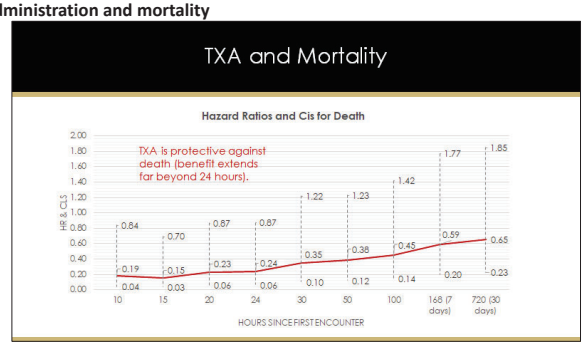

Figure 2: TXA is protective against mortality

LIMITATIONS

- Time from injury was not incorporated in pilot data analyses.
- Hemorrhagic (likely candidates for TXA administration) and non-hemorrhagic deaths were analyzed together
- We did not incorporate time to event analysis.

RESULTS

Table 1: Descriptive statistics means (SD) and frequencies (percentages) for key study characteristics by TXA administration

Characteristics	TXA eligible (n=647)	
	No TXA (n=562) Mean (SD), n (%)	TXA (n=85) Mean (SD), n (%)
Age	32.8 (10.9)	33.3 (10.6)
Triage Early Warning Score	4.7 (1.9)	6.8 (2.5)
New Injury Severity Score	6.0 (9.4)	18.0 (15.6)
Sex		
Male	371 (66.0)	71 (83.5)
Female	191 (34.0)	14 (16.5)
Injury force		
Blunt	256 (45.6)	28 (32.9)
Penetrating	244 (43.4)	50 (58.8)
Burn	19 (3.4)	0 (0.0)
Two or more/other	41 (7.3)	7 (8.2)
Injury mechanism		
Stabbing or cut	206 (36.7)	37 (43.5)
Vehicular Injury	91 (16.2)	15 (17.7)
Firearm	42 (7.5)	18 (21.2)
Other	210 (37.4)	14 (16.5)
Injury intent		
Intentional/legal/war	399 (71.0)	68 (80.0)
Unintentional (or accidental)	163 (29.0)	17 (20.0)
Blood products received within 24 hours since arrival		
No	526 (93.6)	46 (54.1)
Yes	36 (6.4)	39 (45.9)
Died within 24 hours since arrival		
No	553 (98.4)	77 (90.6)
Yes	9 (1.6)	8 (9.4)
Died within 7 days since arrival		
No	546 (97.2)	74 (87.1)
Yes	16 (2.9)	11 (12.9)

- 13% received TXA within first 24 hours of injury. Of the 46 deaths in the first 30 days, 22 died within 24 hours and 36 died within 7 days.
- The hazard of death at 7-day mortality among the TXA group was 41% lower than no-TXA group (HR:0.59; 95%CI:0.20, 1.77, p value: 0.35)
- The hazard of death at 30-day mortality among TXA group was 35% lower than the no-TXA group (HR:0.65; 95%CI:0.20, 1.77, p value: 0.42)

CONCLUSIONS

- Evidence suggests TXA administration in adults at risk for hemorrhagic shock from trauma is associated with lower likelihood of 30-day mortality
- These results suggest TXA is most effective when administered early in trauma
- On-going analysis will continue, providing evidence for advancements in clinical practice guidelines for U.S. military

Funding Information: U.S. Department of Defense (DHA award #s: W81XWH-20-2-0042 [2019-2022] and W81XWH-19-2-0055 [2020-2024]; PI: Mould-Millman)

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Deadline: 30 June 2022

Word limit: 300

Theme: The Role of Emergency Medicine in Achieving Universal Health Care: Research. Education. Clinical Care.

Sub-Theme: Trauma and Orthopedic Emergencies including wound management

Title (20 words): Epidemiology and Outcomes of Prolonged Trauma Care (EpiC): Overview of a Major Trauma Cohort.

Background: Traumatic injuries are a leading cause of mortality worldwide. In South Africa, injury is a major contributor to the burden of disease, accounting for over 50,000 deaths annually (10% of all causes of death). EpiC aims to develop a scalable model of a clinical database useful for providing accurate real-time data to drive local operations, quality improvement, and research. We provide a descriptive analysis of key EpiC findings.

Methods: A multicenter prospective cohort study ("*EpiC"*) was implemented in the Western Cape of South Africa in 2021 to collect data on major trauma patients at 12 sites (6 hospitals, 4 ambulance bases, 2 pathology labs). Data from prehospital, in-hospital, and autopsy records were inputted into a secure REDCap database. We ran descriptive statistics from August 28, 2021-April 25, 2022 to provide an overview of the injury and patient characteristics.

