



DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS



22 MAY 2017

MEMORANDUM FOR ST
ATTN: MAJ JOSEPH MADDRY

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **The Impact of Transport Time on Outcomes Following Evacuation from Point of Injury** presented at/published to **SURF, San Antonio TX, 16 June 2017** in accordance with MDWI 41-108, has been approved and assigned local file #**17230**.
2. Pertinent biographic information (name of author(s) title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.
3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are a 59 MDW staff member, we can forward your request for funds to the designated Wing POC at the Chief Scientist's Office, Ms. Alice Houy, office phone: 210-292-8029; email address: alice.houy.civ@mail.mil.
4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

Linda Steel-Goodwin

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

INSTRUCTIONS

USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON AF E-PUBLISHING

1. The author must complete page two of this form:
 - a. In Section 2, add the funding source for your study [e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE) (SG5 O&M); SG5 R&D; Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRDP); NIH; Congressionally Directed Medical Research Program (CDMRP) ; Grants; etc.]
 - b. In Section 2, there may be funding available for journal costs, if your department is not paying for figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form, if you need publication funding support.
2. Print your name, rank/grade, sign and date the form in the author's signature block or use an electronic signature.
3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g. case report, QA/QI study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box.
4. Attach a copy of your abstract, paper, poster and other supporting documentation.
5. Save and forward, via email, the processing form and all supporting documentation to your unit commander, program director or immediate supervisor for review/approval.
6. On page 2, have either your unit commander, program director or immediate supervisor:
 - a. Print their name, rank/grade, title; sign and date the form in the approving authority's signature block or use an electronic signature.
7. Submit your completed form and all supporting documentation to the CRD for processing (59crdpubsres@us.af.mil). **This should be accomplished no later than 30 days before final clearance is required to publish/present your materials.** If you have any questions or concerns, please contact the 59 CRD/Publications and Presentations Section at 292-7141 for assistance.
8. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations, 502 ISG/JAC (Ethics Review) and Public Affairs (59 MDW/PA) for review and then forward you a final letter of approval or disapproval.
9. Once your manuscript, poster or presentation has been approved for a one-time public release, you may proceed with your publication or presentation submission activities, as stated on this form. **Note:** For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.
10. If your manuscript is accepted for scientific publication, please contact the 59 CRD/Publications and Presentations Section at 292-7141. This information is reported to the 59 MDW/CC. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DITC). See 59 MDWI 41-108, *Presentation and Publication of Medical and Technical Papers*, for additional information.
11. The Joint Ethics Regulation (JER) DoD 5500.07-R, *Standards of Conduct*, provides standards of ethical conduct for all DoD personnel and their interactions with other non-DoD entities, organizations, societies, conferences, etc. Part of the Form 3039 review and approval process includes a legal ethics review to address any potential conflicts related to DoD personnel participating in non-DoD sponsored conferences, professional meetings, publication/presentation disclosures to domestic and foreign audiences, DoD personnel accepting non-DoD contributions, awards, honoraria, gifts, etc. The specific circumstances for your presentation will determine whether a legal review is necessary. **If you (as the author) or your supervisor check "NO" in block 17 of the Form 3039, your research or technical documents will not be forwarded to the 502 ISG/JAC legal office for an ethics review.** To assist you in making this decision about whether to request a legal review, the following examples are provided as a guideline:

For presentations before professional societies and like organizations, the 59 MDW Public Affairs Office (PAO) will provide the needed review to ensure proper disclaimers are included and the subject matter of the presentation does not create any cause for DoD concern.

If the sponsor of a conference or meeting is a DoD entity, an ethics review of your presentation is not required, since the DoD entity is responsible to obtain all approvals for the event.

If the sponsor of a conference or meeting is a non-DoD commercial entity or an entity seeking to do business with the government, then your presentation should have an ethics review.

If your travel is being paid for (in whole or in part) by a non-Federal entity (someone other than the government), a legal ethics review is needed. These requests for legal review should come through the 59 MDW Gifts and Grants Office to 502 ISG/JAC.

If you are receiving an honorarium or payment for speaking, a legal ethics review is required.

If you (as the author) or your supervisor check "YES" in block 17 of the Form 3039, your research or technical documents will be forwarded simultaneously to the 502 ISG/JAC legal office and PAO for review to help reduce turn-around time. If you have any questions regarding legal reviews, please contact the legal office at (210) 671-5795/3365, DSN 473.

