PROTOCOL FOR

REFINEMENT OF THE COMPREHENSIVE MOBILE ASSESSMENT OF PRESSURE (CMAP) SYSTEM FOR PREVENTION OF PRESSURE INJURIES: PHASES 1 & 2 & 3

IRBNet 1758786

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PURPOSE and BACKGROUND

This project's focus is an individualized education strategy for learning and maintaining healthy pressure distribution behaviors in wheelchair users with spinal cord injuries or disorders (SCI/D). Pressure injuries experienced by individuals with SCI/D continue to be a leading cause of rehospitalization and mortality across their lifespan [1]. The need for effective prevention strategies for improved self-management of their skin health is critical. While factors leading to pressure injuries are complex [2-5], there is consensus that pressure applied to the skin, with duration and magnitude of pressure in relation to the individual's physiological tolerance to that pressure, is a primary factor [6].

The Department of Veterans Affairs serves more than 27,000 Veterans with SCI/D and related disorders [7]. Spinal cord injuries disrupt sensation and motor function below the site of injury, resulting in the use of a manual or power wheelchair for mobility. Prolonged sitting in a wheelchair or on other surfaces combined with a lack of skin sensation poses a severe and persistent threat to the health of skin and can lead to life- threatening sitting-related pressure injuries. In the US, 25% of adults with paralysis will have a pressure injury at any given time [8-10], and Veterans with an SCI/D averaged four pressure injuries each over a 3-year observational study period [11]. Pressure injuries and related complications are a primary reason for hospital readmission for those with an SCI/D across all time periods [12].

Educating patients with SCI/D about pressure injury risks and how to manage those risks is a primary task during clinician contact. However, prevention knowledge remains suboptimal as found in previous studies and evidenced by increasing incidence of pressure injury over the past few decades [1, 13, 14]. *A key conclusion from recent reviews is an emphasis on the need for an individualized approach toward pressure injury prevention education, with a focus on modifiable factors,* due to the array of complex factors impacting each person's risk [3, 6, 13, 15-17]. Modifiable factors can be controlled by the at-risk individual through change in behavior and adopting healthy skin-protection behaviors that can potentially offset the impact of non-modifiable factors [13].

One component that addresses a modifiable factor for the prevention of sitting-related pressure injury development is education to minimize pressure under the sacral, ischial and sacrococcygeal areas through pressure-redistribution movements [14, 18-21]. This education includes verbal and written instruction and demonstration of movements to redistribute weight throughout the day. The specific instructions for consistency, frequency, and duration of redistribution are based on several published guidelines and vary [15, 20, 21]. Veterans with SCI/D hospitalized with severe pressure injuries report that they have difficulty following these guidelines [13] and in our clinical experience, similar concerns have been expressed by our patients. We also know from recent remote-monitoring studies of wheelchair users in their homes that pressure reliefs are performed inconsistently and at a rate far lower than recommended through clinical guidelines [15, 22]. In a study recently completed by co-investigators of this current study, Drs. Vos-Draper and Morrow, twenty-three individuals with SCI/D reported their lowest self-efficacy scores for the quality of their weight shift movements. They were asked how confident they felt about their ability to move far enough to remove pressure from their most at-risk areas during weight shifts. These scores for self-efficacy were lower than those for similar questions related to frequency, consistency, and duration of weight shift movements. This information highlights the unique challenge individuals with SCI/D have in completing weight shifts in a way that provides adequate protection against skin breakdown.

Overall Hypotheses: To improve consistency, frequency, duration, and most importantly, the quality of pressure relief movements, our overall hypothesis is that *individualized patient education provided by clinicians will apply effectively in real-world contexts and that it can be improved with better tools to visualize and monitor pressure distribution at the sitting surface.* Our prediction is based partly on the success shown in the clinical setting with nurses utilizing real-time pressure visualization and monitoring for bed positioning [23-26] and we believe this success can apply to wheelchair users in their home environments as effectively. We see the power in providing a similar visual and monitoring feedback tool to clinicians and their patients during SCI/D rehabilitation, to foster greater success and independence in managing skin health.

Seat interface pressure mapping has been an effective clinical tool used to facilitate cushion selection or to guide

positioning for several decades. In research related to pressure injury prevention, the focus has typically been on interface pressure values (average or peaks), and comparison of values across the studies is impossible due to the varied study designs [15]. This traditional seat interface pressure mapping assists the clinician in determining optimal seating and mobility equipment selection, source(s) of errant pressure when a problem arises, and to demonstrate pressure redistribution through weight shifts. Clinicians typically perform this service during a treatment visit and time spent on the pressure map is short, usually under 1 hour. *The identified issue is that the wheelchair user does not have access to the same visual feedback once they leave the clinical setting.*

CMAP System Screen Shots



Figure 1. Examples of CMAP function: (Left) live pressure map and countdown to next weight shift and (Right) Settings page for weight shift reminders.

Through DoD funding (SCIRP W81XWH-15-1-0484), we developed the Comprehensive Mobile Assessment of Pressure (CMAP) system that currently provides real-time images of sitting-related pressure distribution with integrated reminders and pressure-based alerts on an iOS-based smartphone. The CMAP system was developed as a self-management tool. The CMAP system consists of a pressure mat that sits atop the wheelchair cushion, a smart phone application (app) and the connection between the two. The CMAP app currently provides real-time images of sitting-related pressure distribution with integrated reminders and pressure-based alerts on an iOS-based smart phone. (Figure 1). Specific features for facilitating self-management over the long-term include reminders for performing weight shifts, alerts to increases in pressure, and the ability to track weight shift performance over time. The CMAP system is intended to be used for the entire time a wheelchair user is in the wheelchair to provide on- demand feedback on pressure distribution. The pressure map display of relative distribution is meant to serve as a compensation for lack of sensation. Our research to date has focused on whether the visual feedback, provided to the wheelchair user, provides pertinent information about how their pressure is distributed at any given time and shows the user if their attempts to shift pressure away from bony areas that are at higher risk are effective. We think that providing this visual feedback will facilitate improved motivation to take action to mitigate higher pressure distribution around at-risk areas. *Through movement, and observation of success in redistributing pressure, we believe that the wheelchair user will build self-efficacy for performing these movements and for managing pressure more effectively.*

We also learned during the DoD study, (SCI/DRP W81XWH-15-1-0484) that Veterans prefer the CMAP system be introduced and set up with clinician guidance. Building on that knowledge, another important element to motivating Veterans with SCI/D to conduct regular pressure reliefs is centered on the education provided during their initial rehabilitation and regular clinic visits. In this vein, *our current research project is focused on how to adapt the CMAP app to help clinicians develop individualized education strategies for Veteran learning and maintaining healthy pressure distribution behaviors.* Utilizing the CMAP during clinician-delivered education would provide the patient with the ability to see their sitting-related pressure distribution and assess if their attempts to offload pressure are successful. The individual, with the clinician, could find which movements are most effective and feasible for the individual to use in their daily routines and rituals. Additionally, the CMAP system can provide clinicians the ability to assess baseline pressure-relief behaviors, determine education needs, set individualized and relevant goals, revise their intervention approach if needed, and monitor patient progress toward goals. The clinician could then assist the patient in setup using individualized parameters for independent use of CMAP at home as a self-management tool.

