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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

PRINCIPAL INVESTIGATOR: James S Krause, PhD

RECIPIENT: Medical University of South Carolina  
Charleston, SC 29425

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E-Mail: <a href="mailto:Krause@musc.edu">Krause@musc.edu</a> ; <a href="mailto:jarnecke@musc.edu">jarnecke@musc.edu</a> ; <a href="mailto:hutsonr@musc.edu">hutsonr@musc.edu</a>					<b>5f. WORK UNIT NUMBER</b>	
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<b>14. ABSTRACT</b> Spinal cord injury (SCI) is associated with secondary health conditions, such as pressure ulcers and infections, which 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 3, building upon the success from year 2. We conducted a total of 69 health screens, 65 full individual interviews, and 28 family/caregiver interviews. We conducted 12 focus groups with 54 SCI participants and 3 focus group with 10 family/caregivers. We addressed several complex issues and challenges, including utilizing multiple types of groups to collect data including in person, virtual, and phone in. The virtual groups were highly successful in particular, compared with in-person groups where there were difficulties for people logistically. We received approval to modify one of our data collection procedures to supplement our current sampling strategy with those from the Paralyzed Veterans of America (PVA) to augment inclusion of veterans (n= 30 veterans, reaching our target). We have been conducting multiple data processing and data analytic activities. We utilize the data to classify an individual's pattern of health outcomes into multiple categories. We first identify whether they indeed had experienced a negative health cycle (a minimum of 2 conditions over six months). We also classified participants as to whether they had a negative health spiral (3 conditions over the same time frame). We identified the sequence of events leading to the negative health spirals, whether they lead to long-term potential decline, or whether they are resolved. In terms of dissemination, we made 2 presentations to the national PVA meeting, one on iatrogenic causes and the other on global factors related to health, negative health cycles, and negative health spirals.						
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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 identifying 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 proposed to 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 had 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 proposed to 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 proposed to enroll 60 participants with SCI, representing an equal mix of military veterans and civilians, and to enroll 30 participants who are family members of someone with SCI who has experienced health decline related to SHCs. We proposed to conduct interviews with each of the 60 SCI participants and 30 family members to identify the pattern of SHCs over time. We further proposed to 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 to draw out common themes and patterns. We proposed to analyze the data using state-of-the-art data analytic software to learn from people what has and has not worked with the prevention of SHC or preventing from SHC from spiraling.

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 proposed to elicit input from multiple stakeholders. This is 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-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:**

	<b>Timeline</b>	<b>Progress</b>
<b>Major Task 1: Obtain Approval for Human Subjects Research</b>	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
<i>Milestone Achieved: MUSC IRB approval</i>	6	Complete
<i>Milestone Achieved: HRPO approval</i>	6	Complete
<p>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. At present, we are awaiting approval of an amendment that would allow us to collect data from more recently identified deceased cases, by interviewing family members or other reporters. This has been approved locally with our IRB, but awaits approval from HRPO.</p>		

<b>Major Task 2: Develop semi-structured interview</b>		
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
<i>Milestone Achieved: Structured interview is complete</i>	6	Complete
<p>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).</p>		

<b>Major Task 3: Select and recruit participants for interviews/focus groups</b>		
Subtask 1: 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
<i>Milestone Achieved: At least 30 veterans and 30 civilians with spinal cord injury identified who fit criteria.</i>	9	Complete
Subtask 2: Identify potential participants who are a family member, friend, or significant other		Complete
Review of existing health history from 15-year and 40-year studies	9-12	Complete
Selection of 30 participants	9-12	Complete
<i>Milestone Achieved: Up to 30 participants identified who fit criteria.</i>	12	Complete
<p>Brief narrative about accomplishments and issues remaining if incomplete: We completed interviews with 28 family members/significant others and with 65 SCI participants. The portion of family members who could be identified is somewhat less than what we had predicted, so it was very difficult to achieve the 28 cases. The major reason for this is that, to our surprise, there have been a great many participants for whom there is <u>nobody</u> familiar with their care, including among those 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.. We have exhausted our database in terms of the number of military veterans <i>with significant health problems</i>, so we reached out to the Paralyzed Veterans Administration (PVA) to identify additional military veterans. This allowed us to fully meet our actual enrollment goal of 30 military veterans with SCI. participants.</p>		

