Title: Understanding, Predicting, and Preventing Life-Changing and Life-Threatening Health Changes among Aging Veterans and Civilians with Spinal Cord Injury

Principal Investigator: James S Krause, PhD

Recipient: Medical University of South Carolina
               Charleston, SC 29425

Report Date: October 2017

Type of Report: Annual

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

Distribution Statement: Approved for Public Release; Distribution Unlimited

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

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**
   - October 2017

2. **REPORT TYPE**
   - Annual

3. **DATES COVERED**
   - 30 Sep 2016 - 29 Sep 2017

4. **TITLE AND SUBTITLE**
   - Understanding, Predicting, and Preventing Life-Changing and Life-Threatening Health Changes among Aging Veterans and Civilians with Spinal Cord Injury

5a. **CONTRACT NUMBER**
   - W81XWH-16-1-0629

5b. **GRANT NUMBER**
   - W81XWH-16-1-0629

5c. **PROGRAM ELEMENT NUMBER**

5d. **PROJECT NUMBER**

5e. **TASK NUMBER**

5f. **WORK UNIT NUMBER**

6. **AUTHOR(S)**
   - James S Krause, PhD; Jennifer Coker, MPH

7. **PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)**
   - Medical University of South Carolina, 171 Ashley Ave, Charleston, SC 29425

8. **PERFORMING ORGANIZATION REPORT NUMBER**

9. **SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)**
   - U.S. Army Medical Research and Materiel Command
   - Fort Detrick, Maryland 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**
   
   Spinal cord injury (SCI) is associated with secondary health conditions, such as pressure ulcers and infections, that occur either in isolation or in combination. Our purpose is to identify how multiple secondary health may occur simultaneously and the factors that lead to their occurrence, so that preventative strategies may be developed. During the past year, we have completed the groundwork for our qualitative study of negative health spirals that will include interviews and focus groups of people with SCI who have experienced a health spiral, as well as family members. Our preliminary tasks completed include the important and time-consuming task of detailing the interview schedule and guide for the qualitative groups. We have sought and obtained feedback from our advisory panel that includes individuals with differing roles with military veterans and they helped us to review and finalize our interviews and focus group schedules. We submitted and successfully obtained IRB approval and secondary approval from HRPO to conduct this research. This led to some delays in the timeline, which were balanced by the development of a detailed interview and group schedule that ultimately will lead to study success. We were able to successfully quantify individuals' health histories and identify a large number of those who were eligible. This will allow us to identify those who have experienced the greatest problems and most likely have experienced health spirals. Although, proportionally, we have a larger number of civilians, we are categorizing potential participants so as to balance the data collection between civilians and military veterans. Data collection will begin in the first quarter of year 2.

15. **SUBJECT TERMS**
    - health, spinal cord injury, veterans, civilians, aging, hospitalization, health decline

16. **SECURITY CLASSIFICATION OF:**
    - a. REPORT Unclassified
    - b. ABSTRACT Unclassified
    - c. THIS PAGE Unclassified
    - 17. **LIMITATION OF ABSTRACT** Unclassified
    - 18. **NUMBER OF PAGES** 9
    - 19a. **NAME OF RESPONSIBLE PERSON**
    - 19b. **TELEPHONE NUMBER** (include area code)

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

1. Introduction 1
2. Keywords 2
3. Overall Project Summary 2
4. Key Research Accomplishments 3
5. Conclusion 3
7. Inventions, Patents and Licenses 5
8. Reportable Outcomes 5
9. Other Achievements 5
10. References 5
11. Appendices: Quad Chart 6
1. INTRODUCTION:

Maintaining health is very difficult for both military veterans and civilians in the years and decades after the onset of spinal cord injury (SCI). People with SCI are particularly vulnerable to secondary health conditions (SHC), such as pressure ulcers, urinary tract infections, and respiratory complications. Even when a single SHC occurs, there is a risk of more serious complications. Although not very well understood, the onset of one SHC may elevate the risk of others. A fracture leads to immobility, which may in turn trigger a sequence of events, such as the development of pressure ulcers that ultimately become infected. Or, the development of a pressure ulcer may lead to respiratory complications by virtue of immobility. Clearly, we need to understand how these negative health spirals occur, if we are to have any hope of preventing them.

Our purpose is to better understand the how and why of the development of negative health spirals and how they may best be prevented. We will use qualitative methods, meaning simply we will identify these health problems from the perspective of those with SCI. What can those who have experienced negative health spirals tell us about how they occur and how they feel they could have been prevented? What worked for them in ultimately stopping the negative health spiral, if indeed they were able to stop it? What were the other consequences? And, in those sad instances where the negative health spiral led to loss of life, what can the family members tell us so we can prevent these consequences from happening to others?