This project will fill several gaps. First, while individuals with SCI/D can be motivated to manage their skin health, they also lack effective strategies to facilitate engaging in day-to-day behaviors, consistently, over time that help protect them from pressure injury development. Second, without relevant feedback about whether they've effectively

relieved pressure by moving, individuals may lack motivation to continue performing the behavior, especially with consistency across time. The CMAP provides this potentially helpful information.

There are no competing or similar feedback methods that show relative distribution of pressure directly between the user's body and the surface they are sitting on. Third, we learned from Veterans and civilian participants in previous studies using CMAP that there are challenges with the usability of the hardware aspects of the overall system and these will be addressed in this project. Finally, we have not yet engaged clinicians, other than the researchers who have clinical backgrounds, in further development of features that will allow the system to be utilized during patient education for measurement and goal setting.

An updated CMAP app will serve two important long-term objectives: 1) assisting clinicians in assessing baseline performance, establishing individualized education plan, forming relevant intervention goals, and monitoring progress to promote the Veteran with SCI's success toward pressure injury prevention behaviors in the hospital setting; 2) assisting outpatient-based clinicians with meeting the education needs of the Veteran with SCI and facilitating individualized setup of the CMAP system for use in the community setting.

Further, during the recent DoD study, we learned Veterans with SCI, who used CMAP at home, indicated the positive utility of the system and the Veterans' desire to use the system on a daily basis; however, significant improvements to the hardware are needed to make the overall system more durable, easier to use, and more dependable. This current proposal will address those identified needed hardware improvements, e.g. durability, and also take the natural next step of the CMAP system development focusing on adding software functionality to the app for clinician use for patient education.

This is a funded four-year project. Three phases of the project will occur, using focus groups in the first phase to inform the second and third phases. This amended protocol is adding the third phase activities- See page 12 for Phase 3.

In March 2024 upon Dr. Olney's retirement Dr. Eddy, DO assumed the PI role for Phase 3 of the study.

Phase 1: (projected to be completed by December 31, 2021)

Aim 1: Expand functionality of CMAP app system. (Years 1-2)

- Sub Aim 1a: Improve hardware design and features. We will use iterative focus groups (Veterans with SCI; n = 10) to learn: 1) the best functioning docking design for their wheelchair(s); and 2) expand the CMAP app to a smart watch. Outcomes will be measured using standardized metrics for usability.
- Sub Aim 1b: Software Expansion for clinical monitoring and education usage. We will use iterative focus groups with clinicians (n = 10) to learn what data and format are needed to assist in monitoring and educating their patients. We will use standardized metrics for usability.

RESEARCH DESIGN AND METHODS (Phase 1)

Overview

For Phase 1 of the study, we will convene Veteran focus groups (up to three) to advise on specific aspects of hardware re-design; second, we will convene Clinician focus groups (up to three) to advise on software updates to the CMAP system towards a clinical interface (also known as a dashboard).

Sampling

We will use purposeful sampling for Aim 1a to ensure we have both power and manual wheelchairs users represented. Veterans with a SCI/D who receive care at the MVAHCS Spinal Cord Injury & Disorder (SCI/D) Center will be considered for enrollment and will not be excluded based on sex, race or ethnicity. The MVAHCS SCI/D treats all Veterans from all service branches and reaches patients from across the upper Midwest. There are 20 new traumatic and non-traumatic SCI/Ds seen yearly and more than 300 adults with SCI/D are seen yearly for follow-up.

Convenience sampling will be used to recruit clinicians (SCI/D Physical and Occupational Therapists and Nurses

and Ancillary Clinicians) to participate in Aim1b.

Recruitment (Aim 1)

Veterans with SCI/D: Dr. Olney will oversee all aspects of recruitment. Following Institutional Review Board (IRB) approval, clinicians from the MVAHCS SCI/D Center will identify Veterans with traumatic or non- traumatic SCI/D who meet inclusion criteria for Aim 1a. We will give flyers to clinicians to hand to Veterans and place flyers in the MVAHCS SCI/D Center. We may also present to local organizations such as the Paralyzed Veterans of America Minnesota Chapter to gain exposure and volunteers. A follow-up call will be made to any Veterans who have stated interest in the study to clinician, given that the clinician has annotated such in an electronic medical record (EMR) note. A letter (meeting our IRB requirements) about the study can be sent to identified potential participants if they have not yet stated their interest along with notation as such in EMR. In this case, we will follow up with a phone call within one week to disclose details and discern if the Veteran is interested in participating and eligible. Upon determining a person's interest and eligibility, an appointment will be made with the study coordinator to explain the research project, re-confirm eligibility, and collect non-identifiable demographic data (e.g. age, type of wheelchair, years with SCI/D, level of SCI/D).

Our method of identification and/or recruitment will not violate participants' expectations of confidentiality regarding their medical records or history in ANY way. We will adhere to VA privacy policies regarding protection of private health information.

Further, by attending the focus groups Veterans are implying consent. This is the standard practice at the MVAHCS for involvement in focus groups and is called "Waiver of Documentation of Consent", for which we will obtain IRB approval prior to starting.

Inclusion Criteria:
For Aim 1a: Veteran adults aged 18-80, male and female or non-binary, with a spinal cord injury (C4 and below) or spinal cord disorder with impaired sensory function and a wheelchair user for at least one year.

Exclusion Criteria:
For Aim 1a: Any Veteran with SCI/D who is unable to verbally and cognitively communicate with the study team.

Clinicians: For Aim 1b: Clinicians will be invited to participate in up to three focus groups to inform researchers of: 1) their needs for use of the CMAP system when educating the Veteran about use of weight shifts during sitting to manage pressure; 2) give feedback to the study engineers about success of the CMAP app additions and whether they meet their recommended requirements. Our clinicians will participate during their lunch hours or after work hours. Before the focus group begins, clinicians will be informed of purpose and expected role during the focus group. Further, by attending the focus groups they are implying consent. This is the standard practice at the MVAHCS for involvement in focus groups and is called "Waiver of Documentation of Consent", for which we will obtain IRB approval prior to starting.

We will ask for non-identifying demographics (e.g. professional title, area of work).

Inclusion Criteria for Aim 1b: Clinicians (SCI/D Physical and Occupational Therapists and Nurses and Ancillary Clinician) who, in their normal scope of work, provide patient education for pressure injury prevention.