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement:

"The views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components"

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving humans:

"The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402."

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving animals, as required by AFMAN 40-401_IP :

"The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication No. 80-23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended."

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1. TO: CLINICAL RESEARCH	2. FROM: (Author's Name, Rank, Grade, Office Symbol) Joseph Maddry, Maj, MC, 59th MDW/ST	3. GME/GHSE STUDENT: <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	4. PROTOCOL NUMBER: FWH20150080H
--------------------------	---	---	-------------------------------------

5. PROTOCOL TITLE: (NOTE: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.)
The Impact of Transport Time on Outcomes Following Evacuation from Point of Injury

6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED:
Poster and Presentation title: The impact of transport time on outcomes following evacuation from point of injury

7. FUNDING RECEIVED FOR THIS STUDY? YES NO FUNDING SOURCE: JPC6

8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: YES NO

9. IS THIS MATERIAL CLASSIFIED? YES NO

10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.?
 YES NO NOTE: If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.

11. MATERIAL IS FOR: DOMESTIC RELEASE FOREIGN RELEASE
CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED.

11a. PUBLICATION/JOURNAL (List intended publication/journal.)

11b. PUBLISHED ABSTRACT (List intended journal.)

11c. POSTER (To be demonstrated at meeting; name of meeting, city, state, and date of meeting.)
SURF, San Antonio, TX, June 16th, 2017

11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meeting.)
SURF, San Antonio, TX, June 16th, 2017

11e. OTHER (Describe: name of meeting, city, state, and date of meeting.)

12. HAVE YOUR ATTACHED RESEARCH/TECHNICAL MATERIALS BEEN PREVIOUSLY APPROVED TO BE PUBLISHED/PRESENTED?
 YES NO ASSIGNED FILE # _____ DATE _____

13. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC
NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC).

DATE
December 2017


14. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email) Maddry, Joseph, K, joseph.k.maddry.mil@mail.mil	15. DUTY PHONE/PAGER NUMBER 210-539-9573
---	---


16. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.

LAST NAME, FIRST NAME AND M.I.	GRADE/RANK	SQUADRON/GROUP/OFFICE SYMBOL	INSTITUTION (If not 59 MDW)
a. Primary/Corresponding Author Maddry, Joseph K	Maj	USAF 59th MDW/ST	
b. Perez, Crystal A	CTR	USAF 59th MDW/ST	
c. Lear, Jill	CTR	USAF 59th MDW/ST	
d. Reeves, Lauren K	CTR	USAF 59th MDW/ST	
e. Bebart, Vikhyat	LtCol	Colorado Air National Guard	University of Colorado

17. IS A 502 ISG/JAC ETHICS REVIEW REQUIRED (JER DOD 5500.07-R)? YES NO

I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401 JP, AND 59 MDWI 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.

18. AUTHOR'S PRINTED NAME, RANK, GRADE Joseph Maddry, Maj, MC USAF	19. AUTHOR'S SIGNATURE 	20. DATE 05/08/2017
---	--	------------------------

21. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE William Terry, Program Analyst, GS13	22. APPROVING AUTHORITY'S SIGNATURE 	23. DATE 05/08/2017
---	---	------------------------

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1st ENDORSEMENT (59 MDW/SGVU Use Only)

TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions.	24. DATE RECEIVED 9 May 2017	25. ASSIGNED PROCESSING REQUEST FILE NUMBER 17230
26. DATE REVIEWED 10 May 2017		27. DATE FORWARDED TO 502 ISG/JAC
28. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: <input type="checkbox"/> NO <input checked="" type="checkbox"/> YES If yes, give date. <u>10 May 2017</u> <input type="checkbox"/> N/A		
29. COMMENTS <input checked="" type="checkbox"/> APPROVED <input type="checkbox"/> DISAPPROVED The author provided the needed research approval. The poster presentation and podium presentation are approved.		
30. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Rocky Calcote, PhD, Clinical Research Administrator	31. REVIEWER SIGNATURE CALCOTE.ROCKY.D.11782 45844 <small>Digitally signed by CALCOTE.ROCKY.D.1178245844 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USAF, cn=CALCOTE.ROCKY.D.1178245844 Date: 2017.05.15 09:08:19 -05'00'</small>	32. DATE

2nd ENDORSEMENT (502 ISG/JAC Use Only)