We will identify participants from two existing studies, the first of which was initiated in 1973 and the second of which was initiated in 1997. There have been a total of 2,207 participants in the first study and 5,971 in the second. Participants have completed questionnaires, but there has not been a qualitative study conducted by our team in the past 20 years. There are a significant number of military veterans in our study. A great many participants have also experienced health decline and negative health spirals at different times since the onset of their SCI. Because we have a large existing database, with detailed information on health on more than 1 occasion, we can identify those who have experienced these complications and enroll them in our qualitative study. We will specifically approach those who have reported multiple SHCs, who have indicated general health decline or significant health problems, and have had a number of recent medical treatments.

We will enroll 60 participants with SCI, representing an equal mix of military veterans and civilians. We will also enroll 30 participants who are family members of someone with SCI who has experienced health decline related to SHCs. We will conduct interviews with each of the 60 SCI participants and 30 family members to identify the pattern of SHCs over time. We will then conduct focus groups with 6-9 individuals each where those with SCI and their families may interact with each other to engage in a rich discussion of SHCs and negative health spirals. This will allow us to draw out common themes and patterns. We will learn from what has and has not worked for people when trying to prevent SHCs or trying to avoid SHCs from spiraling. We will analyze the data using state-of-the-art data analytic software.

We will publish the results in journals for professionals and also disseminate the results directly to people with SCI and their families. The results of the research will be used to help us better measure multiple SHCs and negative health spirals in our future research. To help us accomplish this, we will bring together an advisory board comprised of members who are military veterans, representatives of the PVA or VAMC, and stakeholders who have SCI. This group will be particularly important in helping interpret the interview and focus group data, so that it can be used for developing intervention strategies. Our ultimate goal is to improve the health and well-being of both military veterans and civilians with SCI by identifying better ways of preventing multiple SHCs, particularly stopping multiple negative health spirals.
2. **KEYWORDS:** health, spinal cord injury, veterans, civilians, aging, hospitalization, health decline

3. **OVERALL PROJECT SUMMARY:**

<table>
<thead>
<tr>
<th>Major Task 1: Obtain Approval for Human Subjects Research</th>
<th>Timeline</th>
<th>Progress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subtask 1: Complete all necessary regulatory review and approval processes for research involving human subjects</td>
<td>Months</td>
<td>Complete</td>
</tr>
<tr>
<td>Refine eligibility criteria, exclusion criteria, screening protocol</td>
<td>1-3</td>
<td>Complete</td>
</tr>
<tr>
<td>Finalize consent form &amp; human subjects protocol</td>
<td>1-3</td>
<td>Complete</td>
</tr>
<tr>
<td>Identify interviewer (currently to be named)</td>
<td>1-3</td>
<td>Complete</td>
</tr>
<tr>
<td>Submit project approval to MUSC IRB review</td>
<td>1-6</td>
<td>Complete</td>
</tr>
<tr>
<td>Submit project approval for Military 2nd level IRB review (ORP/HRPO)</td>
<td>1-6</td>
<td>Complete</td>
</tr>
<tr>
<td>Submit amendments, adverse events and protocol deviations as needed</td>
<td>As Needed</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Submit annual IRB report for continuing review</td>
<td>Annually</td>
<td>Ongoing</td>
</tr>
<tr>
<td><strong>Milestone Achieved: MUSC IRB approval</strong></td>
<td>6</td>
<td>Complete</td>
</tr>
<tr>
<td><strong>Milestone Achieved: HRPO approval</strong></td>
<td>6</td>
<td>Complete</td>
</tr>
</tbody>
</table>

Brief narrative about accomplishments: We successfully obtained approval for human subjects from both the institutional IRB and the military secondary IRB (HRPO). There was a delay in the approvals past the projected time in the scope of work. Specifically, the institutional IRB approval was granted on 7/19/2017 and HRPO approval was received on 7/31/2017.

<table>
<thead>
<tr>
<th>Major Task 2: Develop semi-structured interview</th>
<th>Timeline</th>
<th>Progress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subtask1: Identify health decline factors from 15yr data to assist with content development for interviews</td>
<td></td>
<td>Complete</td>
</tr>
<tr>
<td>Develop interview</td>
<td>1-3</td>
<td>Complete</td>
</tr>
<tr>
<td>Advisory board review of interview</td>
<td>4</td>
<td>Complete</td>
</tr>
<tr>
<td>Finalization of interview</td>
<td>5-6</td>
<td>Complete</td>
</tr>
<tr>
<td><strong>Milestone Achieved: Structured interview is complete</strong></td>
<td>6</td>
<td>Complete</td>
</tr>
</tbody>
</table>

Brief narrative about accomplishments: We were very pleased to have developed an outstanding interview protocol. It addresses the study needs and we are confident that it will be successfully used to identify negative health spirals among those with spinal cord injury (SCI), as intended. Our advisory group reviewed the interview and made recommendations prior to finalization and we were grateful for their input, as it improved the final interview measures (individual and family).
Major Task 3: Select and recruit participants for interviews/focus groups

<table>
<thead>
<tr>
<th>Subtask 1: Identify veterans and civilians with spinal cord injury</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Review of existing health history from 15-year and 40-year studies</td>
<td>1-9 Complete</td>
</tr>
<tr>
<td>Analysis of health history based on merge of data</td>
<td>1-9 Complete</td>
</tr>
<tr>
<td>Selection of participants based on health status</td>
<td>6-9 Complete</td>
</tr>
</tbody>
</table>

*Milestone Achieved:* At least 30 veterans and 30 civilians with spinal cord injury identified who fit criteria.

