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TITLE: Impact of Hemodynamic Events at Altitude on Outcomes for Critically Ill Patients

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CONTRACTING ORGANIZATION:

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13. SUPPLEMENTARY NOTES					
14. ABSTRACT Prior En Route Care (ERC) research evaluating the impact of air transport on combat wounded has analyzed in-flight hemodynamic events as binary outcomes based on handwritten data recorded on Critical Care Air Transport Teams (CCATT) medical records. These low frequency data are usually recorded at one-hour intervals, so the prevalence, severity, and duration of in-flight hemodynamic abnormalities remains a research gap. Insensitive data capture for in-flight events likely contributes to the conflicting results and clinical equipoise related to operational and medical decisions such as cabin altitude restriction (CAR) for critically ill combat wounded. Technology advancements enable direct download of hemodynamic parameters from Zoll Propaq monitors, which are currently in use by Critical Care Air Transport Teams (CCATT) as usual Patient Movement Items (PMI). Both commercial (COTS) and government off-the-shelf (GOTS) materiel solutions can enable electronic transfer of vital signs in the form of Zoll Case Review and Battlefield Assisted Trauma Distributed Observation Kit (BATDOK), respectively. This electronic data transfer will enable analysis of high frequency in-flight hemodynamic measurements.					
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1. INTRODUCTION:

The impact of stresses of flight on clinical outcomes for combat wounded remains a research gap and has been identified as a top En Route Care (ERC) research priority. Recent reviews by ERC leaders call for additional research on the impact of flight stresses such as noise, vibration, hypobaria, humidity, and thermal changes on different injury patterns for combat wounded requiring air transportation. The objective of this study is to conduct an observational cohort study of adults transported by Critical Care Air Transport Team (CCATT) who receive in-flight monitoring with a Zoll Propaq monitor. Propaq monitors measure and record hemodynamic data at brief intervals (multiple times per minute) during usual care. The purpose of this study is to investigate the potential impact of material solutions enabling transfer of hemodynamic monitoring data from Patient Movement Request (PMR) into the electronic medical record for handoff of more complete vital sign trends. An additional objective of the study is to provide a more definitive answer for Cabin Altitude Restrictions (CAR) impact on hypoxia events given that the most common indication for CAR in combat wounded is to optimize oxygen delivery.

2. KEYWORDS:

Hemodynamic events, in-flight hypoxia, Critical Care Air Transport Team, en route care, air transport

3. ACCOMPLISHMENTS:

What were the major goals of the project?

- Specific Aim 1: Assess frequency of in-flight hemodynamic abnormality events during CCATT evacuation as captured by patient movement items.
- Specific Aim 2: Compare clinical outcomes of CCATT patients flown with cabin altitude restrictions (CAR) versus non cabin altitude restriction controlling for in-flight hypoxia events.
- Specific Aim 3: Assess agreement between electronically capture vital signs and written documentation.

What was accomplished under these goals?

Major Task 1: Obtain required approvals and agreements.

- Final IRB Determination - EXEMPT STUDY
- MOU with ERCC (CCATT) Pilot Unit.
- DHA DSA approved and fully executed.

Major Task 2: Hire and train staff for study sites.

- Hired 2 research staff.
- Both staff in-processed and trained.
- Staff provided with resources and working to meet project objectives.
- Obtained access to required patient record systems for study coordinators

Major Task 3: Data collection

Electronic Data Capture

- Database created and finalized methods for data capture from Zoll Propaq and BATDOK Case Export
- Pilot data downloads and abstraction
- Successful site visit and actively collecting prospective data at all sites
- Data successfully transferred to and downloaded by ECRC
- Data abstracted directly from CCATT records
- Study database test complete, minor revisions accomplished
- Abstraction guide revised
- Abstraction of flight records initiated; 110 potentially eligible in-flight vital sign records abstracted and ready for matching to medical record data.
- Process to match records to electronic data established and tested.

Quality assurance measures

- Interrater agreement addressed in meetings and with early quality assurance processes

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

Research Coordinator and Research Assistant have had the opportunity to learn from the PI and Nurse Scientist throughout the year, to include becoming proficient in the electronic data capture and coordinating data collection from multiple sites.

How were the results disseminated to communities of interest?

Nothing to report.

