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

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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. We made outstanding progress on the collection of data in year 2, including each type of data to be collected (individual, focus group, family). We conducted 51 health histories, 49 individual interviews, and 22 family/caregiver interviews. We conducted six focus groups with participants and another focus group with family/caregivers. We have a total of 22 participants in the individual focus groups and 3 family members. This work built directly upon the preliminary work in year 1. This is a very complex project, given the many types of data to be collected (three types per participant). We have addressed several challenges, including the need to utilize virtual focus groups, with cameras, for those who could not attend in person groups. Because we are investigating people with significant, life-threatening health challenges, many simply cannot attend in person. Furthermore, we identified significant limitations in social support systems for those who have historically been independent in their care, as many participants literally had no one else familiar with their care. We received approval to modify one of our data collection procedures to supplement our current sampling strategy with those from the Paralyzed Veterans Association (PVA) to augment inclusion of veterans (we have interviewed 16 veterans with a target of 30). Interviews of PVA members are underway as part of year 3.

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

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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:

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

Major Task 2: Develop semi-structured interview		
Subtask1: Identify health decline factors from 15yr data to assist with content development for interviews		
Develop interview	1-3	Complete
Advisory board review of interview	4	Complete
Finalization of interview	5-6	Complete
Milestone Achieved: Structured interview is complete	6	Complete
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		
Subtask1: Identify veterans and civilians with spinal cord injury		
Review of existing health history from 15-year and 40-year studies	1-9	Complete
Analysis of health history based on merge of data	1-9	Complete
Selection of participants based on health status	6-9	Complete
Milestone Achieved: At least 30 veterans and 30 civilians with spinal cord injury identified who fit criteria.	9	Complete
Subtask 2: Identify potential participants who are a family member, friend, or significant other		In progress
Review of existing health history from 15-year and 40-year studies	9-12	Complete
Selection of 30 participants	9-12	In progress
Milestone Achieved: Up to 30 participants identified who fit criteria.	12	In progress
Brief narrative about accomplishments and issues remaining if incomplete: We completed interviews with 22 family members/significant others. All these individuals were identified through the primary data collection that has been completed with 49 study participants. The portion of family members who could be identified is somewhat less than what we had predicted. The major reason for this is that, to our surprise, there have been a great many participants for whom there is nobody familiar with their care. These are individuals who have historically been physically independent in their care. This actually is indicative of a significant vulnerability for those with SCI, because, once secondary conditions develop, there is no one secondary to the individual who may intervene. It also is indicative of a limited support network and places the individual in a position where there is limited support. We have exhausted our database in terms of the number of military veterans *with significant health problems*, so we will now turn toward a modified procedure to identify more participants and family members. We reached out to the Paralyzed Veterans Administration (PVA) to identify additional participants who are military veterans. The request to modify the procedure was approved by the DOD, IRB, and HRPO. We have begun enrolling PVA participants. We anticipate approximating enrollment of the targeted goal of 30 individuals who are family members or significant others by completion of the study.		

Major Task 4: Conduct interviews		
Subtask 1: Collect updated self-report on 60 participants	10-24	In progress
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.	10-24	In progress
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.	10-24	In progress
Milestone Achieved: 30 interviews completed with SCI participants	18	Complete
Milestone Achieved: 60 interviews completed with SCI participants	24	In progress
Milestone Achieved: up to 15 interviews completed with family members	18	Complete
Milestone Achieved: up to 30 interviews completed with family members	24	In progress

Brief narrative about accomplishments and issues remaining if incomplete: We now have completed interviews on 49 individuals (82% of the goal) and 22 family members (73% of the goal). We are in the process of identifying additional military veterans to bring the number of veterans up to 30 participants. It is likely that we will actually exceed the targeted goal of 60 total interviews. This will help us approximate, if not reach, the targeted goal of 30 family members of persons with SCI. Again, the primary difficulty in obtaining family members is that we have discovered a significant portion of individuals with SCI have no one familiar with their care.		