<b>Major Task 4: Conduct interviews</b>		
Subtask 1: Collect updated self-report on 60 participants	10-24	Complete
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	Complete
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	Complete
<i>Milestone Achieved: 30 interviews completed with SCI participants</i>	18	Complete
<i>Milestone Achieved: 60 interviews completed with SCI participants</i>	24	Complete
<i>Milestone Achieved: up to 15 interviews completed with family members</i>	18	Complete
<i>Milestone Achieved: up to 30 interviews completed with family members</i>	24	93% Complete

Brief narrative about accomplishments and issues remaining if incomplete: We now have completed interviews on 65 individuals (exceeding the goal of 60) and 28 family members (93% of the goal). The reason for exceeding the initial goal of 60 was that we needed to come as close as possible to goal of 30 military veterans, which we actually reached. We are very close to the goal of 30 family/secondary reporters. Given the difficulties that we have had because there many people simply do not have anyone aware of their care needs, this number is an outstanding accomplishment. members of persons with SCI.		
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<b>Major Task 5: Conduct focus groups</b>		
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	Complete
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	Complete
<i>Milestone Achieved: 4 focus groups completed with SCI participants</i>	18	Complete
<i>Milestone Achieved: 8 focus groups completed with SCI participants</i>	24	Complete
<i>Milestone Achieved: 2-4 focus groups completed with family members</i>	24	Complete
Brief narrative about accomplishments and issues remaining if incomplete: The focus groups have been very successful. We have 54 individuals who participated in one of our 12 focus groups. The group numbers were smaller than we initially anticipated, but this allowed for more information to be obtained from any particular individual. We utilized multiple modes including in person, virtual, and teleconference. Each produced strong data. Given that those people selected for the study by definition had significant health problems, the virtual groups were an outstanding option. There were no issues with no-shows or people not being ready groups. We also conducted three groups with family and secondary reporters with 10 participants. This never was a primary focus, as initially proposed, so we feel we obtained the information that we needed to obtain across all groups.		
<b>Major Task 6: Develop Coding Book</b>		
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	Complete
Interviewer / group facilitators will compare transcript to the recording as a check on accuracy and completeness.	26-27	Complete
Enter “cleaned” transcripts into qualitative software to facilitate the processing and analysis	27	In process
<i>Milestone Achieved: Transcripts are clean and ready for analysis.</i>	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	In process
Project investigators will review and code the text of the transcribed interviews	28-30	In process
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	In process
<i>Milestone Achieved: Coding Book developed and maintained</i>	30	
Brief narrative about accomplishments and issues remaining if incomplete: These tasks require completion of the data collection and we are still awaiting to see whether we can get HRPO approval for enrolling additional family members of those deceased. We feel that this is added value at this point, so we plan on proceeding with finalizing the codebook by the end of the current quarter, including any potential additional data.		

<b>Major Task 7: Data Analysis</b>		
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	
<i>Milestone Achieved: Report findings from overall studies</i>	36	

<b>Major Task 8: Dissemination and Utilization of Project Data</b>		
Subtask 1: Perform all dissemination of materials.	31-36	
Prepare all data for data sharing	31-36	Not yet started
Utilize advisory panel to draw interpretations from the qualitative interviews and focus groups	31-36	In process
Manuscripts completed and submitted for publication	31-36	In process
Develop new items for future research	31-36	In process
<i>Milestone Achieved: all advisory group meetings completed</i>	36	In process
<i>Milestone Achieved: newly developed items prepared and ready for use</i>	36	In process
<i>Milestone Achieved: Report results from data analyses complete</i>	36	In process

**4. KEY RESEARCH ACCOMPLISHMENTS:** We have made substantial progress on dissemination, although we still have the proposal into HRPO to interview some individuals who are family members of those deceased. We made two presentations at the annual meeting of the Paralyzed Veterans Association in August. The first of the presentations was more global in nature and provided an overview of the study, preliminary findings, and methodological issues. The second presentation was specifically focused on iatrogenic causes of mortality, including physician practices. We are in the process of developing manuscripts within each of our three primary aim areas. The first manuscript will be based on conceptual refinements at our overall analysis of negative health spirals but with this being at the heart of identification of the nature of the problem. We cannot identify the scope of the problem with qualitative data alone, but this first manuscript will serve as the prelude to larger studies using quantified methods. The second manuscript is focusing on iatrogenic causes as one of the primary risk factors for the development of negative health spirals. The final manuscript, yet to be started, will focus on the interrelationships of negative health spirals and other indicators of quality of life and participation.