33. DATE RECEIVED	34. DATE FORWARDED TO 59 MDW/PA	
35. COMMENTS <input type="checkbox"/> APPROVED (In compliance with security and policy review directives.) <input type="checkbox"/> DISAPPROVED		
36. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	37. REVIEWER SIGNATURE	38. DATE

3rd ENDORSEMENT (59 MDW/PA Use Only)

39. DATE RECEIVED May 15, 2017	40. DATE FORWARDED TO 59 MDW/SGVU May 15, 2017	
41. COMMENTS <input checked="" type="checkbox"/> APPROVED (In compliance with security and policy review directives.) <input type="checkbox"/> DISAPPROVED		
42. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Kevin Inuma, SSgt/E-5, 59 MDW Public Affairs	43. REVIEWER SIGNATURE <small>Digitally signed by INUMA.KEVIN.MITSUGU.1296227613 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USAF, cn=INUMA.KEVIN.MITSUGU.1296227613 Date: 2017.05.15 11:47:57 -05'00'</small>	44. DATE May 15, 2017

4th ENDORSEMENT (59 MDW/SGVU Use Only)

45. DATE RECEIVED	46. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> COULD NOT BE REACHED <input type="checkbox"/> LEFT MESSAGE	
47. COMMENTS <input type="checkbox"/> APPROVED <input type="checkbox"/> DISAPPROVED		
48. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	49. REVIEWER SIGNATURE	50. DATE

The Impact of Transport Time on Outcomes Following Evacuation from Point of Injury

Shelia Savell, PhD, RN
Senior Scientist (CTR)
En route Care Research Center
59th MDW/ST, USA ISR



The opinions expressed on this document are solely those of the author(s) and do not represent an endorsement by, or the views of the United States Air Force, the Department of Defense, or the United States Government

This study was conducted under a protocol reviewed and approved by the Wilford Hall Ambulatory Surgical Center IRB and in accordance with the approved protocol

This study was funded by the Joint Program Committee 6
Combat Casualty Care Research Program DoD FY15
En Route Care Research Award

Background

While it is accepted that shorter pre-hospital time is associated with improved survival, little is known about the influence of transport time on patient outcomes or the influence of transport time on specific injury types



MEDEVAC

- Air ambulance
- Evacuates from POI to MTF
- Transfer from MTF to MTF (Role II to Role III)
- Short flight time <60 min
- Challenges:
 - Confined space
 - Limited supplies and equipment
 - Limited diagnostic capability
 - Hostile environment



Objectives

- Determine the effect of transport time in patients with major traumatic extremity amputation (AMP).
- Determine the effect of transport time in patients with non-compressible torso injury (NCTI).



Methods

- Retrospective review of pre-hospital and MEDEVAC care records
- Traumatically injured patients who were evacuated from the POI in Afghanistan
- Subjects were grouped by those with amputation only (AMP), both AMP and NCTI (AMP+NCTI), and neither AMP nor NCTI (Non-AMP/NCTI)
- Study dates between 2011 and 2014
- US Casualties

Data Source



Patient Care Report (PCR)

DoD Trauma Registry (DoDTR)

Demographics

MTF VS

POI & en route VS

Labs

Injury description

Procedures

Provider type

Complications

Procedures

Disposition at discharge from each MTF

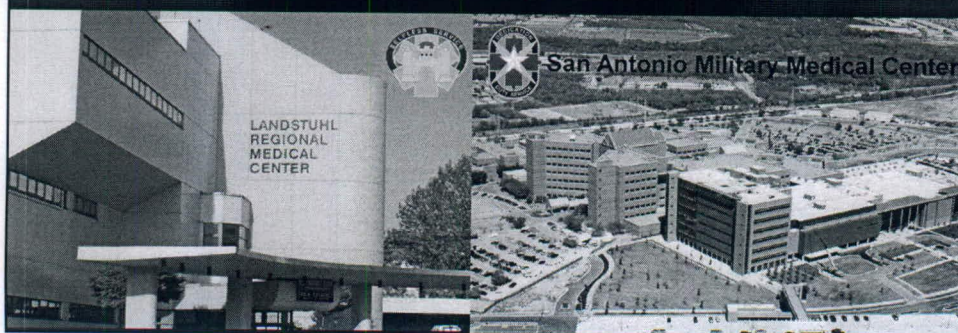
Complications

Mortality

Analgesics administered

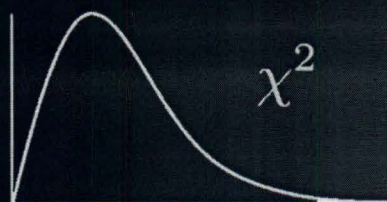
Long term outcomes

- Hospital
- ICU days
- Ventilator Days
- Mortality



Statistics

- Descriptive review of the data
- Categorical data were evaluated using chi-square or Fisher's exact tests and reported as percentages
- Continuous data were analyzed using ANOVA/Student's t-tests and reported as frequencies (%) and median [interquartile range (IQR)]
- Significance was set at $p < 0.05$



