

AD _____
(Leave blank)

Award Number: W81XWH-07-1-0222

TITLE: "Serum and Exudate Calcitonin Precursors as Predictors of Wound Infection
and Dehiscence in Wartime Penetrating Injuries"

PRINCIPAL INVESTIGATOR: MAJ Benjamin Kyle Potter, MD, PI

CONTRACTING ORGANIZATION: The Geneva Foundation
Lakewood, WA 98496

REPORT DATE: February 2011

TYPE OF REPORT: Addendum to Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: (Check one)

☒ Approved for public release; distribution unlimited

☐ Distribution limited to U.S. Government agencies only;
report contains proprietary information

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE) 28 February 2011		2. REPORT TYPE Addendum to Final		3. DATES COVERED (From - To) 1 JUL 2008 - 31 JAN 2011	
4. TITLE AND SUBTITLE "Serum and Exudate Calcitonin Precursors as Predictors of Wound Infection and Dehiscence in Wartime Penetrating Injuries"				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-07-1-0222	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Dr Benjamin Kyle Potter, MD, ; kyle.potter@us.army.mil ;				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) The Geneva Foundation PO Box 98687 Lakewood, WA 98499				8. PERFORMING ORGANIZATION REPORT	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) Us Army MRMC Ft. Detrick, MD 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S) USAMRMC	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT - Approved for public release; distribution unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT To date, we have enrolled 148 patients into the study that have either been wounded in Iraq or Afghanistan and 5 control tissue patients who have had their patella tendon repaired and donated pieces of the Autologous tendon.					
15. SUBJECT TERMS War Wounds, Blast Injuries, Infection, Debridement, Procalcitonin, Cytokines					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF 6	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

Table of Contents

	<u>Page</u>
Introduction.....	3
Body.....	3
Key Research Accomplishments.....	3
Reportable Outcomes.....	6
Conclusion.....	6
References.....	6
Appendices.....	6

INTRODUCTION:

This controlled variable study will demonstrate that ProCT and other cytokines are detectable in wound exudate. It will also determine the sensitivity, specificity, and both positive and negative predictive values of serum and exudate ProCT/cytokines with respect to wound dehiscence and infection. Finally, it will compare the efficacy of serum or exudate ProCT/cytokine levels to established serum or exudate markers for infection in predicting the risk of wound infection and dehiscence. Participants of this study are wounded U.S. service members that sustain high-energy penetrating injuries to a single extremity and evacuated from Iraq, Afghanistan and any future area of US combatoperations that are admitted to Walter Reed Army Medical Center (WRAMC) or National Naval Medical Center (NNMC). Local antibiotic delivery, high-pressure irrigation and wound evacuation dressings have advanced the treatment of high-energy penetrating injuries, but the decision to primarily close or perform flap coverage of a wound remains subjective. Considerable intra-observer variability exists and despite meticulous debridements and antibiotic therapy, some clean appearing wounds go on to dehiscence and become infected. Conversely, because of this uncertainty, benign appearing wounds may undergo unnecessary surgical debridements, exposing patients to additional anesthesia risks and surgical morbidity. A serum or exudate marker that correlates with wound dehiscence and infection could prevent life and limb-threatening complications caused by premature wound closure and eliminate the morbidity associated with unnecessary debridement procedures.

BODY:

Project accomplishments include: continued development of infrastructure to implement AIM I, AIMS II, & III; hiring and training of a second Research Assistant to assist with study supervision, sample handling, and data entry; and coordination with key personnel conducted including correspondence with study consultants, study statistician, and critical contacts at processing facilities, NMRC and VAMC. In addition, techniques for collection, processing and shipment of serum and exudate samples have been established and executed. Systems have been implemented to identify, screen, and enroll incoming patients that meet inclusionary criteria. The following is the enrollment for the past year (1 January 2010 to 31 December 2010) 69 patients have been enrolled into the study; 36 patient enrolled from National Naval Medical Center and 33 from Walter Reed Army Medical Center for a total of 69 patients enrolled into this study. The total enrollment since this study has been initiated is 148 patients enrolled.

KEY RESEARCH ACCOMPLISHMENTS:

Administrative and logistical matters.

a. Personnel.

- 1) Mr. Wesley Stepp, Research Assistant, resigned 19 July 2010.
- 2) Mr Felipe Lisboa replaced Mr. Stepp 2 September 2010.

- 3) Fred Gage PhD has supervised Research Assistants while continuing to provide study support through patient sampling and data collection.
- 4) Mr Samuel Han was terminated on 7 December 2010.

b. Database.

- 1) Data collected and data entered into study database.
- 2) Minor alteration of study database completed to enhance data manipulation ability during data analysis phase.

c. Equipment. New Apple I MAC was purchased for the WRAMC office.

d. Materials, supplies and consumables. Supplies and materials for NNM C, NMRC, VAMC, and WRAMC study requirements continue to be coordinated.

e. Institutional Review Board.

- 1) National Naval Medical Center (NNMC). There has been four (5) protocol amendments made by Responsible Conduct of Research Department at NNMC.
 - A) Mr Samuel Han became an Associate Investigator to replace Ms Cenicerros.
 - B) Control tissue collection was added to the protocol.
 - C) Change in the Negative Pressure machine went from an older model to a newer model.
 - D) Mr Wesley Stepp resigned his position and was removed as Associate Investigator from protocol.
 - E) Mr. Felipe Lisboa was added as an AI to the protocol.
 - F) Mr Samuel Han was removed as an AI from the study.
- 2) Walter Reed Army Medical Center (WRAMC) There has been four (4) protocol amendments by DCI at WRAMC this past year.
 - A) Mr Samuel Han was added as an Associate Investigator.
 - B) Dr. Fred O'Brien was added as an Associate Investigator.
 - C) Mr Felipe Lisboa was added as an AI to the protocol.
 - D) Mr. Samuel Han was removed from the protocol as an AI.
- 3) Completion of NNMC IRB Continuing Review 18 March 2010 and renewed approval of NNMC protocol Informed Consent Forms (ICF) and Health Insurance Portability and Accountability Act (HIPAA) forms 02 APRIL 10.
- 4) Completion of WRAMC IRB Continuing Review and renewed approval of WRAMC protocol Informed Consent Forms (ICF) and Health Insurance Portability and Accountability Act (HIPAA) forms.

f. Subject Enrollment.

- 1) Collection of data for AIM II & III has been conducted.
- 2) Currently 148 subjects have been enrolled and consented into the study Protocol; 77 patients enrolled from National Naval Medical Center and 71 from Walter Reed army Medical Center.
- 3) Data collected has been continued to be entered into the study database.
- 4) Samples have been forwarded to VA and NMRC for analysis.

REPORTABLE OUTCOMES: Nothing to Report

CONCLUSION:

We have consented and collected data from 148 patients total since the study began, 69 the past year have been enrolled into the study at NNMC and WRAMC. We have started collecting control tissue from the autologous patella tissue transplants in the past year. We have not analyzed the data but continue to collect data and enroll patients.

REFERENCES:

Nothing to Report

APPENDICES:

Nothing to Report

SUPPORTING DATA:

Nothing to Report