Results: Of 3,128 patients, a majority were young (median age 30.9-years) males (80%), with moderate to severe injuries [stabbings (46%), assaults (21%), vehicular (15%), and firearm (7%) injuries, triaged as TEWS ≥ 3 (80%), and SATS red (20%) and orange (61%)]. The most severe injuries (AIS Severity Score ≥ 3) were in spine (8.8%), head (5.8%), abdomen (5.7%), and thorax (5.2%). About 45% each of EMS transferred patients and those admitted in hospital received (any one or more) critical (ABCD) interventions, 7% received blood products, 4% received tranexamic acid, 9% received an operative intervention within the first 24-hours, and 3% were admitted to the ICU. 73% were discharged home, 21% required transport to another facility, and 2% died in hospital.

Conclusions: Trauma databases and registries can identify opportunities to ameliorate post-injury morbidity and mortality. Data from EpiC will enable a system-wide assessment on how trauma care, resources, and policies (or lack of) influence outcomes and identify key areas to strengthen.

Keywords: Global Health, Trauma, Mortality, Morbidity, Trauma Care System

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Abstract Disclaimer:

The views expressed in this paper are those of the authors and do not necessarily represent the official position or policy of the University of Colorado, Western Cape Department of Health, U.S. Government, the Department of Defense, the Department of the Army, or the Department of the Air Force.

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Appendix 11.10 EpiC Prehospital abstract, AfCEM

Deadline: 30 June 2022

Word limit: 300

Theme: The Role of Emergency Medicine in Achieving Universal Health Care: Research. Education. Clinical Care.

Sub-Theme: Emergency Medical Services/Pre-hospital Medicine

Title (20 words): Epidemiology and Outcomes of Prolonged Trauma Care (EpiC): Overview of the Prehospital Cohort

Background and Objectives: In South Africa, injuries are a leading cause of morbidity and mortality. A key contributor to the high mortality is prolonged injury-to-treatment time. Prehospital care reduces the global trauma burden by providing early and cost-effective trauma care to help avert poor outcomes. We examine prehospital trauma patient characteristics to elucidate future research and development efforts.

Methods: A prospective multicenter cohort study ("EpiC") was established in the Western Cape Government health system to collect data on trauma patients who seek care at 4 EMS bases, 6 facilities, and 2 pathology labs. Prehospital data were linked with in-hospital and autopsy records and inputted into a secure REDCap database. Injured patients transported by ambulance were identified from the EpiC database between August 28, 2021 – April 25, 2022. Descriptive statistics were generated to provide an overview of the patient population and the care received in ambulance.

Results: Of 3,128 patients enrolled in EpiC, 45% were transported from the scene and 22% were inter-facility transfers. EMS patients were relatively young (median age 31.5 years), predominantly male (80%), with moderate to severe injuries [penetrating (48%) and blunt (42%) injuries from stabbings (39%), assaults (22%), vehicles (21%), and firearms (8.5%), triaged as TEWS ≥ 3 (88%), SATS red (25%) and orange (61%), with 68% in shock]. Few EMS scene patients received airway (2%) and breathing (14%) interventions, or medications (5%). Most interventions were for circulation (37%) [e.g., IV fluids and manual pressure for hemorrhage control] and disability (19%) [e.g., scoop, backboard, and c-collar]. Though few EMS patients died (3%), many required onward transport to higher levels of care (36%).

Conclusions: The Western Cape has a mature prehospital system relative to other African countries. Considering the severity of injuries relative to a low proportion of interventions, EpiC can help identify missed opportunities to strengthen care.

Keywords: Global Health, Emergency Medical Services, Trauma, Prehospital Care, Trauma Care System

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Preference for oral or poster presentation: Oral

Deadline: 30 June 2022

Word limit: 300

Theme: The Role of Emergency Medicine in Achieving Universal Health Care: Research. Education. Clinical Care.

Sub-Theme: Battlefield/Combat/Deployed Medicine

Title (20 words): An Innovative Civilian Research Model to Inform Combat-Relevant Prolonged Casualty Care

Background and Objectives: Trauma care in future military conflicts will feature prolonged durations of field resuscitation and care, termed prolonged casualty care (PCC). Current trauma data reflects care in non-PCC scenarios, so more data from prolonged care environments are needed. We developed a model using South Africa's Western Cape (WC) tiered trauma care system as a framework for studying trauma and outcomes in a natural PCC environment. Our objective is to describe the research model and present data relevant to PCC.