No exclusion criteria for clinicians.

Methods (Aim 1)

We will improve the CMAP hardware (Aim1a). We will use an experience-based design [29] to conduct focus groups. With this design, iterative focus groups of Veterans with SCI/D *(n = 6 to 10* sample size based on Krueger *and Casey, 2009, pages 67-68* [30]) in varying types/structures of wheelchairs will inform the research team of how they would conceptualize an on-board, under-seat, integrated docking storage and charging station for the CMAP hardware to improve access, dependability, and ease of use of the CMAP system. See Figure 11. We learned from our previous study (DoD SCI/DRP W81XWH-15-1- 0484, PI: Morrow) that Veterans did not like the bag that contained the CMAP parts (minicomputer, battery and cords) hanging off their wheelchair. This sense of inconvenience was expressed by the participants of the NIH study as well. Several participants mentioned that a docking station for the CMAP parts and the smart phone would be ideal. Further, Dr. Olney and colleagues have been successful conducting a study (Office of Higher Education, State of Minnesota, PI: Goldish and Hansen) using this experience- based design and iterative process, asking Veterans with SCI/D to help conceptualize and design an upper body control system for their wheelchair. We have learned through these experiences that the Veteran must be involved from the beginning of the idea, streamlining the process toward an end product. We expect the participants inform us about tolerable dimensions of this docking station so as to not interfere with seating preferences such as getting up to a table. *If we find, and we think we will, that one size does not fit all, then we will choose to develop a docking station for each of the top three used wheelchairs by Veterans.*

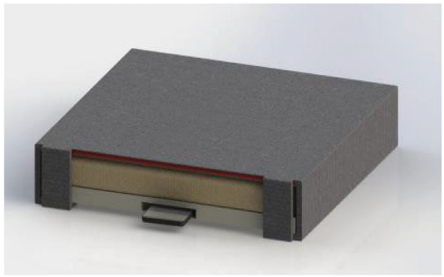


Figure 11: Possible concept for onboard under-seat, integrated docking storage and charging station for the CMAP hardware

During the focus groups **(Aim 1a)** we will also explore expanding the CMAP app to a smart watch. Currently the data (real-time images of sitting-related pressure distribution with integrated reminders and pressure-based alerts) from the CMAP system is uploaded to a smart phone. In our previous study (DoD SCI/DRP W81XWH- 15-1-0484, PI: Morrow), the data were loaded to an iOS-based smart phone for participant viewing and interaction with the app. In a separate study (NIH R01 AG056255), Drs. Morrow and Vos-Draper have been successful adapting the app to an Android platform. Therefore, in the current proposal, we will expand the capability of the data to load to both Android and iOS- based smart watches. We learned in the previous studies that the most important and frequented feature the Veteran with SCI/D used with the CMAP system was the real-time image of their seated pressure distribution. Participant CMAP users and investigators (Drs. Goldish and Vos-Draper) proposed the idea of this feedback being available on a smart watch (Figure 12), possibly with haptic feedback for reminders and alerts. Therefore, during the same iterative focus groups conducted for the docking station, we will also explore the concept of this feedback being made accessible on a smart watch. Based on the outcomes from the Veteran focus groups, our software engineer will use these data to guide the smart watch platform development within constraints of our budget.



Figure 12: Smart watch image of data captured by the CMAP system.

We will have the Veterans give further advise on the docking station designs at the second and third focus groups. For the smart watch, we will demonstrate the apps on the study smart watches and allow the Veterans to handle the smart watch prototype. They will not be sitting on the CMAP system in the focus groups (our study coordinator will sit on the map to allow an image to upload to the smart watch app. The Veteran will advise our team regarding the desired data. The Veteran will complete the System Usability Scale (SUS) and User Experience Questionnaire (UEQ), which are validated surveys for objective feedback on usability during each of the planned focus groups. Usability scores will be compared across the sessions to ensure development is progressing in a positive direction and meets the requirements desired by the Veterans. For focus groups, Veterans will be compensated $25 each of the three sessions.

We will use an experience-based study design [28], to expand the utility of the CMAP system for use by clinicians with Veterans with SCI/D during routine patient education for pressure injury prevention **(Aim 1b).** SCI clinicians will inform the research team of their needs/requirements for use of the CMAP system for this purpose. To do this, SCI/D occupational and physical therapists and nurses (*n = 6-10*), sample size based on Krueger *and Casey, 2009, pages 67-68* [30]) will engage in an iterative process that involves three focus groups that include using the CMAP system, structured interviews around self-efficacy of their ability to provide effective patient education around performing weight shifts as part of their pressure injury prevention education interventions, and usability testing to make these software adaptations to the CMAP app. Examples of potential ways the CMAP app could be redesigned for clinician use include addition of features that allow gathering of baseline weight shifting patterns, goal setting with the Veteran, and measuring progress towards those goals. The ability to monitor progress would allow clinicians to adjust educational approaches based on feedback provided by the CMAP system.

Once the research team learns the needs of our clinicians we will update the CMAP app with those needed data capture capabilities by prioritizing the requirements when working with our software engineers. Our software engineer will complete the mobile app software updates. We will return to the clinician focus group members to gain verification that we effectively addressed their prioritized requirements. A third focus group is planned so that if critical required features were not adequately addressed during usability testing in the second focus group, the software engineer can address the needed modifications. For an objective measure we will have each clinician test the CMAP app's updated design on smart phones (the study will provide the test Android or iOS formats, smart tablet, and smart watch) and then ask the clinicians to complete the SUS and UEQ surveys for objective feedback on usability and we will ask several confidence questions to assess self-efficacy. Scores will be compared across each successive focus group scores to verify that updates meet clinician requirements. For focus groups, clinicians will be compensated $25 each of the three sessions.

To summarize: 1) we believe the addition of a smart watch app will enhance usability for the Veteran, and 2) an updated CMAP app will serve two important objectives: a) assisting clinicians in assessment, goal-setting, and monitoring the Veteran with SCI's progress toward pressure injury prevention behavior goals while in the hospital setting; b) assisting clinicians with setup and education of the Veteran with SCI for using the CMAP system in the independent setting.

Data Collection and Analyses (Aim 1)

Aim	Outcome	Instrument	Analysis	When
1a	Docking station and smart watch design	Focus group	Rapid Turn-Around [30]	Y1Q2 Y1Q4 Y2Q2
	Usability, repeated	SUS	LMER Model*	Y1Q2 Y1Q4 Y2Q2
	Usability, repeated	UEQ	LMER Model	Y1Q2 Y1Q4 Y2Q2
1b	CMAP app design for Clinicians	Focus group	Rapid Turn-Around	Y1Q2 Y1Q4 Y2Q2
	Usability, repeated	SUS	LMER Model	Y1Q2 Y1Q4 Y2Q2
	Usability, repeated	UEQ	LMER Model	Y1Q2 Y1Q4 Y2Q2

Data Management and Analyses Discussion

All data will be secured per VA policies. The study team has worked with the facility ISSO to ensure all PHI and PII data throughout the study are always secure. Please consult the ERDSP application for details. We will transcribe the recordings of the focus groups. Drs. Olney and Vos Draper will conduct analysis of the qualitative data using Rapid Turn-Around process [33], to share with the engineers for device and app design and re-designs.