Results

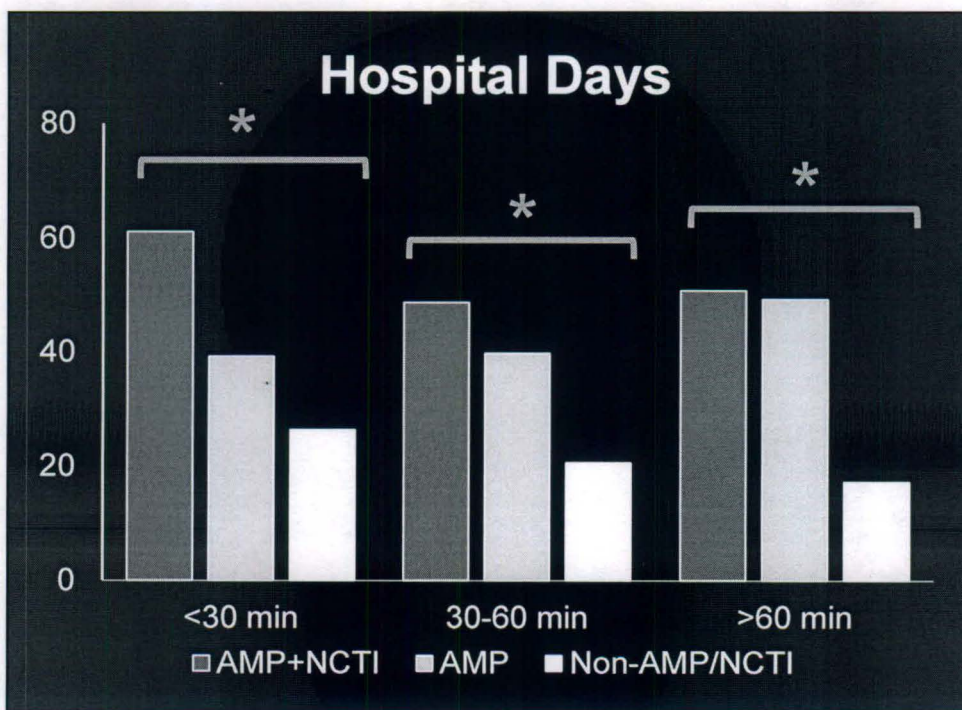
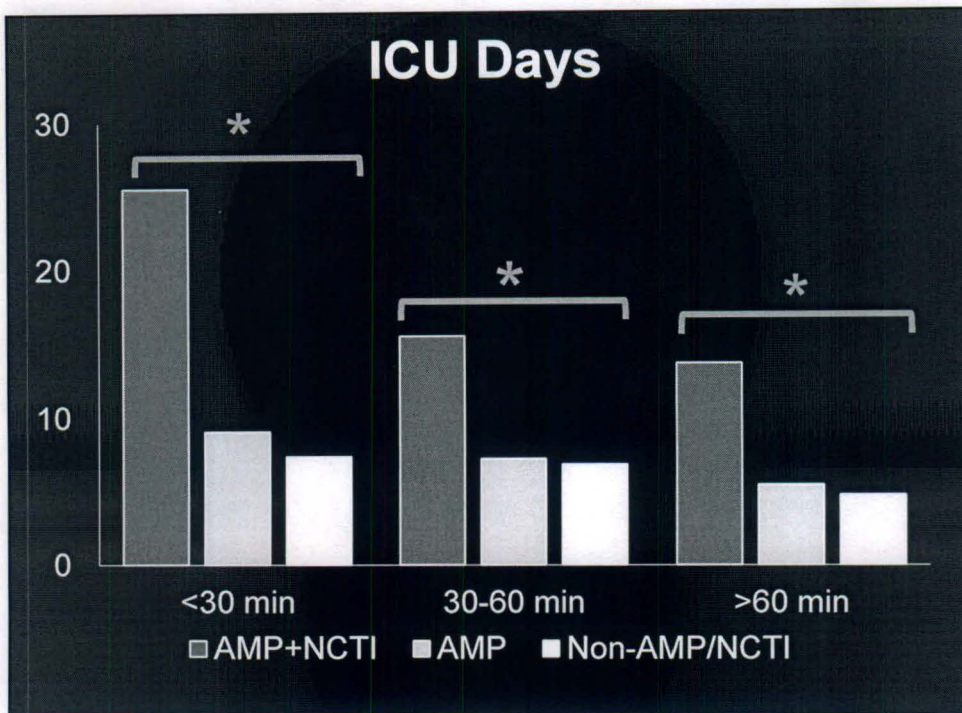