Methods: We used published data, reports, and expert opinions to identify, define, and compare the WC trauma system to the U.S. military system. We consolidated all findings in the WC civilian and U.S. military trauma care systems, to develop the final research model. We used patients from the DOD-funded EpiC study in the WC to depict how patients flow through the system and to illustrate similarities to U.S. combat casualties.

Results: From March 23-Agusut 27, 2021, 1202 patients were enrolled in EpiC. Mean age was 34.5 (±12.5) years. The distribution of mechanisms (9.4% firearm, 31.3% stabbing, 22.0% vehicular), high prevalence of penetrating injuries (39.8%), lengthy times from injury to tertiary facility (27% were >12-hours) and overall injury severity (68% were high acuity) are military-relevant features of the WC system. Further, 25% of patients were transported from primary and secondary to tertiary facilities, which is analogous to escalating care during U.S. military evacuation and care.

Conclusions: The WC civilian and U.S. military settings have several similarities (for research) in that patients are critically injured and receive resource-limited care, in escalating tiers, for prolonged durations before reaching a trauma center. This is a useful research model for studying prolonged civilian trauma care in South Africa and for informing future military combat care.

Keywords: Emergency Medicine, Combat Care, Trauma, Prolonged Casualty Care

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Appendix 11.12 Survival from TXA abstract, AfCEM

Deadline: 30 June 2022

Word limit: 300

Theme: The Role of Emergency Medicine in Achieving Universal Health Care: Research. Education. Clinical Care.

Sub-Theme: Trauma and Orthopedic Emergencies including wound management

Title (20 words): Survival from Tranexamic Acid (TXA) in Traumatic Hemorrhage: A Prospective Cohort Study in a High Trauma Setting.

Background
Trauma-induced hemorrhagic shock is a leading cause of preventable deaths, with hyperfibrinolysis being an independent predictor of mortality. 25-35% of trauma patients with severe injuries have early coagulopathy which imparts a four-fold increased risk of mortality. More data from resource-limited settings is needed regarding the mortality benefit of Tranexamic Acid (TXA), an antifibrinolytic drug. We aim to provide survival data among South African patients at risk for hemorrhagic shock who received TXA.

Methods
EpiC is a prospective, multi-center, observational study in the Western Cape. Eligible patients were adult trauma patients at risk for hemorrhage (systolic blood pressure <100mmHg or shock index >0.7) We analyzed the association between TXA administration (yes/no) and mortality at 24-hours and 30-days using inverse probability weighted and adjusted multivariable regression (Cox) models.

Results
Of 647 eligible patients, 68% were male, 33 years median age, 72% intentional injuries, with a median injury severity score of 7.3 (+/-11). Non-compressible bleeding occurred in the torso (30%) and head (18%). 13% received TXA within the first 24-hours of injury. Overall mortality was 3.4% at 24-hours and 7.1% at 30-days. Weighted models suggest that at 24-hours, those who receive TXA were 52% (RR 0.48, 0.13-1.78; p=0.27) less likely to die compared to controls. At 30-days, the TXA arm experienced 28% (RR 0.72, 0.27-1.16; p=0.09) lower mortality than control. The temporal hazard of death was 76% (HR 0.24; 0.06-0.87; p=0.03) lower among the TXA cohort, which was significantly different.

Conclusion/Discussion
Preliminary evidence suggests that in the Western Cape, TXA administration in trauma is associated with a lower likelihood of mortality, with the largest mortality benefit experienced earlier in the post-injury time course. The mortality benefit of TXA extends to 30-days, although statistically non-significant in our sample. The EpiC study continues to enroll patients to more definitively answer this clinical question.

Keywords: Trauma, Hemorrhage, Tranexamic Acid, Emergency Medicine

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Appendix 11.13 Blood Products abstract, AfCEM

Deadline: 30 June 2022

Word limit: 300

Theme: The Role of Emergency Medicine in Achieving Universal Health Care: Research. Education. Clinical Care.

Sub-Theme: Resuscitation

Title (20 words): Survival of Trauma Patients Receiving Blood Products in the Western Cape Province of South Africa.

Background
Hemorrhage is a leading cause of death among injured persons worldwide.[1] The majority of deaths occur within the first 24-hours.[1-4] Blood (and component) transfusions are a critical part of multimodal resuscitation in hemorrahge.[5] EpiC is a multicenter, prospective, epidemiologic study of critically injured persons in the Western Cape of South Africa. We evaluated the effects of blood product transfusions on mortality in this natural prolonged care setting.