Phase 2: (projected to start in January 2022)

DESIGN:

For Phase 2 of the study, we will conduct a prospective pilot study in the Minneapolis SCI/D Center where Physical and Occupational Therapists (PT / OT) will test feasibility of the CMAP system clinical dashboard during their seating behavior education with inpatient Veterans with SCI.

Aim 2: Determine usability of refined CMAP system for clinician and patient use within the hospital setting. (Years 2-3) Study staff clinicians (PT/OTs) will implement the CMAP system with newly injured Veterans (n = 6). The PT/OTs will inform the study team of improvements needed to the dashboard throughout the year of testing. We will also informally interview the Veteran user regarding needed improvements. We will ask the clinicians and Veterans to complete self-efficacy and usability measures.

RESEARCH METHODS Phase 2

Three SCI/D therapists identified by the service chief (Lori Danzl, Chief, Physical Therapy Department) and Ryan Bouslog, SCI/D Therapy Program Coordinator, will be study staff for this aim. Dr. Olney and Dr. Vos Draper and other team members will provide the three therapists with an introduction to the Veteran participant's CMAP app functions and provide training for the CMAP clinical dashboard features and functions. Therapists will access the dashboard on a study provided password protected tablet. Prior to the start of their training sessions, we will assess the therapists' confidence in their ability to conduct effective seating behavior education (See Attachment 1). After having implemented the CMAP system into their usual pressure injury prevention education with the Veterans, at the end of Aim 2 activities, we will ask these same questions, with a goal to understand if the CMAP system improved their confidence for educating on pressure injury prevention seating behavior. We will also ask the three study staff therapists to complete several commonly used usability scales: the System Usability Scale (SUS) and User Experience Questionnaire (UEQ) resulting in objective feedback regarding device usability. See Attachments 2 and 3. Informal conversations to improve the CMAP dashboard features and functions will occur throughout the study period. This iterative process between our VA therapists and engineers has proven to be a very successful in device development methodology for several of the MADE inventions.

Sampling

For **Aim 2** we will use convenience sampling. Veterans with a SCI/D who receive care at the MVAHCS Spinal Cord Injury & Disorder (SCI/D) Center will be considered for enrollment and will not be excluded based on sex, race or ethnicity. The MVAHCS SCI/D treats Veterans from all service branches and reaches patients from across the upper Midwest. There are approximately 20 new traumatic and non-traumatic SCI/Ds seen yearly and more than 300 adults with SCI/D are seen yearly for follow-up at the MVAHSC SCI/D Center.

Recruitment (Aim 2)

Veterans with SCI/D: Dr. Olney will oversee all aspects of recruitment. Following Institutional Review Board (IRB) and R&D approval, clinicians from the MVAHCS SCI/D Center will identify Veterans with traumatic or non- traumatic SCI/D who meet inclusion criteria for Aim 2.

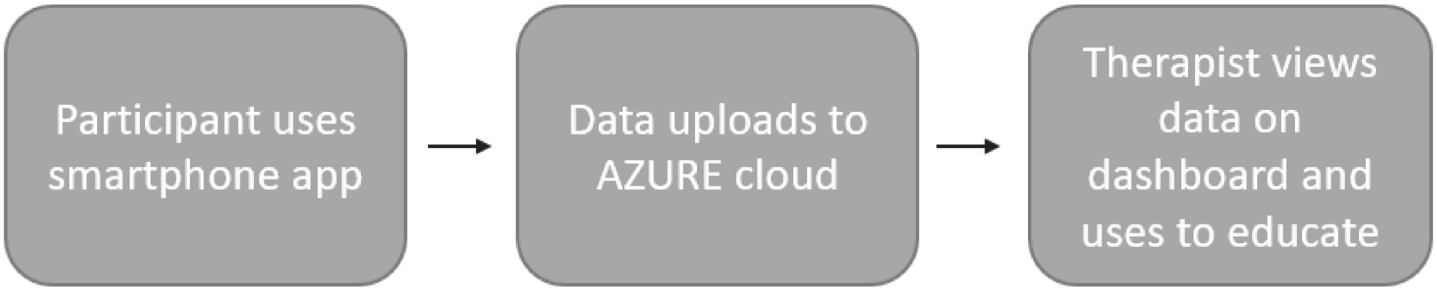
Veteran Inclusion Criteria:

Veteran adults aged 18-80, male and female, with a SCI (C4 and below) or a SCI/D, with impaired sensory function, who are currently in inpatient rehabilitation with at least two weeks prior to discharge. The SCI/D physiatrist (Dr. Eddy) will screen the potential participant for any potential medical barriers to safe participation. Our study staff

therapists will screen the potential Veteran participant for appropriateness for participation. After consent, to complete enrollment, the participant must be able to demonstrate their ability to access the CMAP system application on a mobile phone independently [i. e. turn phone on, open app, use touchscreen to change app screen]. If unable to access the CMAP app independently, the participant will be thanked, given $25.00 for their time, but no further study activities will occur.

Veteran Exclusion Criteria:
Any Veteran with SCI/D who has an active pressure injury that contacts their seating system or with in the post six months of a flap surgery; Any Veteran with SCI/D who is unable to use a smart phone (physical ability) or to communicate with the study team verbally and cognitively; Any Veteran for whose primary seat cushion's pressure relief properties may be compromised by the mat as determined by the therapist. Cognition screening will be verified through the consenting process, if the potential participant is able to correctly respond to 3-5 questions about the study after going through the consent form. Also, after consent, verifying the participant's ability to access the app (digital and cognitive capability) will help the team know if the participant has the ability of completing study tasks.

Procedures
After being consented, the participant will be introduced and trained by Dr. Olney and Dr. Vos Draper and study staff to the updated CMAP app functions on a smart phone (provided by the study team), with the CMAP system mat in place on their wheelchair seat. The Veteran will practice using the app. Henceforth, the Veteran will have access to CMAP visual feedback whenever they are sitting in their wheelchair.
The below diagram depicts the data flow from the CMAP phone app to the Therapist's dashboard:



Study staff therapists will work with the Veteran using CMAP system to establish baseline information about the Veteran's weight shifts. By focusing on identifying frequency, consistency, duration, and effectiveness of weight shifts, the clinician will work with the Veteran to refine the Veteran's personal goals about actual performance of weight shift behaviors. Goals for Veteran behavior will be set between the Clinician and the Veteran, and set up in the Veteran's smart phone CMAP app. After goals are inputted into the smart phone app settings (e.g. frequency of reminders), the clinician will be able to track the performance of weight shifts throughout the remainder of the ten days of in-seat testing. During the testing period, the therapist will utilize these data to provide feedback to the Veteran about their performance in areas that are challenging or in need of change. This is targeted education.