Major Task 5: Conduct focus groups		
Subtask1: 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.	10-24	In progress
Subtask2: 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).	10-24	In progress
Milestone Achieved: 4 focus groups completed with SCI participants	18	Complete
Milestone Achieved: 8 focus groups completed with SCI participants	24	In progress
Milestone Achieved: 2-4 focus groups completed with family members	24	In progress
Brief narrative about accomplishments and issues remaining if incomplete: We have made substantial progress, despite some very difficult parameters because of selection of participants who are experiencing significant health problems. We conducted 2 focus groups in Atlanta, GA; 2 in Minneapolis, MN, and 2 virtual groups from Charleston, SC. We have a total of 22 participants across the 6 groups. We also have conducted one focus group with family members (n = 3 participants). Participants have been highly supportive of the focus groups, even when it has been difficult to attend in person. One participant delayed surgery to attend a group. Another was going on hospice within a few days, then called because he still wanted to participate because of its importance. He participated in a virtual group. We are confident we will reach approximately 60 individual focus group participants as proposed, although we likely will need to exceed individual interviews to achieve this goal (i.e., not everyone can attend a group, even virtual).		
Major Task 6: Develop Coding Book		
Subtask 1: Transcribe, "clean" data from interviews and enter into qualitative software		
Send digital recordings of in-depth interviews and focus groups to a professional transcription service with expertise in medical transcription and transcripts	10-25	In progress
Interviewer / group facilitators will compare transcript to the recording as a check on accuracy and completeness.	26-27	
Enter "cleaned" transcripts into qualitative software to facilitate the processing and analysis	27	
Milestone Achieved: Transcripts are clean and ready for analysis.	27	
Subtask 2: Code interviews		

Use theoretical concepts embedded in the research questions and precise and standard definitions to develop index system and coding scheme (Coding Book)	28-30	
Project investigators will review and code the text of the transcribed interviews	28-30	
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	29-30	
Milestone Achieved: Coding Book developed and maintained	30	
Brief narrative about accomplishments and issues remaining if incomplete: These tasks require completion of the data collection, so they will be addressed as we complete the data collection. We are hopeful we can wrap up data collection before the end of the year, although the focus groups may not be wrapped up until the 2nd quarter of the 3rd year. We look forward to having the opportunity to analyze this extremely important and interesting data.		

Major Task 7: Data Analysis		
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	

4. **KEY RESEARCH ACCOMPLISHMENTS:** Nothing yet to report, as the data collection has not yet been completed.

5. **CONCLUSION:** We implemented each type of data collection during the past year, including individual interviews, family member interviews, in person and virtual focus groups, and family focus groups. It has been highly productive and instructive. We feel that, despite the 3 decades of research experience and 47 years of lived experience with SCI, the study is bringing out new and important observations. We only touch upon these now because they are observations and not yet confirmed by data analysis which can only be done after completion of the data collection. Nevertheless, the study is one of great importance that is deemed critical to the lives of people with SCI *by our research participants*. We have collected individual interviews on 49 individuals with SCI, including 14 military veterans and 22 family members. We have conducted 4 in person and 2 virtual groups, which have included 22 individuals with SCI and 3 family members. It is very difficult to conduct in person groups because we essentially need to ask individuals who are experiencing extraordinary health complications to attend, when many are home or bedridden. We are confident we will complete the original goals of the study, with some modification to procedures that have been approved by the DOD, IRB, and HRPO. Specifically, in terms of the conduct of focus groups, because it is clear that many people cannot attend in person, we are conducting virtual groups. The first 2 virtual groups were extraordinarily successful in that we could see individuals with cameras, and they were fully engaged for over 2 hours in each group. There will need to be other accommodations for those who are not tech savvy, using more of a conference call format. Even using both of these types of groups, there will simply be some people who do not participate in the groups, but who were enrolled in the study. For that reason, we will modestly exceed the original interview goal of 60 (probably somewhere in the neighborhood of 70-75). The PVA has agreed to help with recruitment, and we are fully confident this will be productive to round out and complete our enrolling of military veterans who meet all the health concern criteria (in reality, this has already been implemented but after completion of the last project year). We initially proposed to conduct 2-4 family groups. This is one area where we were uncertain of participation and where we will likely conduct no more than 3 groups. It seems more prudent to continue to focus on bringing in as many individuals with SCI who are experiencing negative health outcomes as possible and focus our efforts on virtual groups to gain maximal insight into the precipitating factors.