Methods
Patients were identified in the EpiC study from March 23 to August 27, 2021 who met at least one transfusion criteria of systolic blood pressure <100-mmHg or shock index >0.9, with penetrating or blunt injury. The exposure was any blood product transfusion within the first 24-hours post-injury. Outcomes of interest were all-cause pre- or in-hospital 24-hour and 7-day mortality. Inverse probability weighted (for age, triage scores, and tranexamic acid administration) and adjusted (for injury force, comorbidities, and life-saving interventions) Cox Hazard models were used to analyze the associations between transfusion and mortality.

Results
Preliminary descriptive analysis demonstrated 328 (33%) of 997 patients met the transfusion criteria: 84 (26%) received transfusions. Overall, injuries were intentional (80%), penetrating (51%) and blunt (37%). Transfusion recipients were mostly (79%) males with a median age of 31 years. 16% had one or more comorbidities and a high Injury Severity Score (median 26). Weighted and adjusted models showed that the mortality hazard was 73% lower (OR: 0.27; 95% CI: 0.09, 0.82) among blood transfusion recipients as compared to non-recipients at 24-hours. The corresponding hazard ratio at 7-days was 0.99 (0.43, 2.28).

Conclusion
Blood transfusion may be protective against mortality. The majority of the survival benefit from blood appears to occur early and in the first 24-hours post-injury. Future analyses will assess the estimates at effect of specific types of blood products and body areas injured.

Keywords: Trauma care, Resuscitation, Hemorrhage, Blood Products

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Appendix 12 - SUN News High trauma article

High trauma caseload impedes delivery of healthcare services

Author: FMHS Marketing & Communication / FGGW Bemarking & Kommunikasie – Sue Segar

Published: 08/09/2022

The relentless burden of trauma cases – physical injuries which need immediate medical attention – is "squeezing out" the healthcare system's ability to keep up with basic healthcare needs, including care for chronic diseases, maternal and child health.

So said Professor Heike Geduld, head of the Division of Emergency Medicine in the Faculty of Medicine and Health Sciences (FMHS), in an interview following a high-level summit on preventable trauma deaths in the Western Cape.

The meeting, hosted jointly by Professor Elmin Steyn from the FMHS' Department of Surgery, Dr Janette Verster from the Division of Forensic Pathology, and the Division of Emergency Medicine, comprised key stakeholders in trauma care, public health, community safety as well as provincial health-care leaders.

In April, a multi-disciplinary panel conducted a comprehensive review of trauma-related mortalities across the region with the goal of determining which deaths were preventable, potentially preventable, or non-preventable; identifying common factors that may have contributed to both in-hospital and out-of-hospital deaths; and identifying potential interventions to avert preventable deaths.

Geduld said the review was exceptionally helpful and important. "The resources we have to put towards trauma care in this country are seriously impeding general healthcare service delivery," she said.

Geduld added that while there is a strong need to prioritise a co-ordinated trauma system across the province in terms of clinical care, the health sector plays a key role in "advocating for and supporting trauma-prevention strategies including road traffic incidents, gender-based violence (GBV) and community justice. A whole-of society approach is needed of which health – which feels the burden of care – is a critical part."

Geduld said healthcare workers at the coalface of trauma cases had, for a long time, witnessed the burden of these cases on the system, "but we have never really had the data to drive our advocacy message," she said. "We haven't had the opportunity to do extensive research before."

The EpiC study (Epidemiology and Outcomes of Prolonged Trauma Care: A Prospective Multi-centre study of trauma in the Western Cape), had provided the first opportunity to do extensive research and to assess what happens along the trauma care pathway in the Western Cape, she added.

The study – a multi-site cross-sectional study of major trauma patients, that began in September 2019 in sites located in the Cape Town metro and Cape Winelands areas – provided data and logistical support for the review of 138 trauma-related deaths. The study, which is ongoing, collects data beginning at the time of injury, until the patient is discharged from hospital, including in-ambulance care and pathology records as applicable.

The summit acknowledged that alcohol plays a role in many trauma cases.

It also described trauma as a "predictable epidemic". "We know there are surges over weekends, and times associated with pay cycles – so there is a need to map our activities and resources to match."

A further key finding was that the under-reporting of incidents results in fewer safety and security resources being allocated to those under-reported areas.

Emergency worker burnout and compassion fatigue were also highlighted as notable challenges: "Healthcare workers, police, social workers, and everyone working in the system are repeatedly traumatized by their work experiences. This affects their functioning and therefore the quality of care they give. There is a high turnover rate of staff working in this area which affects the capacity to deliver service."

