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TITLE: Establishment of Peripheral Nerve Injury Data Repository to Monitor and Support Population Health Decisions

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14. ABSTRACT The current award is to carry out an Ambispective (prospective and retrospective) epidemiologic chart reviews of patients who were referred to San Antonio Military Medical Center (SAMMC) and Walter Reed National Military Medical Center (WRNMMC) for Peripheral Nerve Injury (PNI) treatment. A database, the Peripheral Nerve Injury Database (PNIDB), will be established to catalog and describe the characteristics, mechanisms, management, and outcomes of PNIs using both retrospective chart review and prospective patient enrollment. Collected data will be utilized to 1) describe the outcomes of various PNI and 2) suggest outcomes that support population health decisions for patients with PNIs. These outcomes could be used in future study to further characterize PNIs and delineate which management techniques have the best outcome for any PNI, leading to an improved standard of care and patient quality of life. Follow-up data collection will accurately document PNI recovery outcomes. This prospective data will aid healthcare professionals to accurately evaluate the time course of a patient's recovery and the efficacy of treatment decisions. Data collected will include combat related and non-combat related PNIs to fully characterize all forms of PNI.			
15. SUBJECT TERMS Peripheral Nerve Injury, Database, Data Repository, Nerve			
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1. INTRODUCTION:

The purpose of this study is to catalog and describe the characteristics, mechanisms, management, and outcomes of PNIs using both retrospective chart review and prospective patient enrollment. Collected data will be utilized to 1) describe the outcomes of various PNI and 2) suggest outcomes that support population health decisions for patients with PNIs. These outcomes could be used in future study to further characterize PNIs and delineate which management techniques have the best outcome for any PNI, leading to an improved standard of care and patient quality of life. Follow-up data collection will accurately document PNI recovery outcomes. This prospective data will aid healthcare professionals to accurately evaluate the time course of a patient's recovery and the efficacy of treatment decisions.

KEYWORDS: Peripheral Nerve Injury, Database, Data Repository, Nerve

2. OVERALL PROJECT SUMMARY:

The start of the project was delayed for over 200 days due to delays with WRNMMC IRB. With this delay in mind, it was decided by the investigator to switch site emphasis to SAMMC as the lead site for this project. A Clinical Research Manager and a Clinical Research Assistant were hired at SAMMC to complete the regulatory submissions. With the addition of the additional team members at SAMMC Major Task 1 was completed. The team submitted all documentation and received approval from HRPO.

Major Task 2 is ongoing with the help of a database manager at SAMMC. Data collection commenced in summer of 2017. Retrospective data has been entered for patients 2001 to 2009 and additional data entry is still ongoing. Data analysis is underway for patients 2001 to 2009. To date: San Antonio has collected 69 patients and Walter Reed 250 patients.

3. KEY RESEARCH ACCOMPLISHMENTS

IRB approval obtained with IRB and data collection in progress. Post data collection, data analysis is underway for patients 2001 to 2009. Additionally, biological sample acquisition and analysis are still ongoing.

4. CONCLUSION:

We are approximately one year behind schedule due to the extended delay in obtaining IRB approval at WRNMMC, but the project tasks have not deviated from the original proposal or SOW.

Advanced database development is underway and the database team is responsive to the changing needs. The plan is to integrate the database with MOTION database if funding permits.

Biological sample collection is planned for current and future patients to expand capabilities and assist with algorithm development.

5. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:

Publications: Noting to report

Abstracts: Nothing to report

Presentations: Nothing to report

6. INVENTIONS, PATENTS AND LICENSES:

Nothing to report

7. REPORTABLE OUTCOMES

Nothing to report

8. OTHER ACHIEVEMENTS:

Nothing to report

9. REFERENCES:

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10. APPENDICES:

None

11. TRAINING OR FELLOWSHIP AWARDS:

None

12. COLLABORATIVE AWARDS:

No collaborative awards were executed

13. UPDATED QUAD CHART & SOW: