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TITLE: Neurogenic Bowel and Bladder Management After Spinal Cord Injury: Examining Factors Involved in Successful Decision-Making Processes

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Living with SCI requires the ability to make extensive and complex decisions to address the many associated health issues and complications. Persons with SCI make daily decisions about their care that directly and indirectly impact the management of their condition, especially in relation to neurogenic bladder and bowel (NBB) dysfunction. Very few studies discuss decision-making on NBB management among persons with SCI. Of those, none focus on patient decision making and enactment. This study aims to examine veterans and civilians NBB management decisions and resulting outcomes. The aims are: 1) to identify the factors influencing the decision-making process and potential changes across time considering age and time since injury; 2) to assess participants' abilities and coping styles in carrying out NBB management decisions; and 3) to assess the outcomes of these decisions on their health and wellbeing, overall satisfaction, and quality of life (QoL) while comparing these decisions to clinical practice guidelines. To address these aims we will interview 60 SCI participants (30 veterans, 30 civilians). Data will be analyzed using content analysis to identify topics, themes and patterns. Matrices will be generated for each aim. Data counts will be compared to scores from selected quantitative assessments. Implications for treatment will be drawn from this study and specific recommendations will be made for clinician care on how to educate and share the decision-making process with their patients. It is anticipated that findings may impact existing clinical practice guidelines by suggesting patient involvement in their future development and revisions. An earlier study by our team found that veterans with SCI more frequently chose surgical and more invasive methods for NBB management than did civilians with SCI. By comparing the narratives from veterans in terms of factors related to decision making, their cognitive and coping strategies and resulting outcomes with a civilian cohort, we will better understand factors that influence decisions and propose recommendations for NBB management, treatment of complications and implications for NBB clinical practice guidelines.

15. SUBJECT TERMS

Neurogenic bladder and bowel. SCI. Decision making. Qualitative methodology. Mixed methodology.

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1. **INTRODUCTION**

Living with spinal cord injury (SCI) requires extensive personal decision making to address the many associated health issues and complications[1,2]. These decisions become particularly complex in that neurogenic bladder and bowel (NBB) broadly affect the *whole person* across multiple domains of daily life. As a result, NBB dysfunction remains one of the most life changing and stigmatizing consequences of SCI[3]. Complications of NBB can affect all aspects of life including physical functioning, pain, mental health, sexual functioning and overall life satisfaction[4-7]. The most frequent complications associated with neurogenic bladder include urinary tract infections (UTIs), bladder incontinence, and bladder and renal stones; while bowel complications include constipation, incontinence and hemorrhoids[8]. The effects of these complications on quality of life (QoL) highlight the importance of avoiding complications through appropriate NBB management decision making.

NBB dysfunction has a deeply personal and intimate impact, which heightens the salience of decision-making enactment for improved management. New research on patient-centered and self-management approaches to care emphasize the importance of patients as decision makers. Little is known about how patients with SCI make these complex decision regarding NBB issues, and the related outcomes of these decisions. Making decisions is particularly difficult given the high number of attendant medical and cognitive issues due to the accelerated aging process in SCI[9]. For example, the Veterans Administration (VA) sees a large number of aging and long-term SCI patients, for whom treatment of secondary medical conditions is the primary focus, including pressure ulcers, UTIs, constipation, pain and spasticity[10]. Finally, there is no clarity about recommendations regarding clinical practice guidelines (CPGs) for NBB, especially for bowel management, which were issued in 1998 and do not include patients' personal perspectives as a factor to consider when selecting management methods[11,12].

Three aims guide this investigation. The first aim seeks to identify and describe the factors influencing the decision-making process and changes in NBB management and related complications across time, considering age and time since injury. The second aim seeks to assess participants' abilities and coping styles in carrying out NBB management decisions. The third aim seeks to assess the outcomes of these decisions on improving problems related to the management of NBB and reducing associated complications.

This project has continued to move forward even though it has faced administrative and veteran subject recruitment delays. With assistance from the National Office of Paralyzed Veterans of America (PVA), the study team has made great strides in recruitment, nearing 100% enrollment, are midway through data collection and are preparing for data analysis. A number of presentations have been given at domestic and international conferences and meetings, as the topic of neurogenic bowel and bladder is a high priority for many clinicians and lay people. Initial results of a scoping review indicate a distinct lack of US produced literature on neurogenic bowel and bladder decision making, which supports the importance of the study team's dissemination activities. The main focus in Year 2, however, has been on data collection. Over half of the qualitative interviews have been conducted, as have more than one-third of the quantitative interviews. Outreach and engagement have also been a core activity of Year 2, with team members working to build relationships with critical community partners. Year 3 planning includes focus groups, data analysis and dissemination activities.

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2. KEYWORDS

DECISION MAKING, SCI, NEUROGENIC BLADDER AND BOWEL, QUALITATIVE METHODOLOGY, MIXED METHODOLOGY

3. ACCOMPLISHMENTS

What were the major goals of the project?