<table>
<thead>
<tr>
<th>Subtask 2: Identify potential participants who are a family member, friend, or significant other</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Review of existing health history from 15-year and 40-year studies</td>
<td>9-12 In progress</td>
</tr>
<tr>
<td>Selection of 30 participants</td>
<td>9-12 In progress</td>
</tr>
</tbody>
</table>

*Milestone Achieved:* Up to 30 participants identified who fit criteria.

Brief narrative about accomplishments and issues remaining if incomplete: We have reviewed the health histories of our research participants from both sources and have classified individuals according to the number of secondary health conditions and the number of additional negative health indicators (e.g., hospitalizations, treatments). Based on this analysis, we have developed a hierarchy of health status and desirability of individuals to serve as participants. These individuals have also been broken into categories by veteran status (civilian vs. military veteran), the geographic location in which they were identified, and other relevant variables including their age and years since SCI onset. From this, we have developed a selection scheme which will be utilized as we begin the data collection. In doing so, we will select individuals such that we have sufficient cases within each geographic location who can participate in the data collection. We have structured the participants accordingly and are ready to begin the data collection. In terms of family members, our protocol is that we will identify them when we solicit participation from individuals with SCI (i.e. they will name a potential family member), so this step cannot occur until we begin the actual data collection. We have made the necessary preparations to begin the interviews (originally scheduled for the last quarter of year 1; now will start in the first quarter 2, given the delay in IRB approval).

4. **KEY RESEARCH ACCOMPLISHMENTS:** Nothing yet to report.

5. **CONCLUSION:** Our future plans are to implement the data collection during the current quarter. To do that, we are bringing our consultant to Charleston to meet with study staff and to do some training so that we may synchronize our interviews and group data collections, both across format (interview vs. group) and between participants-family versus individual with SCI. This is consistent with major task 4 which needs to be completed by the end of year 2. We anticipate that we will achieve our milestone of 30 interviews completed by the end of month 18, despite the delay in the IRB and HRPO approvals, as well as completing 15 interviews with family members, also a milestone for month 18. Additionally, we anticipate having completed 4 focus groups by the end of the 18-month milestone. It is difficult to project any potential difficulties until we initiate the first stage of actual data collection. We believe that the first focus group or two will provide us with major learning experiences regarding any specific unforeseen issues that may come up with this particular investigation. We are pleased with the progress thus far and are confident that the steps we are taking, including bringing our consultant in and consulting with our advisory members, will facilitate a smooth transition to data collection and maximize the outcomes from the study.
<table>
<thead>
<tr>
<th>Major Task</th>
<th>Description</th>
<th>Milestone Achieved</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>4: Conduct interviews</td>
<td>Subtask 1: Collect updated self-report on 60 participants</td>
<td></td>
<td>10-24</td>
</tr>
<tr>
<td></td>
<td>Subtask 2: Schedule and conduct interviews with 60 study participants with SCI with military and non-military backgrounds at times and locations convenient to the participants.</td>
<td></td>
<td>10-24</td>
</tr>
<tr>
<td></td>
<td>Subtask 3: Schedule and conduct interviews with up to 30 study participants who are family members of persons with SCI at times and locations convenient to the participants.</td>
<td><em>Milestone Achieved: 30 interviews completed with SCI participants</em></td>
<td>18</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>Milestone Achieved: 60 interviews completed with SCI participants</em></td>
<td>24</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>Milestone Achieved: up to 15 interviews completed with family members</em></td>
<td>18</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>Milestone Achieved: up to 30 interviews completed with family members</em></td>
<td>24</td>
</tr>
<tr>
<td>5: Conduct focus groups</td>
<td>Subtask 1: Schedule and conduct focus groups with 60 study participants with SCI with military and non-military backgrounds at times and locations convenient to the participants.</td>
<td></td>
<td>10-24</td>
</tr>
<tr>
<td></td>
<td>Subtask 2: Schedule and conduct focus groups with up to 30 study participants who are family members of persons with SCI at times and locations convenient to the participants (Family members may choose interview only).</td>
<td><em>Milestone Achieved: 4 focus groups completed with SCI participants</em></td>
<td>18</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>Milestone Achieved: 8 focus groups completed with SCI participants</em></td>
<td>24</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>Milestone Achieved: 2-4 focus groups completed with family members</em></td>
<td>24</td>
</tr>
<tr>
<td>6: Develop Coding Book</td>
<td>Subtask 1: Transcribe, “clean” data from interviews and enter into qualitative software</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Send digital recordings of in-depth interviews and focus groups to a professional transcription service with expertise in medical transcription and transcripts</td>
<td></td>
<td>10-25</td>
</tr>
<tr>
<td></td>
<td>Interviewer / group facilitators will compare transcript to the recording as a check on accuracy and completeness.</td>
<td></td>
<td>26-27</td>
</tr>
<tr>
<td></td>
<td>Enter “cleaned” transcripts into qualitative software to facilitate the processing and analysis</td>
<td></td>
<td>27</td>
</tr>
<tr>
<td></td>
<td><em>Milestone Achieved: Transcripts are clean and ready for analysis.</em></td>
<td></td>
<td>27</td>
</tr>
<tr>
<td></td>
<td>Subtask 2: Code interviews</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Use theoretical concepts embedded in the research questions and precise and standard definitions to develop index system and coding scheme (Coding Book)</td>
<td></td>
<td>28-30</td>
</tr>
<tr>
<td></td>
<td>Project investigators will review and code the text of the transcribed interviews</td>
<td></td>
<td>28-30</td>
</tr>
<tr>
<td></td>
<td>Update and modify coding book to ensure detailed documentation of the procedures, decisions, and rationale for decisions made, which should support consistency, dependability, and duplicability of results</td>
<td></td>
<td>29-30</td>
</tr>
<tr>
<td></td>
<td><em>Milestone Achieved: Coding Book developed and maintained</em></td>
<td></td>
<td>30</td>
</tr>
<tr>
<td>7: Data Analysis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Subtask 1: Complete all qualitative data analysis