We implement the CMAP system for a total of 10 days. We will not be using the system over the weekends. Therapists do not work on weekends, and study staff are not present to address potential trouble shooting over the weekend. We have conducted studies in the past with earlier versions of the CMAP system and are fully aware of potential technology issues with a new app and system, therefore study staff will be available to trouble shoot any evolving issues with the app and CMAP system during implementation phases. We will also supply a user manual, updating it as we move through the year to reflect any changes that are appropriate. We have attached a copy of the app user manual as it stands now (Attachment 4).

Sub-Epidural Moisture Measurements
Due to the rate of pressure injuries in this population, this study will take steps to detect early signs of pressure injury with participants before visual signs of skin breakdown are apparent. The Provisio Sub-Epidermal Moisture Scanner 200 (SEM) (Bruin Biometrics, LLC, Los Angeles, CA, USA) (see Fig.13) is an FDA-approved device designed to quantify pressure injury risk over the sacrum and heel via sub-epidermal moisture presence, a sign of tissue pressure/ischemia, up to 5 days prior to visible signs of early skin breakdown[34]. This device calculates a

biocapacitance/delta (Δ) value of pressure injury risk where ≥0.6 suggests potential early stage pressure injury. The SEM has been utilized in inpatient and nursing home settings, and a small study has been completed on SCI/D feasibility in a VA setting [35,36]. During participation in Phase 2 of this study, research nursing staff will utilize the SEM device for early pressure injury detection. The CMAP system has been utilized for long durations (e.g., up 1 month) without skin breakdown, however, the addition of the SEM will maximize risk protection and allow early intervention pathways to further protect the Veteran's skin.



Figure 13. Image of the Provizio SEM Scanner 200

Research nursing staff will conduct daily skin checks as per clinical standard of practice for visual signs of sign breakdown (e.g., visual inspection, capillary refill, blanching). In addition to the visual skin inspection, nursing research staff will use the SEM device to scan the skin covering the sacrum, and bilateral ischial tuberosities of each participant during daily nursing cares, one time daily. The SEM measurements will begin after consent into the study prior to sitting on the CMAP mat. The SEM measurements will continue throughout use of the CMAP seat mapping system. Visual inspection along with SEM measurements are intended to identify skin areas of breakdown/concern or pressure injury.

Scanning process:

Sacral Assessment (FDA-approved): During typical nursing cares, the participant will be positioned in side lying and hips flexed to approximately 80-90 degrees, to simulate sitting as able. Trained personnel will take six SEM measurements directly on dry, clean skin over the sacrum. The measurements are made by moving sequentially around the bony prominence. The recommended locations for Provizio SEM Scanner readings to complete for an assessment of the sacrum are shown below (Figure 14).



Fig 14. Image (Left) from the Provision SEM Handbook demonstrating the Sacral measurement locations from a posterior view, and Image (Right) shows approximate measurement locations over and around IT for a left ischial tuberosity from a lateral perspective.

Ischial Assessment (Investigational): Six SEM measurements will be taken over bilateral ischial tuberosities (IT). The measures will begin directly over the IT with the patient in side-lying with a simulated seated position (80-90 degrees of hip flexion) so that the skin being assessed is approximate to that on their seating surface under their ITs. Then, the measurements will move directionally outward in all directions: superior, inferior, medial, and lateral, with an additional measurement further laterally from the palpated ischial tuberosity. See Figure 14, above, for the planned sites for SEM measurements over the ischial tuberosities. We do not anticipate any safety issues (less bony than the sacral area) and do not anticipate that we will be establishing any confirmatory outcomes with our n=6 regarding the efficacy of the ischial testing.

If participant's SEM Δ readings are ≥0.6 (an early sign of pressure injury) in any one of the tested areas for 2 consecutive measures, (sacrum or ischial tuberosity), or their visual skin inspection are indicative for pressure injury, their enrollment will be paused. We will notify the clinical team, including study physician, of the pressure injury to invoke clinical standards of practice for pressure injury treatment. Their enrollment will resume if they are cleared to resume sitting activities and normal daily activities. If pressure injury does not resolve over the course of

the study (and while the subject is still inpatient), subject will be withdrawn.

Nursing staff will record daily information including but not limited to information on (1) useability of device, (2) SEM Δ/SEM measurements over both ischial tuberosities and sacrum, (3) time spent dedicated to SEM measures, (4) additional visual skin inspection information (See Attachment 7).

Data Collection and Analyses

Veteran participants will complete several scales before the interventions begin and after intervention is completed: 1) the Pressure Ulcer Knowledge Scale, a scale based on King's Skin Care Belief Scale [32], 2) a Self-Efficacy survey, developed by Dr. Vos-Draper and Dr. Morrow, to collect baseline information on perception of pressure injury risk and beliefs about performance of weight shifts. These scales are being used in parallel funded studies. (Attachments 5 and 6)

Veterans will be compensated up to $100 for participation, with the amount split as follows: $50.00 after consent and training on the app; and if they continue and finish the study $50.00 at end of study period.

Table 2 Aim 2 Outcomes

We will compare the usability scores with those obtained during third focus groups (Aim 1), with the goal of maintaining or improving the scores and also to objectively describe this new group's perception of usability in a specific setting. The self-efficacy measures will be completed prior to implementation and repeated after using CMAP as described earlier.

Aim	Outcome	Instrument	Analysis	When
2	Self-Efficacy (Clinician, repeated pre/post)	Customized scale	LMER Model	Y2Q4 - Y3Q3
	Self-Efficacy (Veteran- repeated pre/post	Customized	LMER Model	Y2Q4 - Y3Q3
	Pressure Ulcer Knowledge (Veteran- repeated pre/post)	Customized from the Skin Care Belief Scale	LMER Model	Y2Q4 - Y3Q3
	Usability (Veteran - repeated pre/post)	SUS	LMER Model	Y2Q4 - Y3Q3
	Usability (Veteran - repeated pre/post)	UEQ	LMER Model	Y2Q4 - Y3Q3
	Usability (Clinician - repeated pre/post)	SUS	LMER Model	Y2Q4 - Y3Q3
	Usability (Clinician - repeated pre/post)	UEQ	LMER Model	Y2Q4 - Y3Q3

*Linear Mixed Effects Regression Model

Data Management and Analyses Discussion Aim 2
All data will be secured per VA policies. The study team has worked with the facility ISSO to ensure all PHI and PII data throughout the study are always secure. Please consult the ERDSP application for details. We have employed Ms. Amy Gravely, our VA research center's statistician, to assist with the quantitative data analysis and interpretation. The Knowledge Scale, SUS, UEQ and self-efficacy repeated measures will be analyzed for each aim separately. All study team members will participate in analysis and interpretation of the data. Linear mixed effects regression modeling will be optimal for the repeated measures of usability and self-efficacy because it accommodates missing data, can accommodate different numbers of subjects across the measurements.