A further takeaway from the summit was that Covid-19 had proven that players across the multi-disciplinary spectrum were able to work well together as a team, highlighting the need for continuing with a team approach and good interdisciplinary communication.

Participants felt a strong need to acknowledge the inherent difference in resources and access to care for the rural population in the province and to prioritise pathways to care.

"The Western Cape Department of the Premier has prioritised the multidisciplinary approach to violence prevention, and health has an important role to play in this. Health can highlight the burden of violence and injury through generating data. It is reassuring to know that there are programs and initiatives within the community and across government aimed at reducing the burden of injury in this province. This includes violence prevention, GBV and road-injury prevention," Geduld said.

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Epidemiology and Outcomes of Combat-Relevant Prolonged Trauma Care: A Prospective Multicenter Prehospital Study in South Africa

Log Number: BA190049; **Award Number:** W81XWH2020042

PI: Nee-Kofi Mould-Millman, MD **PI:** Adit A. Ginde, MD MPH **Org:** Regents of the University of Colorado/The University of Colorado-Denver **Award Amount:** $5,380,562

Study Aim(s)

The overall objective of this study is to conduct an epidemiologic prehospital trauma study in an austere, combat-relevant, foreign environment that innovatively addresses many of the military's current scientific needs, and overcomes limitations experienced by prior U.S.-based prehospital trauma studies.

Aim 1: To assess how prolonged durations of time-to-trauma facility affects morbidity and mortality of trauma patients.

- Aim 1a: We will assess the effect of time on mortality amongst patients experiencing moderate and severe injury severities.
- Aim 1b: We will assess the effect of time on morbidity amongst patients experiencing moderate and severe injury severities.

Aim 2: To analytically assess how key prehospital interventions affects morbidity and mortality of trauma patients.

- Aim 2a: To determine the association of key prehospital interventions on mortality, accounting for time-to-trauma facility arrival.
- Aim 2b: To determine the association of key prehospital interventions on morbidity, accounting for time-to-trauma facility arrival.

Accomplishments: We prospectively collected patient data from 12 sites: 6 facilities, 4 EMS ambulance bases, 2 forensic/pathology labs. We accurately merged and entered 2663 hospital encounters, 1589 unique EMS transports, and 62 deaths. These correspond to **6244 enrolled patients** since 01 SEP 2021.

Timeline and Cost

Activities CY	20	21	22	23	24
Major Task 1: Preparatory Work					
Major Task 2: Data Collection					
Major Task 3: Quality Checks/data analysis					
Major Task 4: Dissemination					
Estimated budget		$850K	$1.387M	$1.547M	$1.602M

Updated: 28 OCT 2022

Goals/Milestones

CY 20 and CY 21 Goals (15 months total):

- ☑ Prepare ethics applications and final Version of detailed study protocols (Complete)
- ☑ Obtain ethic board approvals (Stellenbosch University, Colorado IRB, DoD HRPO) (Complete)
- ☑ Signed letters of approval from research locations (Complete)
- ☑ Obtain data use/share agreements drafted and executed (Complete)
- ☑ Hire and train data collectors at research locations (Complete)
- ☑ Troubleshoot data collection procedures (Complete)
- ☑ EMS, hospital, and autopsy collection/enrollment (month 10-15) (Complete)
- ☑ Assess enrollment, monthly (month 10-15) (Complete)

CY22 Goals (months 13 to 24):

- ☑ EMS, hospital, and autopsy collection/enrollment(month 10-45) (in progress)
- ☑ Assess enrollment, monthly, and then every other quarter (month 10-45) (in progress)
- ☑ Interim outcome analyses (semi-annually) (month 19-45) (in progress)
- ☑ Interpretation of interim analyses (semi-annually) (month 19-45) (in progress)
- ☑ Briefings/presentations to DoD platforms and first report detailing interim analyses (month 19-45) (in progress)

CY23 and CY24 Goals (months 25 to 48):

- ☑ Hospital data collection/enrollment (month 10-45) (in progress)
- ☑ EMS data collection/enrollment (month 10-45) (in progress)
- ☑ Autopsy (pathology) data collection (month 10-45) (in progress)
- ☑ Assess enrollment, every other quarter (month 19-45) (in progress)
- ☐ Completion and interpretation of report on final data analysis (month 48)
- ☐ Manuscripts submitted to journals (month 24-48)
- ☐ Briefings/presentations to DoD platforms (annually)