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

- Continue to work with data collection sites to gather and upload data.
- Ongoing quality assurance measures.
- Coordinating with multiple sites and core to streamline and maximize efficiency.
- Continue active matching of electronic data to CCATT and other record abstraction data.
- Complete GENESIS abstraction guide & test/refine for post-flight outcomes.
- Site visit – Landstuhl Regional Medical Center (LRMC)

4. IMPACT:

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

Nothing to report.

What was the impact on other disciplines?

Nothing to report.

What was the impact on technology transfer?

Nothing to report.

What was the impact on society beyond science and technology?

Nothing to report.

5. CHANGES/PROBLEMS:

Nothing to report.

Remember that significant changes in objectives and scope require prior approval of the agency.

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

Nothing to report.

Changes that had a significant impact on expenditures

Nothing to report.

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

Significant changes in use or care of human subjects

Nothing to report, study requires patient data downloads and records abstraction

Significant changes in use or care of vertebrate animals

Nothing to report, no animals used in this study

Significant changes in use of biohazards and/or select agents

Nothing to report, no use of biohazard or select agents

6. PRODUCTS:

Nothing to report.

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

Nothing to report.

Other publications, conference papers and presentations.

Nothing to report.

- **Website(s) or other Internet site(s)**

Nothing to report.

- **Technologies or techniques**

Nothing to report.

- **Inventions, patent applications, and/or licenses**

Nothing to report.

- **Other Products**

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

<i>Name:</i>	Maj William T. Davis, MD, USAF
<i>Project Role:</i>	Principal Investigator
<i>Researcher Identifier (e.g. ORCID ID):</i>	0000-0003-4141-0738
<i>Nearest person month worked:</i>	1.8
<i>Contribution to Project:</i>	Dr. Davis wrote the IRB protocol. He managed staff efforts initiate and maintain data collection. He made an in-person site visit to Kadena Air Base to initiate data collection procedures there.
<i>Name:</i>	Dr. Gregory Burnett
<i>Project Role:</i>	Co Investigator
<i>Researcher Identifier (e.g. ORCID ID):</i>	NA
<i>Nearest person month worked:</i>	0.6
<i>Contribution to Project:</i>	Dr. Burnett managed staff efforts on BATDOK Case Export to provide engineering support for data collection with BATDOK Case Export at study sites.
<i>Name:</i>	Col(s) Joseph Maddry, MD, USAF
<i>Project Role:</i>	Co Investigator
<i>Researcher Identifier (e.g. ORCID ID):</i>	NA
<i>Nearest person month worked:</i>	0.6
<i>Contribution to Project:</i>	Col(s) Maddry advised Dr. Davis on IRB related matters and assisted with coordination of project collaborators and data collection procedures.
<i>Name:</i>	Dr. Shelia Savell, PhD, RN
<i>Project Role:</i>	Co Investigator
<i>Researcher Identifier (e.g. ORCID ID):</i>	0000-0002-8684-2764
<i>Nearest person month worked:</i>	0.6
<i>Contribution to Project:</i>	Dr. Savell has advised Dr. Davis on IRB related matters, led data collection coordination efforts and assisted with coordination of project collaborators.

Name: Lt Col Wesley Trueblood, USAF
Project Role: Co Investigator
Researcher Identifier (e.g. ORCID ID): NA
Nearest person month worked: 0.6
Contribution to Project: Lt Col Trueblood led preparations and initiation of data collection at 18 Operational Medical Readiness Squadron CCATT.

Name: Jonathan St. Louis
Project Role: Research coordinator
Researcher Identifier (e.g. ORCID ID): NA
Nearest person month worked: 4.0
Contribution to Project: Data collection, regulatory support and study site coordination.

Name: Emily Lockamy
Project Role: Research Assistant
Researcher Identifier (e.g. ORCID ID): NA
Nearest person month worked: 6.0
Contribution to Project: Data collection support and project management.

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

Maj Patrick Ng, MD, USAF transitioned out of the USAF in June 2023, therefore is no longer involved with this project. Capt Cunningham and had a permanent change of station. The BATDOK team continues to support the team.

What other organizations were involved as partners?

711th BATDOK – BATDOK Engineering support
18th Operational Medical Readiness Squadron – Data collection site
86th Medical Squadron – Data collection site

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: N/A

QUAD CHARTS: *If applicable, the Quad Chart (available on <https://www.usamraa.army.mil/Pages/Resources.aspx>) should be updated and submitted with attachments. See attached.*

9. APPENDICES: None