6. **ABSTRACTS, AND PRESENTATIONS:** Nothing yet to report.

7. **INVENTIONS, PATENTS AND LICENSES:** Not applicable.

8. **REPORTABLE OUTCOMES:** The main thing to report is the aforementioned difficulties with asking individuals to attend in person focus groups when they are experiencing negative health outcomes. We certainly want to make sure we do not further compromise their health by them participating in the studies. This is why we have created opportunities for virtual focus groups. Second, we have been particularly surprised by the number of people who are experiencing significant health spirals, truly facing life-changing and life-threatening consequences, yet have nobody knowledgeable of their care or experiences (not even a family member). This has occurred among those who have been physically independent, including those who have been highly successful in other roles, such as work and social participation. Not having anyone aware of their care needs has made it difficult to identify individuals to serve as key informants regarding their situation. We have enrolled 22 individuals, and we will approximate the proposed total of 30, but it has been difficult to obtain these particular participants. Also, the information we have obtained has, on the whole, been less detailed than that which has been obtained from individual participants. The individuals themselves have been truly committed to the process of sharing their experiences, both in individual interviews and in focus groups. This by itself has been an important observation, because the focus group participants have made connections with each other and clearly would benefit from ongoing opportunities to interact with their peers.

9. **OTHER ACHIEVEMENTS:** The PI has been invited to serve on an NIH panel for the 10 year plan for SCI, specifically to address secondary health conditions. There are some logistic concerns for the PI who has C4 SCI of 47 years duration in traveling to Washington, DC in the middle of winter, so we have not confirmed the participation. Regardless, the information will be brought forward regarding negative health spirals and their pivotal role in this project and helping us to understand their development.

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)

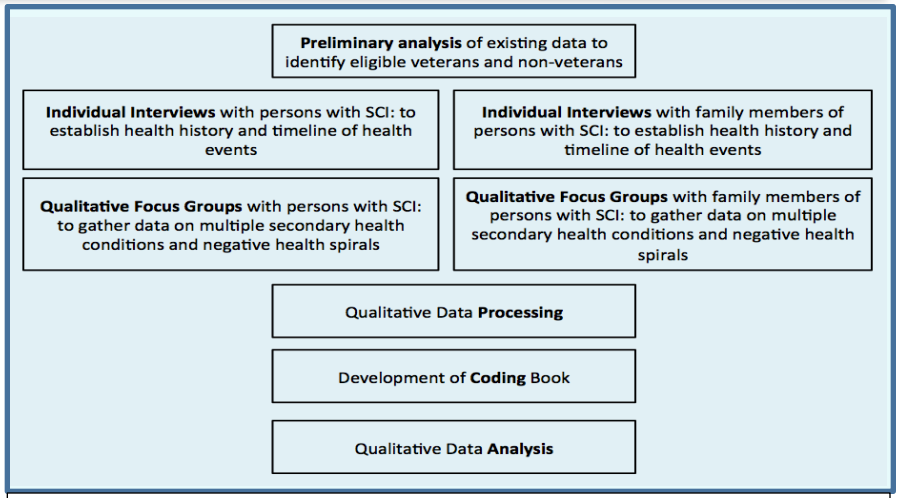
• Aim 1: Identify the nature of negative health spirals and how they develop from multiple SHCs, as viewed from the perspective of people with SCI and their family members, among both military veterans and civilians.

•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.



Accomplishment: We have initiated focus groups and made substantial progress in individual and family interviews.

Timeline and Cost

Activities CY	17	18	19
Project Start-Up			
Primary Data Collection			
Primary Data Analysis			
Dissemination			
Estimated Budget ($K)	**$223**	**$330**	**$195**

Updated: October 29, 2018

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 Goal – 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
- Nothing to report for this quarter

Budget Expenditure to Date

Projected Expenditure: $552,258
Actual Expenditure: $371,219