Major Task 1: Administrative Tasks

Subtask 1: Project Start Up and Maintenance Tasks

1.1a: Award notification and site meetings to coordinate – **completed** (Month 1)

1.1b. Grant administration accounts, faculty appointments- **completed** (Months 1-3)

1.1c. Supplies and equipment purchases – **completed and ongoing as needed** (Months 1-3)

1.1d. Design and implement electronic databases for participant and data tracking – **completed** (Months 1-6)

1.1e. Finalize contract(s) with transcription services – **completed** (Month 4)

1.1f. Team training for standardized use of data collection instruments – **completed** (Months 4-6)

1.1g. Follow-up meetings for feedback and corrections in data collection – **completed and ongoing** (Months 9, 15, 21)

Subtask 2: Regulatory Documents and Research Protocol Maintenance

1.2a. Prepare IRB protocol submission for both sites – **completed** (Months 2-5)

1.2b. Submit amendments, adverse events, and protocol deviations – **completed and ongoing** (As needed)

1.2c. HRPO/ACURO Approval process – **completed** (Months 4-6)

1.2d. Coordinate with Sites for annual IRB reports for continuing review – **completed and ongoing** (Annually)

1.2e. Prepare and submit quarterly reports to the HRPO/CDMRP – **completed and ongoing** (Quarterly)

1.2f. Prepare and submit annual progress report to the HRPO/CDMRP – **completed and ongoing** (Annually)

Subtask 3: On-going Quality Assurance and Progress Review

1.3a. Administrative meeting for progress updates – **completed and ongoing** (Weekly)

1.3b. Project leadership meetings to assure progress along projected timeline – **completed and ongoing** (Quarterly)

1.3c. Collaborators/advisory council meetings to assess data collection & analysis – **completed and ongoing** (Biannually). A new advisory council meeting is planned for late Fall 2019.

Major Task 2: Data Collection Design Refinement

Subtask 1: Design Interview Guides for Qualitative and Quantitative Data Collection

2.1a Develop, refine, and review qualitative & quantitative interview guides – **completed** (Months 1-3)

2.1b Pilot of interviews and survey instruments with volunteer participants – **completed** (Months 4-6)

Subtask 2: Development of Data Collection Tracking Databases

2.2 Design and implement electronic databases for data collection tracking – **completed** (Months 1-6)

Major Task 3: Recruitment

Subtask 1: Identify Potential Research Subjects

3.1a Develop, refine, and finalize recruitment procedures, including letters – **completed** (Months 1-4)

3.1b Identify potential research subjects from UMHS & VAAAHS – **completed and ongoing** (Months 6-8)

3.1c Identify and confirm additional potential research subjects – **ongoing** (As needed)

3.1d Mail first batch contact letters (additional batches mailed as needed) – **completed** (Month 6)

Subtask 2: Formal Screening and Enrollment of Research Subjects

3.2a Develop, refine, and finalize screening forms and procedures –**completed** (Months 1-3)

3.2b Screen potential research subjects for eligibility; enroll those who qualify – **completed and ongoing** (Months 6-9)

3.2c Screen additional potential research subjects, following letters – **ongoing** (As needed)

Major Task 4: Data Collection and Processing

Subtask 1: Schedule and Conduct Interviews; Administer Instruments

4.1a Develop, refine, and finalize informed consent forms and procedures – **completed** (Months 1-6)

4.1b Schedule and conduct interviews, administer standardized instruments – **completed and ongoing** (Months 9-21)

Subtask 2: Develop and Implement Transcript-processing Procedures

4.2a Send electronic audio files to transcriptionist; log and de-identify transcripts – **completed and ongoing** (As needed)

4.2b Check accuracy of transcripts by comparing text to audio – **completed and ongoing** (Quarterly)

Subtask 3: Schedule and Conduct Focus Group (Months 24-32)

Nothing to Report

Major Task 5: Data analysis and evaluation

Subtask 1: Coding Scheme Refinement (Months 16-20)

5.1 Meet with consultants to refine and finalize coding scheme and manual - **ongoing**

Subtask 2: Coding of Interview Data (Months 18-20)

5.2 Conduct inter-rater reliability training for coding work – **ongoing**

Major Task 6: Dissemination and Data Sharing

Subtask 1: Disseminate Findings to Lay Audience (Months 25-35)

Nothing to Report

Subtask 2: Disseminate Findings to Professional Audience

6.2a Attend and present findings at professional meetings - **ongoing** (Months 24-36)

6.2b Prepare manuscripts for publication (Months 30-36) – **ongoing**

What was accomplished under these goals?

Major Task 1: Administrative Tasks

As the project entered its second year, the study team has demonstrated its commitment to quality assurance and progress, developed strong rapport and a common language, and has taken a solution-oriented approach to all facets of the research. Under the guidance of Dr. Tate, the team has met a total of 44 times over the course of the reporting period to discuss data collection, recruitment strategies, allocation of research staff resources, and the scope of publications and journals for future dissemination. In addition to the weekly administrative meetings, the team has held special meetings to discuss data collection accuracy, reviewed qualitative interview transcripts to ensure the quality of information obtained in qualitative interviews, suggested improvements and refinements in data collection, and have performed an initial review of the quantitative interview data collected. Dr. Tate has informed the VA Site PI, Dr. DiPonio and two other physician members, Drs. Cameron and Rodriguez, of the progress of project activities. No concerns were raised.

Two Research Assistants, Ms. Riedman and Ms. Scott, joined the team during the reporting period and were trained in the use of the interview guide and REDCap database. Both RA's conducted pilot qualitative and quantitative interviews to develop skill in implementing the instruments and were provided feedback from Dr. Rohn, Co-Investigator, and Ms. Walsh, Study Coordinator. The assistants refined their interviewing approach and began collecting data.

Check-ins during the weekly team meetings provided the RA's the opportunity to discuss refining their processes and resolving any data collection issues.

As recruitment accelerated, it became apparent that this project required a much wider pool of veteran candidates in order to meet enrollment targets. Fewer of the past participants were able to participate than had been planned. The team submitted an amendment to the UM IRB and was approved in February 2019 to recruit veterans from organizations and associations beyond the Veterans Administration Ann Arbor Hospital System (VAAAHS).

Major Task 2: Data Collection Design Refinement

Per Annual Report 2018, all subtasks for Major Task 2 are complete.

Major Task 3: Recruitment

The study team continued recruitment efforts throughout the second year of the study. To date, 59 of 60 subjects (n=60) across all recruitment categories have been enrolled. Access to University of Michigan Health System (UMHS) research registries, physician surgery lists and internal referrals allowed the team to locate and screen a number of new UM subjects. Of past 2012 study UM participants, 9 are enrolled. Of new UM participants, 17 are enrolled, for a total of 26 UM subjects currently enrolled. The study team intends to identify, screen and enroll at least 5 new UM subjects to ensure we meet our minimum enrollment totals.

As noted above, the team found new veterans to be a difficult group to recruit, despite the relationship with VAAAHS. Ms. Walsh met with Dr. DiPonio, Site PI at the VAAAHS, to clarify VA site recruitment procedures early in the process, but the number of new veteran subjects with SCI who meet the study criteria is null. The IRB approval to recruit outside of the VAAAHS dramatically improved our subject pool. Dr. Rohn and Ms. Walsh conducted outreach with Walk the Line, an outpatient rehabilitation facility in Southeastern Michigan. A presentation about University of Michigan SCI research was given, along with specific discussion about our focus on veterans. Dr. Rohn and Ms. Walsh also hosted an information table at the Michigan Paralyzed Veterans Association Open House, meeting with members and vendors to discuss the various research programs at the University of Michigan. Dr. Tate discussed recruitment assistance with the leadership of the National Paralyzed Veterans of America association in July of this year. They approved her request and announcements were made to their membership about this project. A recruitment flyer was shared with the PVA email list and the result was overwhelming. Within one week, over 50 new veterans with SCI were screened with 23 meeting study criteria who were enrolled. Past 2012 study participants who are veterans also have been contacted and are being screened and enrolled as appropriate. To date, 10 past veterans have been enrolled. There are now 33 veterans enrolled in the study, which exceeds our study target of 30 veterans by 3 (See Table 1 below).

Table 1: Enrollment and Data Collection Achievements as of 8/14/2019

Cohorts/Status	Enrolled	% of Target	Qualitative Interviews Completed	% of Target	Quantitative Interviews Completed	% of Target
New Civilian	17 of 15 n=15	113%	16 (of 17)	94%	16 (of 17)	94%
Past Civilian	9 of 15 n=15	60%	8	53%	7	47%
New Veteran	23 of 15 n=15	153%	8 (of 23)	35%	8 (of 23)	35%
Past Veteran	10 of 15 n=15	67%	6	40%	3	20%
Total	59 of 60 N=60	98%	38	63%	34	57%
% Completed	98%		63%		57%	

Additionally, the Physical Medicine & Rehabilitation department research website at the University of Michigan was updated with the goal of reaching out to the veteran population about this project.

Task 4: Data Collection and Processing

Qualitative and quantitative interviews have been conducted as subjects have enrolled. The study team debriefs regularly on the interview process experience, as well as sharing insights on effective techniques. The team plans to continue this process through the entirety of data collection. The team has collected 38 qualitative interviews and 34 quantitative interviews (see Table 1 above). Nine (9) qualitative interviews and 2 quantitative interviews are scheduled in the next quarter. The study team will continue to schedule interviews until all are completed.

To ensure accuracy, all team members follow the same procedures for managing data. Interview audio files are downloaded from audio recorders and the files are assigned participant ID numbers then uploaded to transcriptionists' secure website. VAAAHS interviews follow similar protocols but utilize the approved VA recorder and transcriptionist. Transcripts are spot checked upon receipt and will undergo data cleaning when the team moves to closer to data analysis. The team has also audited 12 transcripts and reviewed them jointly to ensure that appropriate data was being captured by the interviews conducted so far. By engaging deeply with these transcripts, early in the data collection process, we have improved our data collection techniques to more uniformly discuss and obtain information about decision-making from our participants.

Task 5: Data Analysis and Evaluation

The study team has begun a preliminary coding scheme, using the coding scheme tools from the 2012 DoD sponsored study. The team has begun the process of developing a coding scheme that suits the data and talked through the appropriateness and/or usefulness of codes from the past study in the context of the current study, and discussed new codes that explicate the factors, mechanisms, and outcomes of decision-making. The team has also made plans to incorporate NVivo case classification into the data analysis planning, as well as the use of a parent code for bladder and bowel. The team will continue this discussion as appropriate until data collection is complete, at which point the team will finalize the coding scheme. The next step in this process is to test the preliminary coding scheme, which will occur early in the first quarter following this report, after which we hope to begin coding in earnest by the end of the quarter/early the following quarter.

Major Task 6: Dissemination and Data Sharing

The study team has been actively disseminating and preparing for dissemination this year. In September of 2018, Dr. Tate presented at the 57th International Spinal Cord Society (ISCoS) meeting in Sydney, Australia on SCI patient decision making. In December 2018, Dr. Tate was invited to give the keynote address at the Wellspect Healthcare symposium on the impact of neurogenic bowel and bladder (NBB) on SCI patients wellbeing and quality of life. Dr. Tate presented on the patient's perspective on management and satisfaction with methods and treatments while Dr. Cameron discussed medical issues related to neurogenic bladder after SCI. As part of this presentation Ms. Walsh filmed an interview with a member of the SCI community who manages neurogenic bowel and bladder, which was integrated into the presentation slide deck. At the European Spinal Psychologist Association (ESPA) in March 2019, Dr. Tate presented "*Putting the Patient on the Driver's Seat"* with a focus on decision making on NBB after SCI, and discussed project findings with Dr. Anke Sheer-Sailing, medical director of the SCI unit at Balgrist Hospital in Zurich. Clinical implications were discussed as well as future research collaborations on decision making.