Aim 3: Determine usability and efficacy of refined CMAP system for clinician and patient use in the outpatient and home settings.

* *FROM THIS POINT FORWARD the term "AW-Shift" will be used interchangeably with "CMAP" as the system is in transition to the newer name. AW-Shift stands for Assisted Weight* Shift.

During Phase 1 and Phase 2 we made refinements to the clinical dashboard, based on user feedback, that are intended to optimize the amount of pertinent information provided to clinicians in the limited available clinical time for educating Veterans with SCID about healthy seating behavior. Now, in phase 3 of this 4-year merit funded proposal we will continue the refinements and begin testing the usability and efficacy of the clinical dashboard and the AW-Shift app system among Veterans with SCI in their home or outpatient settings.

Design

This prospective pilot study will ask Veterans with SCI/D (n = 12) to use the AW-Shift system for approximately three weeks, and participate up to six weeks, from first contact to completion of all data gathering . We will over recruit by five (n=5) to ensure we gain our participant goal of twelve and gain a complete data set by end of the study. Therefore, our total consented participants could be up to n=17. SCI/D seating specialists will inform (via surveys and interviews) the study team about usability, their self-efficacy in using this dashboard (a novel system) towards providing targeted education to the Veterans about their seating behavior. We will also query the Veteran with SCID about their experience using the AW-Shift app (surveys and interviews).

Sampling

Convenience sampling of Veterans with SCI/D will be used for Aim 3. Veterans with a SCI/D who receive care at the MVAHCS Spinal Cord Injury & Disorder (SCI/D) Center will be considered for enrollment and will not be excluded based on sex, race or ethnicity. The MVAHCS SCI/D treats all Veterans from all service branches and reaches patients from across the upper Midwest. There are approximately 20 new traumatic and non-traumatic SCI/Ds seen yearly and more than 300 adults with chronic SCI/D are seen yearly for follow-up.

Recruitment Aim 3

Veterans with SCI/D: Dr. Eddy will oversee all aspects of recruitment. Following Institutional Review Board (IRB) and R&D approval, clinicians from the MVAHCS SCI/D Center will identify Veterans with traumatic or non- traumatic SCI/D who meet inclusion criteria for Aim 3.

We will use three strategies for recruitment:

- Clinicians from the MVAHCS SCI/D Center will identify Veterans who meet inclusion criteria for Aim 3 and inform them that they might be eligible for participation in the study; study staff will contact these Veterans if they have given their permission.
- We will post study flyers (Attachment 1)in appropriate locations at the MVAHCS and with local organizations such as the Paralyzed Veterans of America Minnesota Chapter. The flyers would provide contact information for Veterans to contact the study team if interested in learning more about the study.
- We will complete a DART request for a VINCI report of Veterans with SCI/D receiving services at MVAHCS. We would screen records of these Veterans for eligibility and mail them a recruitment letter (Attachment 2) inviting their participation. Approximately seven days after mailing the letter study staff will attempt to contact the Veteran with recruitment phone calls.

Veteran Inclusion Criteria:
For Aim 3:

- Veteran adults aged 18-80, male and female, primarily manual or power wheelchair users who use a lift to get in and out of their wheelchair or seating surfaces;
- Veteran at least one year post SCI onset, AIS level C4 and below, or a spinal cord disorder with impaired sensory function;

- Veteran who is willing to come to the MVAHCS SCI/D Center for an initial study visit, or at the end of their in-house annual visit, or at end of a non-pressure injury stay in the hospital who will be going home;
- Veterans using the AW-Shift system must demonstrate ability to independently access the AW-Shift app on their mobile device;
- Veteran must have personal smart phone/device with access to regular WiFi connection in their home.
- Lives within 1.5 hours of the Minneapolis VA Health Care System, Minneapolis, MN

Veteran Exclusion Criteria:

- Any Veteran with SCI/D who has an active pressure injury with uncontrollable wound drainage, defined as drainage that saturates the wound dressing (that might impact the integrity of the device) or within the post six months of a flap surgery;
- Any Veteran with SCI/D who is unable to use a smart phone (physical ability) or to communicate with the study team verbally and cognitively.
    - Cognition screening will be verified through the consenting process, if the potential participant is able to correctly respond to 3-5 questions about the study after going through the consent form. Also, after consent, verifying the participant's ability to access the app (technology and cognitive capability) will help the team know if the participant has the ability of completing study tasks.
- Any Veteran for whose primary seat cushion's pressure relief properties may be compromised by the AW-Shift pressure sensing mat as determined by the seating specialist therapist e.g. an offloading custom cushion or custom-molded cushion.
- Any Veteran with SCI/D who utilizes a slide board for transfers to their wheelchair, power or manual wheelchair, due to interference with study device.
- Any Veteran with SCI/D who has history of neuropathic pain on the seating surface that interferes with tolerance to sitting on various surface materials.

The SCI/D physiatrist (Dr. Eddy) will screen the potential participant for any potential medical barriers to safe participation. Our study staff therapists will screen the potential Veteran participant for appropriateness for participation. After consent, to complete enrollment, the participant must be able to demonstrate their ability to access the AW-Shift system application on a mobile phone independently [i. e. turn phone on, open app, use touchscreen to change app screen]. If unable to access the AW-Shift app independently, the participant will be thanked, given $25.00 for their time, but no further study activities will occur.

Research Methods Aim 3:

Two SCI/D therapists have been identified by the service leader (Lori Danzl, Chief of Physical Therapy Department, Grace Wilske, Assistant Chief Occupational Therapy Department, and Ryan Bouslog, SCI/D Therapy Program Coordinator), to act as the SCI/D therapists for this aim. These SCI/D therapists are members of the research team. The Veteran will come to the Minneapolis VA for their initial study visit (Visit 1) with the study staff. After the informed consenting and screening process, the study team will place the CMAP system on the Veteran's wheelchair and educate the Veteran on how to use the system and have them conduct a return demonstration. The seating specialist (SCI/D Therapist) will work with the participant to determine user-specific goals/app settings for the performance of weight shifts and for appropriate reminders and alerts. While the SCI/D Therapist will strive for settings that match published guidelines, working with the Veteran to determine a goal that will fit into their daily routine and that they believe they can successfully accomplish will allow for these goals to be highly individualized. Following use, the SCI/D therapists will provide feedback on the process.