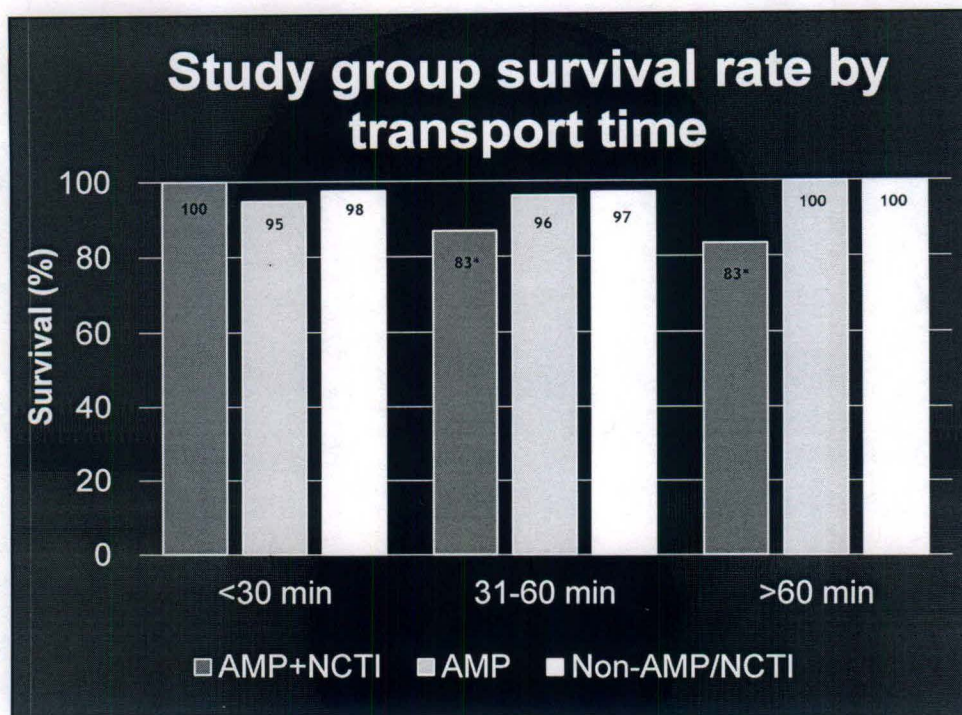
Demographics and Injury Description

Variable	All	AMP+ NCTI	AMP Only	Non- AMP/NCTI	p value
Total Patients	747	72 (10)	104 (14)	571 (76)	-
Male	736 (99)	72 (100)	103 (100)	561 (99)	0.15
Age	24 [22-28]	23 [21-27]	24 [21-27]	24 [22-28]	0.06
Injury Description	All	AMP+ NCTI	AMP Only	Non- AMP/NCTI	p value
Blast	537 (72)	72 (100)	99 (95)	366 (64)	<0.0001
Penetrating	197 (26)	0 (0)	4 (4)	193 (33)	<0.0001
Blunt	13 (2)	0 (0)	1 (1)	12 (2)	0.18
Burn	0 (0)	0 (0)	0 (0)	0 (0)	-
ISS	17 [12-27]	33 [25-40]	18 [14-27]	17 [12-24]	<0.0001
Mortality	67 (10)	6 (8)	4 (4)	57 (11)	0.70
Time Lapse	36 [29-48]	32 [25-40]	32 [27-44]	38 [30-51]	0.81

Injury Severity Score

Time	AMP+NCTI	AMP	Non- AMP/NCTI	p value
<30 min	33 [29-41]	18 [14-26]	17 [12-26]	<0.0001
30-60 min	33 [24-43]	19 [14-26]	16 [11-22]	<0.0001
>60	29 [28-38]	21 [17-27]	14 [10-22]	0.0003