In late August 2018, Dr. Rohn presented preliminary work from this study as part of a larger presentation at the Paralyzed Veterans of American Summit, in Dallas, TX. This was entitled *"Giving Voice to Rehabilitation Patients through Qualitative Research: Lessons to Inform Clinical Practice".* Dr. Rohn's work integrated perspectives from patients with SCI as regards their experiences with clinicians, giving insight to rehabilitation professionals into the lived experiences of the people they treat in the community. Further work in this area should result in a publication summarizing participant insights into clinical care as regards decision-making.

In late August 2018, Mr. Forchheimer gave a presentation which included information from this study as well as another study conducted at the University of Michigan, at the Paralyzed

Veterans of American Summit, in Dallas, TX. This presentation was entitled *“Quality of Caregiving Among People with SCI and Its Impact”*. This presentation discussed the relationship of receipt of caregiving services to the severity of bowel and bladder complications as well as to standardized measures of satisfaction with bowel and bladder-related quality of life.

Ms. Riedman and Ms. Scott initiated a scoping review on neurogenic bowel and bladder decision making. In September 2018, they met with the Medical School Librarian to develop plans for the scoping review. In subsequent weeks they submitted search terms and a research question to the librarian. Searches were conducted on Ovid Medline, Scopus and PsycInfo leading to 2803 results. After removing duplicates, Ms. Riedman and Ms. Scott screened 2097 titles. In the second round, 342 full text articles were reviewed, with a final tally of 58 full text articles included in the scoping review. A draft manuscript has been organized and continues to be refined.

In order to generate fresh thinking about dissemination, in November 2018 Ms. Walsh attended the virtual conference *‘Engaging Ways to Engage Stakeholders’* hosted by the Center on Knowledge Translation for Disability and Rehabilitation Research (KTDRR). The tools discussed in the conference will help inform dissemination efforts.

What opportunities for training and professional development has the project provided?

Dr. Tate discussed with a psychologist attending the ESPA meeting how to best engage SCI patients in decisions about their care and especially related to NBB. This was done as part of her presentation to ESPA members with video clips to illustrate these points.

How were the results disseminated to communities of interest?

Information about this study was disseminated to potential SCI participants during team meetings with Walk the Line in February 2019 and Michigan Paralyzed Veterans of America (MPVA) in April 2019, two consumer based organizations. In addition, flyers containing information about this study were sent to Veterans with SCI who are members of the National Paralyzed Veterans of America. Our study coordinator and other team members have also spoken to veterans reaching out to us about this study.

What do you plan to do during the next reporting period to accomplish the goals?

In order to accomplish the major task goals, during the next reporting period the study team will continue to recruit, screen, enroll and collect data from subjects at the University of Michigan, the VAAAHS, and unaffiliated Veterans. All quantitative and qualitative data will be completed and checked for accuracy. Transcripts will be reviewed for inconsistencies. A preliminary coding scheme will be tested and refined with team members as well as project consultant. Inter-rater reliability training will be scheduled. Coding will begin when the scheme is finalized and training is completed (during the first quarter following this report). In addition, we plan the following activities:

- Complete all transcripts of interviews, conduct quality reviews of these transcripts and enter data into NVivo.
- Complete the quantitative database, and complete quality assurance of data entered into REDCap.
- Develop, test, and refine the coding schema (Fall 2019) and begin coding the data in NVivo immediately after this is completed.
- Perform inter-rater reliability between coders (Fall 2019).
- Schedule and hold an Advisory Council meeting by Fall 2019.
- Begin planning focus group activities – develop guide (Winter 2019/20)
- Begin qualitative and quantitative data analyses, following coding (Spring 2020)
- Disseminate findings to professional and lay audiences (Spring to Fall 2020)
- Review current and new CPG bowel guidelines and identify areas for discussion. Review CPGs for bladder management as well.
- Complete all data analyses as time permits and/or request a no cost extension as needed.
- An article about the project was written by Ms. Walsh, study coordinator, and disseminated through our newsletter to SCI consumers and families, SCI Access, in Spring of 2019. We plan to provide an update to this article Fall 2019.

4. IMPACT

What was the impact on the development of the principal discipline(s) of the project?

Nothing to Report

What was the impact on other disciplines?

Nothing to Report

What was the impact on technology transfer?

Nothing to Report

What was the impact on society beyond science and technology?

Nothing to Report

5. CHANGES/PROBLEMS

Changes in approach and reasons for change

Nothing to Report

Actual or anticipated problems or delays and actions or plans to resolve them

Due to delays with the HRPO process, recruitment and data collection were delayed. Although an accelerated recruitment schedule has been successful in identifying subjects, the team expects to continue data collection through December 2019, approximately three (3) months beyond initial expectation. A no cost extension following Year 3 is likely to be needed to ensure sufficient time for completing data analysis and disseminating results.

Changes that had a significant impact on expenditures

Nothing to Report

6. PRODUCTS

Publications, conference papers, and presentations

- Conference presentation given at the Paralyzed Veterans of America Summit, August 2018, in Dallas, TX. Mr. Forchheimer presented “Quality of Caregiving Among People with SCI and Its Impact”. This presentation focused on persons with SCI and their caregiver relationships. See Appendix C.
- Conference presentation given at the Paralyzed Veterans of America Summit, August 2018, in Dallas, TX. Mr. Rohn presented “Giving Voice to Rehabilitation Patients through Qualitative Research: Lessons to Inform Clinical Practice”. This presentation focused on how to use qualitative research to provide agency and voice for rehabilitation patients. See Appendix C.
- Poster presentation given at the 57th International Spinal Cord Society (ISCoS) meeting, September 2018, in Sydney, Australia. This presentation focused on SCI patient decision making. See Appendix B.
- Keynote presentation given at Wellspect Healthcare, December 2018, in Sweden. Dr. Tate presented “Bladder and Bowel and their Impact on Wellbeing: Putting the Patient in the Driver’s Seat”. This invited presentation focused on neurogenic bowel and bladder and their impact on SCI patient wellbeing and quality of life.
- Conference presentation given at the European Spinal Psychologist Association (ESPA) meeting, March 2019, in Switzerland. Dr. Tate presented “*Putting the Patient on the Driver’s Seat”* with a focus on decision making after SCI. She also discussed findings with Dr. Anke Sheer-Sailing, medical director of the SCI unit at Balgrist Hospital in Zurich.

Books or other non-periodical, one-time publications.

Nothing to Report

Other publications, conference papers, and presentations.

- Physical Medicine & Rehabilitation Department research website at the University of Michigan was updated with the goal of reaching out to the veteran population about this project.
- A poster was presented at the 12th International Society of Physical and Rehabilitation Medicine (ISPRM) meeting, July 2018, in France. Dr. Tate presented this poster focused on Patient Decision Making in Relation to Neurogenic Bowel and Bladder.
- Our Winter/Spring 2019 newsletter ***SCI Access*** designed for patients and families or caregivers of persons with SCI featured an article with advisory council member Mike Harris, Executive President of the Michigan PVA about bowel issues, an article on our project entitled making decisions about bowel and bladder management, authored by Suzanne Walsh, study coordinator, was also included in this issue.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Denise Tate, PhD, ABPP
Project Role:	Principal Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0001-5210-3704
Nearest person month worked:	1.8
Contribution to Project:	Dr. Tate has provided guidance to the project team and will ensure that all activities are being implemented as proposed. She has reviewed the proposed measures, interview guides, literature so far, and recruitment plans. She will begin the process of reviewing clinical practice guidelines to ensure its inclusion in the project, coordinate meetings with consultants and advisory council as needed. Dr. Tate has led regular team meetings, reviewed transcripts, presented on

	project findings so far, reviewed project budget and assisted on the preparation of reports.

Name:	Edward Rohn, PhD
Project Role:	Co-Investigator/Project Manager
Researcher Identifier (e.g. ORCID ID):	0000-0002-6092-2301
Nearest person month worked:	3.0
Contribution to Project:	Dr. Rohn has continued to oversee data collection and analysis, as the project unfolds. Currently, he is refining and implementing qualitative data analysis procedures. He continues to serve as point-of-contact for DoD HRPO requirements. He provides oversight on the operations of the study, helping guide the work of the study team towards completing data collection and developing the coding scheme for data analysis.

Name:	Martin Forchheimer, MPP
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0002-7709-9622
Nearest person month worked:	0.6
Contribution to Project:	Mr. Forchheimer has provided guidance on the application and the selection of standardized measures. He is also conducting analysis

	of quantitative measures for the project. He has worked with the study coordinator and RA in the development of the REDCap database to capture responses on the quantitative measures.

Name:	Suzanne Walsh, MBA/MA
Project Role:	Study Coordinator
Researcher Identifier (e.g. ORCID ID):	0000-0001-5210-3704
Nearest person month worked:	9.4
Contribution to Project:	Ms. Walsh has worked the recruitment of participants, including screening, enrolling and scheduling eligible participants. Ms. Walsh has also worked to build community relationships, provide oversight to study staff, and ensure study procedures and guidelines are followed.

Name:	Elizabeth Riedman, MA
Project Role:	Research Assistant
Researcher Identifier (e.g. ORCID ID):	0000-0001-6781-7523
Nearest person month worked:	3.6
Contribution to Project:	Ms. Riedman has worked on the recruitment of participants, including screening, enrolling and scheduling eligible participants. She has also

	conducted both qualitative interviews and quantitative measures. She is leading the team on work on a scoping review of the current literature.

Name:	Haley Scott, MA
Project Role:	Research Assistant
Researcher Identifier (e.g. ORCID ID):	0000-0003-3956-4033
Nearest person month worked:	3.6
Contribution to Project:	Ms. Scott has worked on the recruitment of participants, including screening, enrolling and scheduling eligible participants. She has also conducted both qualitative interviews and quantitative measures. She is working on the scoping review.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to Report

What other organizations were involved as partners?

Nothing to Report

8. **APPENDICES:** *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc. Reminder: Pages shall be consecutively numbered throughout the report.* ***DO NOT RENUMBER PAGES IN THE APPENDICES.***

** **ADDITIONAL NOTES:**

MARKING OF PROPRIETARY INFORMATION: Data that was developed partially or exclusively at private expense shall be marked as "Proprietary Data" and Distribution Statement B included on the cover page of the report. Federal government approval is required before including Distribution Statement B. The recipient/PI shall coordinate with the COR/GOR to obtain approval. **REPORTS NOT PROPERLY MARKED FOR LIMITATION WILL BE DISTRIBUTED AS APPROVED FOR PUBLIC RELEASE.** It is the responsibility of the Principal Investigator to advise the COR/GOR when restricted limitation assigned to a document can be downgraded to "Approved for Public Release." **DO NOT USE THE WORD "CONFIDENTIAL" WHEN MARKING DOCUMENTS. DO NOT USE WATERMARKS WHEN MARKING DOCUMENTS.**

Appendix A: Q4 Quad Chart

Neurogenic Bowel and Bladder Management After Spinal Cord Injury: Examining Factors Involved in Successful Decision-Making Processes

SC160219
W81XWH-17-1-0494

PI: Denise Tate, PhD **Org:** Regents of the University of Michigan **Award Amount: $774,994**

Study/Product Aim(s)

- **<u>Aim 1</u> – Factors**: *Identify and describe the factors influencing the decision-making process and changes in NBB management and related complications across time, considering age and time since injury.*
- **<u>Aim 2</u> – Mechanisms**: *Assess participants' abilities and coping styles in carrying out NBB management decisions.*
- **<u>Aim 3</u> – Outcomes**: *Assess the outcomes of these decisions on improving problems related to the management of NBB and reducing associated complications.*

Approach

A qualitative methodology complemented by the use of selected quantitative measures. The sample consists of 60 persons with spinal cord injury; 30 recruited from our previous DOD study and 30 participants new to us. The objective is to investigate the factors, mechanisms, and outcomes of decision-making.

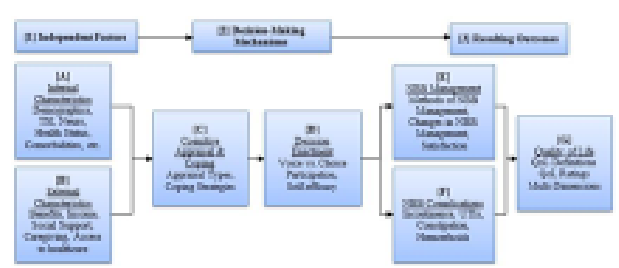


Figure 1: Theoretical Approach Illustrating Domains and Components in NBB Decision Making and Outcomes

UM IRB is approved. VA IRB is approved. HRPO has approved data collection for UM site and VA site. Data collection is nearing completion at UM. Recruitment is nearing completion of Veterans and data collection is in process. Preliminary transcript coding has begun.

Timeline and Total Cost

Activities CY	17	18	19	20
Admin & instrument design	🟩	🟩		
Recruitment		🟩	🟩	
Data collection		🟩	🟩	
Analysis & dissemination			🟩	🟩
Estimated Budget ($K)	$16,500	$316,747	$316,747	$125,000

Updated: Aug 15, 2019

Goals/Milestones (Example)

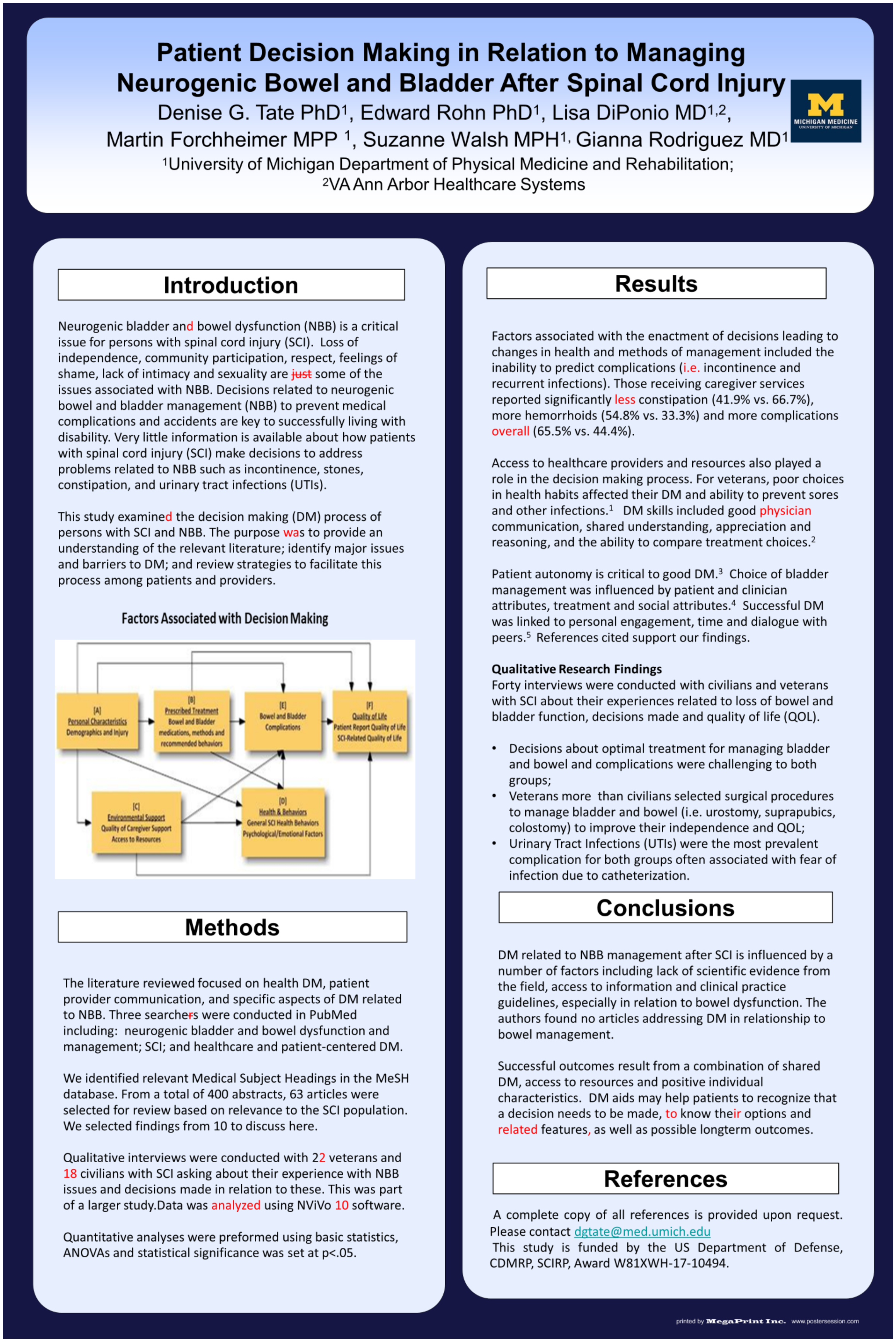
CY17 Goal – Project start-up
✓ IRB development and submission
✓ Instrument design & finalization
CY18 Goals – Recruitment & data collection
✓ Implement recruitment strategies
✓ Begin data collection
CY19 Goal – Data collection & analysis
✓ Conduct interviews; adjusting for sample
✓ Begin coding of transcripts
CY20 Goal – Analysis & dissemination
☐ Identify and develop case reports
☐ Disseminate findings to professional meetings and journals