**5. CONCLUSION:** This has been an outstanding year that has resulted in the completion of our primary proposed data collection, as well as initiation of dissemination and knowledge translation activities. We still hope to collect a very small amount of additional data from family members of those deceased after negative health spirals, but we moved forward with our most basic dissemination activities. Exceeding the goal for enrolling participants has resulted in our collection of outstanding data, including that from a balance of civilians and military veterans. We also learned a great deal from enrollment of family members significant others. This gives us a combination of multiple sets of data – (1) preliminary screening which has helped us to more fully understand health history, (2) intensive qualitative interviews with the individual experiencing the negative health cycle, (3) qualitative focus groups, and (4) qualitative interviews with secondary reporters. As stated previously, even after 3 decades of research experience and 48 years of lived experience with SCI, conducting this study has been very impactful interview of SCI and what happens as individuals age, face health changes, and attempt to prevent or manage negative health spirals and SHC. We have collected individual interviews on 65 individuals with SCI, including 30 military veterans and 35 civilians. Additionally, we have collected data on 28 family members. We have conducted a total of 15 focus groups, which have included 12 groups with 54 individuals with SCI and 3 groups with 10 family members. Despite the difficulties in conducting in-person focus groups because of having participants who were experiencing the most extreme health problems, we have made great progress toward meeting our original goals. We are impressed with the quality of data from the virtual groups, as well as in person groups. In many ways, the virtual groups were better than the in person, because there were no issues of people unable to attend the meeting, being delayed, or ending up with smaller groups. They provided much more control. We were particularly pleased to complete our enrollment with 30 military veterans, as well as 35 civilians. Within our own data set, we obtained a significant number of military veterans, but also had a large number simply did not qualify because they did not have significant enough health problems (thankfully). We are excited about being at the dissemination phase of the study.

**6. ABSTRACTS, AND PRESENTATIONS:** 2 presented and 1 submitted:

Krause, J.S., Manley, K., & Meade, M.A. A qualitative study of negative health spirals in spinal cord injury: Conceptual and methodologic considerations. Oral presentation at the annual conference of Paralyzed Veterans of America Summit an Expo, Orlando, FL: August 2019.

Meade, M.A. Krause, J.S. Iatrogenically induced secondary health conditions (SHC) among civilians and veterans with spinal cord injury (SCI). Oral presentation at the annual conference of Paralyzed Veterans of America Summit an Expo, Orlando, FL: August 2019.

Krause, J.S., Meade, M.A., & Cao, Y. A qualitative study of negative health spirals among aging civilians

and veterans after spinal cord injury. Abstract submitted to the annual conference of the American Spinal Injury Association, New Orleans, LA: May 2020.

- 7. INVENTIONS, PATENTS AND LICENSES:** Not applicable.
- 8. REPORTABLE OUTCOMES:** We are very pleased with the progress of the study and to have so few problems. Certainly, it has been a very difficult data collection that has required us to work through issues of reaching response goals, particularly those related to focus groups, with the individuals we are studying are by definition experiencing extreme health problems. We also were caught off guard by the number of individuals who simply had no one aware of their care issues and health concerns. This has identified a clear area where we need more research to better identify the scope of the problem and to develop intervention strategies to help people better build their support networks prior to needing them. We are truly grateful to our research participants and their commitment to the research. Certainly, facing so many health problems, it would be possible for people to be solely concerned about their own experiences or to be overwhelmed by the barriers and issues that they are facing. Yet, the participation has been outstanding and this is the key to our success.
- 9. OTHER ACHIEVEMENTS:** The PI served on an NIH panel for the 10 year plan for SCI, specifically to address secondary health conditions. The PI also was just recognized as one of two healthcare heroes at MUSC, recognition that comes from the broader community and includes multiple types of healthcare providers and researchers.
- 10. REFERENCES:** Not applicable.
- 11. APPENDICES:** See updated Quad Chart that follows