The Veteran will be sent home with the AW-Shift system in place unless the seating specialist (SCI/D Therapist) is concerned about seating system and/or significant pressure injury risk. If concerned, the clinician may refer the participant to the VA seating clinic and defer AW-Shift deployment until seating system concerns have been addressed. If the Veteran has an Apple Watch, they will also be offered to download the AW-Shift application to their watch for testing of the Apple Watch application.

The procedural activities are reflected in the Table below:

Table 3. Aim 3 Timeline

Study Timeline	Initial In-person visit (Visit 1)	AWS Home use: 7 days OFF	AWS Home use: 7 days ON	VVC Visit (Visit 2)	AWS Home use: 7 days ON		Veteran Final evaluation WebEx
Therapist actions	Pressure relieving goals	Monitor dashboard as able	Monitor dashboard as able	Provide individualized education & update AW-Shift Settings	Monitor dashboard as able		
Study staff actions	Consent/ Screening process, AW-Shift set up & Training Interview therapist	Daily data checks and troubleshooting; Call PPT on Day 7 to change app to ON	Daily data checks and troubleshooting; Present summarized 2-weeks' data to therapist	Facilitate VVC meeting between PPT and Therapist	Daily data checks and troubleshooting		WebEx interview with PPT Summary for Vet PPT
Vet PPT actions	Consent AW-Shift set-up at MVAHCS	Uses AW-Shift	Uses AW-Shift	Meets with therapist: review activity patterns and recommended changes			WebEx interview; Return AW-Shift via mail
Data collection	Therapist Pre-surveys Veteran Pre-surveys, Interview therapist			Interview therapist			Veteran Post-surveys Qualitative data

Once AW-Shift system is deployed, our study team will contact the participant every week and the participant will be able to contact the study team if needed to screen for concerns with the system or the participant (e. g. skin concerns, WiFi issues, questions about notifications from the app). Further, the study team will look at the data (on the cloud) twice a day to check that the system is uploading the system data and to understand if there are needed interventions in the data transmission. We will work closely with the participant to ensure there aren't long periods without data uploads. For example, if we observe no data on the cloud from an enrolled participant by 10 AM we may call the participant to ensure they are up and, in their wheelchair, and trouble shoot from there e. g. maybe their WiFi/Bluetooth is not turned on, maybe the battery on the system is dead, maybe they are still in bed. If trouble shooting is unsuccessful over the phone or via virtual meeting, we may send two study team members to the home to ensure the connection is complete. We do not anticipate this happening as we have conducted pilot work locally and believe we will be able to conduct trouble shooting from our office. Relevant statements from troubleshooting and screening calls will be documented for analysis and sharing with SCI/D therapist.

Approximately 14-days after initial visit where the AW-Shift is used (7 days "off", 7 days "on"), the team will create a data summary for SCI Therapists. Study staff will meet with SCI Therapist to review dashboard results from initial home trial. Veteran comments from the weekly calls will also be provided to SCI Therapist (e. g. additional information about pressure relief behavior including barriers, and perceptions during home use). Following use of the device, the SCI Therapists will provide feedback on the process.

Following the therapist reviewing summary of seating behavior information, the SCI/D therapist will meet with the participant, which may in-person or using VA Video Connect (VVC); the study staff will observe an education

session between the Veteran and SCI Therapist. This visit will focus on individualized pressure relief behavior based on AW-Shift clinical dashboard data. This video session maybe recorded and transcribed. Following this session, the participant will continue use of the AW-Shift system with feedback “on” for the next seven days. After an approximately 7-day period, the Veteran will return the AW-Shift system in return packaging (postage paid) supplied by the study. At the conclusion of their participation in the study, study staff will provide participants with a summary of the research activities as well as generic recommendations for frequent repositioning and pressure injury prevention.

Within 3-5 business days after each Veteran participant completes the study, the SCI Therapists will meet virtually to review and interpret results from the clinical dashboard data, complete semi-structured interview, and post-AW-Shift use surveys. Study staff during this same 3 to 5-day period will also ask the Veteran participant to meet via WebEx to complete semi-structured interview and post-AW-Shift use surveys. If the Vet has an Apple watch we will include this evaluation in the semi-structured interviews.

Data Collection and Analyses Aim 3

Veteran participants will complete several scales before the interventions begin and after intervention is completed:

1) Pressure Ulcer Knowledge Scale, a scale based on King’s Skin Care Belief Scale [32],
2) Veterans Self-Efficacy survey, non-validated survey developed by Dr. Vos-Draper and Dr. Morrow,

These two tools (Attachments 4 & 5) will help us understand possible change on perception of pressure injury risk and beliefs about performance of weight shifts. These scales are being used in parallel funded studies.

The therapists will provide feedback on the AW-Shift tool using the Therapist Self-Efficacy for Weight Shifts to Prevent Pressure Injuries Scale, a non-validated survey developed by Dr. Vos-Draper and Dr. Morrow (Attachment 6),

Both SCI Therapists and Veterans will complete the System Usability Scale (SUS) and User Experience Questionnaire (UEQ), which are validated surveys for objective feedback on usability, before and after use of the AW-Shift system (Attachments 7 and 8). Veterans will also be asked to complete the Neurological Assistive Technology Usability (NATU) Questionnaire as it is specific to users with neurological challenges, thus providing validation of our other usability queries. We have asked for and gained permission from the author to use this tool. Attachment 9. Further, following completion of the AW-Shift use at home, study staff will conduct semi-structured interviews of Veteran participants to learn about their subjective experiences using AW-Shift. SCI therapists will provide subjective feedback. (Attachments 10 and 11).

Semi-structured interviews with the participating Veterans may include questions like the following: How did the feedback from the application affect your in-seat movements, or perception of your sitting surface? Additional questions may be asked to clarify individual experiences, but these questions will avoid being personal or probing. SCI/D Therapists will provide feedback such as: what worked for you on the dashboard? Were you able to easily access the important data? Please see Attachments 10 and 11 for list of potential interview questions.

Veterans will be compensated up to $125 for participation during Phase 3, with the amount split as follows: $50.00 after initial in hospital visit and $50.00 at end of study period. The study will also include transportation reimbursement with $25 to cover costs of attending initial in-person visit.

Table 3 Aim 3 Outcomes

We will compare the usability scores with those obtained during Phase 1 third focus groups and Phase 2 pilot testing (Aim 1 & Aim 2), with the goal of maintaining or improving the scores (i. e. refinement) and also to objectively describe this new group’s perception of usability in a specific setting (outpatient/home). The self-efficacy and knowledge measures will be completed prior to implementation and repeated after using AW-Shift as described earlier.