Conclusion

- Prolonged pre-hospital transport times are associated with increased mortality in AMP+NCTI but not in AMP or Non-AMP/NCTI patients
- First priority MEDEVAC should be given to NCTI patients



Limitations

- Retrospective, descriptive study
- Missing or unavailable data
- Subjectivity despite trained data abstractors



Future Efforts

- Better documentation and timestamps
- Understand benefits of each timely intervention
- Identify which interventions should be performed prior to arrival to increase survival



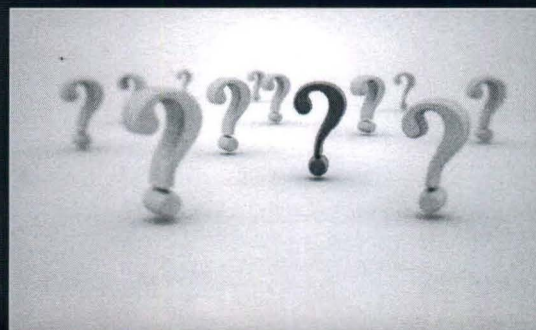
Acknowledgements

USAF En route Care Research Center Team

Joint Trauma System
Department of Defense Trauma Registry



U.S. AIR FORCE



Questions?

The impact of transport time on outcomes following evacuation from point of injury

C Perez¹, S Savell¹, S Russell¹, L Reeves¹, A Mora¹, J Lear¹, T Le², V Bebar^{3,4}, J Maddry^{1,5}

¹United States Air Force En route Care Research Center/59th MDW/ST – United States Army Institute of Surgical Research, JBSA Ft. Sam Houston, TX

²United States Army Institute of Surgical Research, JBSA Ft. Sam Houston, TX ³Department of Emergency Medicine, University of Colorado, Aurora, CO

⁴Colorado Air National Guard, Buckley AFB, CO ⁵Department of Emergency Medicine, San Antonio Military Medical Center, JBSA Ft. Sam Houston, TX



Background

During combat operations, patients with traumatic injuries require urgent medical attention and expeditious evacuation to improve survival. Aeromedical evacuation platforms such as MEDEVAC allow for urgent evacuation to military treatment facilities (MTF). Transport times vary depending on environmental factors and ability to land in combatant locations.



Objective

- The objective was to determine the impact of transport time on patients with traumatic extremity amputation and non-compressible torso injury (NCTI).

Methods

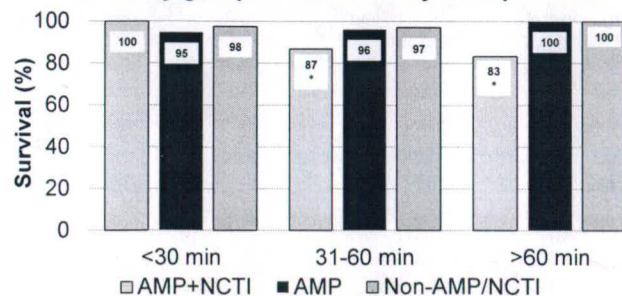
- Retrospective review of patient care records for US military and US contractors in Afghanistan who were evacuated from the point of injury to a MTF between January 2011 and June 2014. ISS <10 excluded.
- Data were abstracted from the MEDEVAC records and supplemental data to include outcomes was queried from the Department of Defense Trauma Registry (DoDTR).
- Subjects were grouped by those with amputation only (AMP), both AMP and NCTI (AMP+NCTI), and neither AMP nor NCTI (Non-AMP/NCTI).
- Categorical data were compared using chi-square (or Fisher's exact test) and reported as percentages.
- Continuous variables were compared using analysis of variance (ANOVA) and reported as frequencies (%) and median [interquartile range (IQR)].