Comments/Challenges/Issues/Concerns

- Nothing to report

Budget Expenditure to Date through Y2Q4 (Total Costs)
Y2Q4 Projected Expenditure: $70,382.00
Y2Q4 Actual Expenditure: $53,617.72

Appendix B: ISCoS Poster



Patient Decision Making in Relation to Managing Neurogenic Bowel and Bladder After Spinal Cord Injury

Denise G. Tate PhD[1], Edward Rohn PhD[1], Lisa DiPonio MD[1,2],
Martin Forchheimer MPP [1], Suzanne Walsh MPH[1], Gianna Rodriguez MD[1]
[1]University of Michigan Department of Physical Medicine and Rehabilitation;
[2]VA Ann Arbor Healthcare Systems

Introduction

Neurogenic bladder and bowel dysfunction (NBB) is a critical issue for persons with spinal cord injury (SCI). Loss of independence, community participation, respect, feelings of shame, lack of intimacy and sexuality are ~~just~~ some of the issues associated with NBB. Decisions related to neurogenic bowel and bladder management (NBB) to prevent medical complications and accidents are key to successfully living with disability. Very little information is available about how patients with spinal cord injury (SCI) make decisions to address problems related to NBB such as incontinence, stones, constipation, and urinary tract infections (UTIs).

This study examined the decision making (DM) process of persons with SCI and NBB. The purpose was to provide an understanding of the relevant literature; identify major issues and barriers to DM; and review strategies to facilitate this process among patients and providers.

Factors Associated with Decision Making

Methods

The literature reviewed focused on health DM, patient provider communication, and specific aspects of DM related to NBB. Three searche~~r~~s were conducted in PubMed including: neurogenic bladder and bowel dysfunction and management; SCI; and healthcare and patient-centered DM.

We identified relevant Medical Subject Headings in the MeSH database. From a total of 400 abstracts, 63 articles were selected for review based on relevance to the SCI population. We selected findings from 10 to discuss here.

Qualitative interviews were conducted with 22 veterans and 18 civilians with SCI asking about their experience with NBB issues and decisions made in relation to these. This was part of a larger study.Data was analyzed using NViVo 10 software.

Quantitative analyses were preformed using basic statistics, ANOVAs and statistical significance was set at $p<.05$.

Results

Factors associated with the enactment of decisions leading to changes in health and methods of management included the inability to predict complications (i.e. incontinence and recurrent infections). Those receiving caregiver services reported significantly less constipation (41.9% vs. 66.7%), more hemorrhoids (54.8% vs. 33.3%) and more complications overall (65.5% vs. 44.4%).

Access to healthcare providers and resources also played a role in the decision making process. For veterans, poor choices in health habits affected their DM and ability to prevent sores and other infections.[1] DM skills included good physician communication, shared understanding, appreciation and reasoning, and the ability to compare treatment choices.[2]

Patient autonomy is critical to good DM.[3] Choice of bladder management was influenced by patient and clinician attributes, treatment and social attributes.[4] Successful DM was linked to personal engagement, time and dialogue with peers.[5] References cited support our findings.

Qualitative Research Findings
Forty interviews were conducted with civilians and veterans with SCI about their experiences related to loss of bowel and bladder function, decisions made and quality of life (QOL).

- Decisions about optimal treatment for managing bladder and bowel and complications were challenging to both groups;
- Veterans more than civilians selected surgical procedures to manage bladder and bowel (i.e. urostomy, suprapubics, colostomy) to improve their independence and QOL;
- Urinary Tract Infections (UTIs) were the most prevalent complication for both groups often associated with fear of infection due to catheterization.

Conclusions

DM related to NBB management after SCI is influenced by a number of factors including lack of scientific evidence from the field, access to information and clinical practice guidelines, especially in relation to bowel dysfunction. The authors found no articles addressing DM in relationship to bowel management.

Successful outcomes result from a combination of shared DM, access to resources and positive individual characteristics. DM aids may help patients to recognize that a decision needs to be made, to know their options and related features, as well as possible longterm outcomes.

References

A complete copy of all references is provided upon request. Please contact dgtate@med.umich.edu

This study is funded by the US Department of Defense, CDMRP, SCIRP, Award W81XWH-17-10494.

Appendix C: Abstracts from Paralyzed Veterans of America Summit

Citation: **Forchheimer M.** Quality of Caregiving Among People with SCI and Its Impact.
Platform Presentation, Paralyzed Veterans of America Summit, Aug 2018, Dallas, TX.

Learning Objectives (4):

1) To provide background information on the literature regarding patient-caregiver relationships.
2) To describe differences between people receiving and not receiving caregiver services.
3) To describe the Quality of Caregiving Measure and the relationship of scores to demographic and neurological status as well as measures of health and well-being.
4) To discuss the implications of findings for clinical care.