Analyze both interview and focus group data to identify negative health spirals, patterns and themes, associated factors, and associated outcomes

31-36

**Milestone Achieved: Report findings from overall studies**

36

---

### Major Task 8: Dissemination and Utilization of Project Data

**Subtask 1: Perform all dissemination of materials.**

31-36

Prepare all data for data sharing

31-36

Utilize advisory panel to draw interpretations from the qualitative interviews and focus groups

31-36

Manuscripts completed and submitted for publication

31-36

Develop new items for future research

31-36

**Milestone Achieved: all advisory group meetings completed**

36

**Milestone Achieved: newly developed items prepared and ready for use**

36

**Milestone Achieved: Report results from data analyses complete**

36

---

### 6. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:

Nothing yet to report.

### 7. INVENTIONS, PATENTS AND LICENSES:

Not applicable.

### 8. REPORTABLE OUTCOMES:

Nothing yet to report.

### 9. OTHER ACHIEVEMENTS:

Nothing yet to report.

### 10. REFERENCES:

Not applicable.

### 11. APPENDICES:

See updated Quad Chart that follows
Understanding, Predicting, and Preventing Life-Changing and Life-Threatening Health Changes among Aging Veterans and Civilians with Spinal Cord Injury
W81XWH-16-1-0629; SC150260

PI: James S. Krause  Org: Medical University of South Carolina  Award Amount: $742,210.00

Study/Product Aim(s)

- **Aim 1**: Identify the nature of negative health spirals and how they develop from multiple SHCs, as viewed from the perspective of people with SCI and their family members, among both military veterans and civilians.

- **Aim 2**: Identify non-modifiable and modifiable factors leading to negative health spirals and multiple SHCs.

- **Aim 3**: Identify the context within which health decline occurs, including the reciprocal effects of health decline with societal participation, QOL, and the family and caregiver network.

Approach

This qualitative investigation uses a systematic and rigorous methodology to investigate multiple SHCs and negative health spirals among both military veterans and civilians with SCI.

Goals/Milestones

**CY17 Goal** – Project Start-up
- ✔ IRB, HRPO approvals received
- ✔ Data analysis to identify potential participants
- ❏ Initiate Individual Interviews
- ❏ Initiate Focus Groups
- ❏ Begin developing Coding Book

**CY18 Goals** – Primary Data Collection
- ❏ Continue Individual Interviews and Focus Groups
- ❏ Continue development of Coding Book

**CY19 Goal** – Analysis and Dissemination
- ❏ Finalize Coding Book
- ❏ Primary data analysis
- ❏ Dissemination of results

Comments/Challenges/Issues/Concerns

- Significant delays in getting IRB approval due to waiting on the legal department to approve a BAA, which delayed implementation of the interviews.

Budget Expenditure to Date

Projected Expenditure: $222,546.00
Actual Expenditure: $159,470.01

Updated: September 19, 2017