Results

Variable	All	AMP+ NCTI	AMP Only	Non-AMP/NCTI	p value
Total Patients	747	72 (10)	104 (14)	571 (76)	-
Male	736 (99)	72 (100)	103 (100)	561 (99)	0.15
Age	24 [22-28]	23 [21-27]	24 [21-27]	24 [22-28]	0.06
Injury Description	All	AMP+ NCTI	AMP Only	Non-AMP/NCTI	p value
Blast	537 (72)	72 (100)	99 (95)	366 (64)	<0.0001
Penetrating	197 (26)	0 (0)	4 (4)	193 (33)	<0.0001
Blunt	13 (2)	0 (0)	1 (1)	12 (2)	0.18
Burn	0 (0)	0 (0)	0 (0)	0 (0)	-
ISS	17 [12-27]	33 [25-40]	18 [14-27]	17 [12-24]	<0.0001
Mortality	All	AMP+ NCTI	AMP Only	Non-AMP/NCTI	p value
Mortality	67 (10)	6 (8)	4 (4)	57 (11)	0.70
Time Lapse	36 [29-48]	32 [25-40]	32 [27-44]	38 [30-51]	0.81



Study group survival rate by transport time

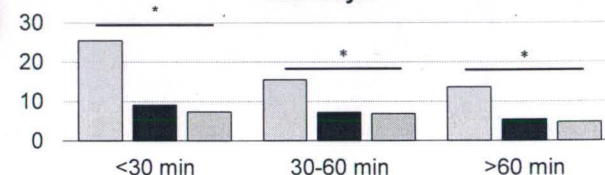


* Denotes significant finding

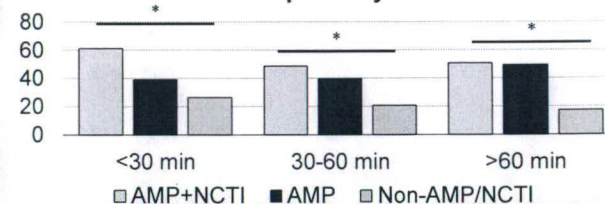
Injury Severity Score

Time	AMP+NCTI	AMP	Non-AMP/NCTI	p value
<30 min	33 [29-41]	18 [14-26]	17 [12-26]	<0.0001
30-60 min	33 [24-43]	19 [14-26]	16 [11-22]	<0.0001
>60 min	29 [28-38]	21 [17-27]	14 [10-22]	0.0003

ICU Days



Hospital Days



Limitations

- Data was collected retrospectively
- Subjectivity despite trained abstractors
- Data missing or unavailable

Conclusions

Prolonged pre-hospital transport times are associated with increased mortality in AMP+NCTI but not in AMP or Non-AMP/NCTI patients. First priority MEDEVAC should be given to NCTI patients.

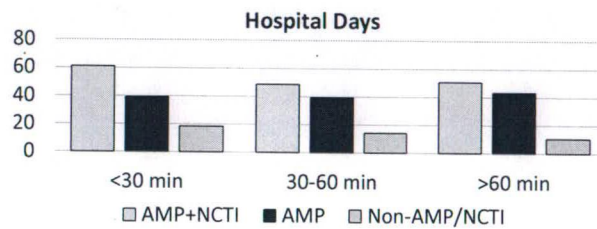
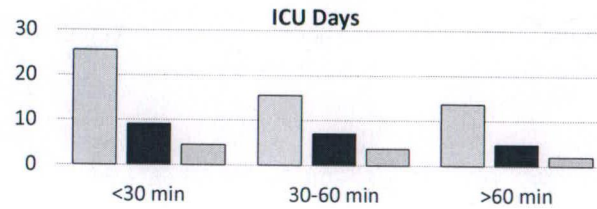
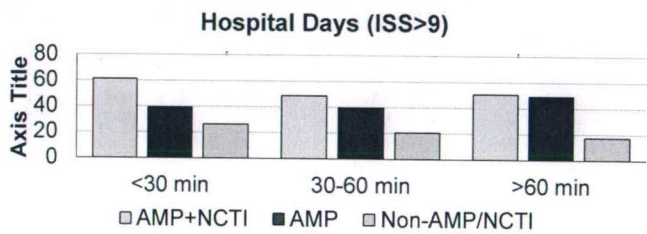
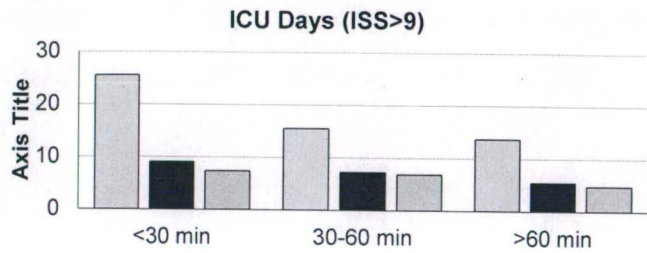
Acknowledgements

DoD-Joint Program Committee (JPC6)
Air Force En route Care Research Center Team
Joint Trauma System – Department of Defense Trauma Registry

This study was conducted under a protocol reviewed and approved by the Wilford Hall Ambulatory Surgical Center Institutional Review Board and in accordance with the approved protocol.