Background: The relationship of people with SCI to their caregivers can have substantial impacts on their physical and mental health, as well as on their activities, community participation and quality of life (QOL). They can also have a significant impact on clinical care, both because caregivers often interact directly with clinicians and because they frequently conduct healthcare activities. Decreased access to caregiver services (CGS) has been linked to increased rates of hospitalization and emergency room visits. Finding the relationship with a caregiver to be problematic has been associated with increased distress and decreased QOL. This research uses data from two studies that addressed receipt and valuation of caregiving.

Design: Both studies providing data for this research were conducted at a Midwestern healthcare center. One included 303 participants in a SCI Model System study; the other, funded by the Department of Defense, evaluated 40 veterans and civilians, half of whom were affiliated with a VA Health System. Both studies focused on bladder and bowel health.

Methods: The measure of relationship with caregivers used in both studies was the Quality of Caregiving Measure (QCM). Analyses appraised differences in demographic and neurologic status as well as in health and QOL as a function of receipt of CGS. They also assessed differences among those receiving services in relations to QCM scores.

Results: Fifty-five percent of subjects received CGS. Receipt differed significantly as a function of impairment severity (p<.0005); those having complete tetraplegia were most likely to receive them (89.0% vs. 40.6% of other subjects). Those receiving CGS had more problematic neurogenic bowel, as measured by the Neurogenic Bowel Dysfunction Score (p<.05) and worse bladder complications, as measured by the SCI-QOL Bladder Complications Scale (p<.05). They also had higher levels of anxiety, as measured by the PROMIS Anxiety Scale (p<.05). Among those receiving CGS, QCM scores were associated with better global physical health (p<.05) and lower levels of depression (p<.05), both as measured by the PROMIS. QCM scores were also associated with healthier lifestyle behaviors as measured by the Spinal Cord Injury Lifestyle Scale (p<.01) as well as with better relationships with clinicians, as assessed by the Working Alliance Inventory (p<.001). There were no differences in either receipt of CGS or QCM scores as a function of military service. QCM scores did not differ as function of if caregivers were paid or any demographic or neurological attributes. QCM scores were heavily skewed, almost 25% of them indicating total satisfaction with services.

Conclusions: Those receiving CGS appear to have greater need for services, as indicated by the severity of their impairments and their problems with bowel and bladder. Among those receiving CGS, higher appraisals of caregiving were associated with better physical and mental well-being though not with demographic or neurological factors. This talk will address limitations of the QCM and related measures as well as a new study addressing these limitations.

Appendix C: Abstracts from Paralyzed Veterans of America Summit

Citation: **Rohn E.** Giving Voice to Rehabilitation Patients through Qualitative Research: Lessons to Inform Clinical Practice, Platform Presentation, Paralyzed Veterans of America Summit, Aug 2018, Dallas, TX.

Learning Objectives (3):

1. Recognize differences between clinical presentations of patients and the lived experiences of the person's life outside the clinic.
2. Recognize the impact and benefit of qualitative inquiry to provide context for patient experiences that are often inaccessible to clinicians.
3. Recognize how different priorities come together in the clinical space between clinicians and patients, and how acknowledging these different priorities can be mutually beneficial.

Background: Recent decades have seen broadening appreciation of qualitative inquiry in understanding the lived experiences of people with chronic conditions. However, the process of converting qualitative findings into operable clinical implications is less well-developed. In this presentation, the author examines stories and lessons from three previous and developing qualitative studies of persons with spinal cord injury (SCI), illustrating that contextual understanding of actual patient experiences constitutes a form of translational application for clinical settings.

Design: Data are from three funded research projects, both past and current, on the lived experiences of SCI. Data are derived from qualitative inquiries of a mix of veterans and civilians, exploring issues of quality of life (QOL), decision-making around bladder and bowel management, and coping with chronic pain. Findings and lessons are derived from separate qualitative analyses. Each analysis involved the discovery of themes and patterns that characterize the lived experiences of those participants living with SCI. Larger lessons and demonstrative stories of clinical experiences were identified especially for this presentation.

Methods: Semi-structured interviews were conducted across the three studies. Study 1 (QOL after SCI) included 40 veterans and civilians with SCI, as well as 20 caregivers. Study 2 (decision-making in bladder and bowel management) includes 60 veterans and civilians with SCI. Study 3 (chronic pain and social participation) includes 30 participants with SCI and chronic pain. This third study also involves immersive ethnographic participant-observation of the day-to-day lives of people with SCI, an underutilized methodology that will be detailed in the presentation. Data were analyzed using repeated reading of interview transcripts, coding with NVivo, and the identification of clinically-useful narratives.

Results: Identified narratives reflect deep personal meaning and the impact of SCI, bladder and bowel dysfunction, and chronic pain on QOL. Within these narratives are a range of themes that are of particular relevance to clinicians, including "resilience," "patient autonomy," and "challenges in daily life with SCI". These themes have direct impact on patient decisions regarding treatment, including in patients' self-management behaviors and responses to clinical practice guidelines. Each patient has a story that works to "make sense" of their experiences, which serves as an important cognitive process in making decisions about their SCI management. A willingness to hear and incorporate patient stories retains the person behind the chart, preserving the patient's voice in his or her own care.

Conclusions: Qualitative findings need not to be predictive to have implications for clinical practice. Understanding how illness experiences extend beyond disease states serves to contextualize the patient outside the clinic. This way of knowing a patient enriches the art of healthcare delivery, while providing direct implications for the effectiveness of the science. Ultimately, seeing and seeking narratives reminds us to practice healthcare delivery that retains the person behind the patient. Seen this way, patients' own cognitions of their autonomous experiences becomes an effective part of healthcare delivery. Such insights then can be used to creatively match patients, providers, and interventions in more effective and adaptive ways. Specific recommendations are made based on qualitative findings.