The opinions or assertions contained herein are the private views of the author and are not to be construed as official or as reflecting the views of the Department of the Army, the Department of the Air Force, or Department of Defense

Corresponding author:
joseph.k.maddry.mil@mail.mil





59th Medical Wing (59th MDW)
Institutional Review Board (IRB)
59 Clinical Research Division/SGVUS
2200 Bergquist Dr, Bldg 4430, Lackland AFB, TX 78236-9908

NOTICE OF ACTION REGARDING IRB REVIEW

Date: 9 Jul 2015

TO: LTC Vikhyat Bebarta, 59 EMDS/SGO3D

Assurance Numbers: 59 MDW DoD assurance F50007 Expires: 11/04/2017

Protocol Number: FWH20150080H

Title: The Impact of Transport Time on Outcomes Following Evacuation from Point of Injury

Your **Expedited Approval of a New Human Research Protocol (Initial Review)** was approved by the 59 MDW IRB Chair or designee on 9 Jul 2015. Expedited approvals are available for review by the other Board members as appropriate at a subsequent IRB meeting. Documents Reviewed: Form A Signature Sheet, CV, CITI, Scientific Review, HIPAA waiver, ICD waiver, MOA, Letter of Support - JTS, Form A2 Study Personnel List

A waiver of the requirement to obtain a valid authorization to access, use and disclose PHI was approved, by an Expedited review procedure. It was determined that the following criteria as required by 45 CFR 164.512(i) were satisfied:

- The PHI use or disclosure involves no more than minimal risk to the privacy of individuals based on at least the presence of (1) an adequate plan presented to the Privacy Board to protect PHI identifiers from improper use and disclosure; (2) an adequate plan to destroy those identifiers at the earliest opportunity, consistent with the research, absent a health or research justification for retaining the identifiers or if retention is otherwise required by law; and (3) adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule.

- The research could not practicably be conducted without the requested waiver or alteration.
- The research could not practicably be conducted without access to and use of the PHI.

The waiver permits the investigators to access the subjects' health records for purposes of collecting research data, as specified in reviewed HIPAA Waiver Request form.

A waiver of consent as specified by **32 CFR 219.116 (d)** was also approved.

This study is approved under **32 CFR 219.110(b)(1) Category 5**: Research involving materials (data, documents, records or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

This is a **single site** collaborative study where the WHASC IRB is reviewing the research on behalf of 59 MDW and the contract companies providing personnel to be engaged in the research at 59 MDW. All assurances and agreements are in place and their scope includes this research study.

The IRB determined:

The study minimizes risks to subjects

The risks to subjects are reasonable in relation to anticipated benefits and the importance of the knowledge that may reasonably be expected to result.

The subject selection is appropriate, just and equitable

The research plan has adequate provisions to protect subject privacy and maintain confidentiality of data

The study is exempt from the AAAHC, Ch 6, M. requirement to annotate visits in the medical record as V70.7.

The Expedited Reviewer determined external monitoring of the study was not necessary. The Expedited Reviewer agreed with the Principal Investigator's designation of the **Treatment/other** category of the Surgeon General's Community Health Project. The Expedited Reviewer also determined this proposal to be **minimal risk** and **not readiness related**. **The study will expire on 7/9/16**. The study will be reviewed in approximately **11 months** for continuing review. **Submit a progress report by 10 May 16**. The protocol will be forwarded to the Surgeon General's Research Compliance and Oversight Office (SGE-C) for a compliance review/concurrence.

If you have requested funds, you should contact the CRD Resource Manager at (2-7295) as to the status of requested funds. **YOU ARE NOT AUTHORIZED TO USE YOUR SECTION'S O&M FUNDS.**

Name of Official

HOWELL, DELLA L Lt Col USAF

Title/Office Symbol/Phone

IRB Chair/SGVUS/916-8251

Signature HOWELL.DELLA.L.113460

4960

Digitally signed by HOWELL.DELLA.L.1134604960
DN: c=US, o=U.S. Government, ou=DoD, ou=PKI,
ou=USAF, cn=HOWELL.DELLA.L.1134604960
Date: 2015.07.09 14:59:44 -05'00'

Info Copy To