Aim	Outcome	Instrument	Analysis
3	Self-Efficacy (Clinician, repeated pre/post)	Customized scale	nonparametric tests
	Self-Efficacy (Veteran- repeated pre/post	Customized scale	nonparametric tests
	Pressure Ulcer Knowledge (Veteran- repeated pre/post)	Customized from the Skin Care Belief Scale	nonparametric tests
	Usability (Veteran - repeated pre/post)	SUS	nonparametric tests
	Usability (Veteran - repeated pre/post)	UEQ	nonparametric tests
	Usability (Clinician - repeated pre/post)	SUS	nonparametric tests
	Usability (Clinician - repeated pre/post)	UEQ	nonparametric tests
	Usability (Veteran - repeated pre/post)	NATU[37]	nonparametric tests

Data Management and Analyses Discussion (Aim 3)
All data will be secured per VA policies. The study team has worked with the facility ISSO to ensure all PHI and PII data throughout the study are always secure. Please consult the ERDSP application for details. We have employed Ms. Amy Gravely, our VA research center's statistician, to assist with the quantitative data analysis and interpretation. The Knowledge Scale, SUS, UEQ, NATU and self-efficacy repeated measures will be analyzed for each aim separately. All study team members will participate in analysis and interpretation of the data. Non-Parametric test will be optimal for the measures of usability and self-efficacy, as the sample size is small.

Potential Benefits

There is no known direct benefit to the participants for any of the phases of this study. We are still in the development phase of the CMAP system, therefore cannot say there will be a participant benefit. Veterans and clinicians in the future may benefit from the knowledge gained from this study's outcomes.

Potential Risks

Aim 1: We will audio record the participants during the focus groups for data analysis by the study team. De-identified audio may be used in publications and presentations. There is the risk that the participants identity will be disclosed by being recognized in publications or presentations.

Clinicians in Phase 1 will be asked for their basic professional credentials and basic demographics. There is minimal risk that they be identified through these data supplied to the study as the professional and demographic data reported as norms.

Because EMR will be accessed for recruitment and payment purposes there is a risk, albeit minimal, that private personal information will be inadvertently viewed by the research personnel.

Participants may experience inconvenience by participating in the study. To compensate for the time and trouble Veterans with SCI/D will receive remuneration. In Phase 1 clinicians will be participating in focus groups over their lunch hour or after their shift. In Aim 2, clinicians will *not* be compensated as they are study staff and the addressing seating behavior is part of standard pressure injury prevention education.

In Aim 2: One potential risk could be the possibility of the Veteran falling during a transfer in and out of your wheelchair. This risk is no greater than falling from transfers in their daily life. Any transfers related to study activities will be done under the care and observation of qualified study staff. It is also possible that impaired skin integrity could occur due to the addition of pressure mat material between the Veteran and their seat cushion. The pressure mat materials could lead to increased heat and/or moisture, which are contributing factors to some pressure injuries. A fold in the material could also occur, creating increased pressure, which could also lead to a pressure injury. Based on preliminary studies that assessed the effect of the mat on skin, the risk of developing a pressure injury due to use of the mat on your wheelchair cushion is minimal. In fact, we have had participants in other studies sit on this mapping system for up to a month with no evidence of skin integrity issues. In addition to placing the mat correctly, daily visual skin checks and daily Sub-Epidermal Moisture (SEM) measures will be taken, which will be necessary to proactively identify any skin problems early. If a skin integrity concern is identified during the skin checks, we will work with the SCI/D staff (Dr. Eddy and wound personnel) to protect the area of concern and we reserve the right to withdraw the Veteran from the study if we feel further participation may cause them harm.

In Aim 3: One potential risk could be the possibility of the Veteran falling during a transfer in and out of their wheelchair during the initial clinic visit. This risk is no greater than falling from transfers in their daily life. Any transfers done in the clinic will be done under the care and observation of qualified study staff. It is also possible that impaired skin integrity could occur due to the addition of pressure mat material between the Veteran and their seat cushion. The pressure mat materials could lead to increased heat and/or moisture, which are contributing factors to some pressure injuries. A fold in the material could also occur, creating increased pressure, which could also lead to a pressure injury. Based on preliminary studies that assessed the effect of the mat on skin, the risk of developing a pressure injury due to use of the mat on your wheelchair cushion is minimal. In fact, we have had participants in other studies sit on this mapping system for up to a month with no evidence of skin integrity issues. During weekly calls study staff will inquire whether a participant might be experiencing a potential pressure injury in their seating area. If a skin integrity concern is identified during the weekly screening calls, we will discontinue study activities until a medical assessment of the skin concern is completed and we are given assurances to restart. We reserve the right to withdraw the Veteran from the study if we feel further participation may cause them harm. That said we will allow persons with known chronic pressure injury into the study, if the wound is managed by SCI/D wound care team and is not draining profusely and the Veteran with SCI/D is not on an offloading custom or custom-molded cushion in which the AW-Shift might negate those cushions properties. Our seating specialists will be the drivers for clinical decisions in this situation (e. g. inclusion criteria are met, and not increasing risk to the participant). The wound team has asked that we allow this as an inclusion as they need to learn how to better approach seating behavior with this high-risk group of Veterans with SCI/D. We believe that the wounds would not progress negatively in this scenario, but rather may improve due to the awareness of off-loading the wound on a regular basis.

During final interviews (WebEx/TEAMS) and VVC visit, we may utilize a video recording for transcription to collect semi-structured interview results for analysis. Only de-identified audio transcriptions and interpretations will be utilized in publications and presentations. Other certified de-identified data may be shared with study collaborators (University of Texas, Galveston and University of Minnesota). There is a risk that the participant identity will be disclosed by being recognized in these publications and presentations or by the study collaborators.

These risks are reasonable in relation to the new knowledge gained. Feedback from users of the AW-Shift system has potential to be highly valuable in guiding development of a more effective pressure injury behavior. This study will improve the potential for commercialization, benefitting many more patients with similar needs.

Compensation for Veterans' and clinicians' participant follows:

Aim 3	Clinic Visit	Completion	Transportation
Aim 3- Veterans	$50.00	$50.00	$25

Participants will be compensated by electronic funds transfer.

Confidentiality and Data Security. All VA sensitive research data for this protocol recorded on paper records will be stored in a locked file cabinet, in the PIs locked office or the Study Coordinator's locked cabinet, inside a security card-controlled research wing of the hospital. It will be available to and used only by approved study personnel. All electronic data collected during the study will be stored on VA servers behind VA firewalls on security card protected computers. Data in transmission and stored at rest will be encrypted, See Attachment 12 for data flow. The PI and staff will ensure the proposed research is in compliance with relevant privacy, confidentiality, and information security requirements. Study staff has worked with a team of VA systems ISSOs (information system security officers) to ensure that the data acquisition, transmission, and storage of the system meets policies regarding digital information security.

Data and Safety Monitoring Plan. A ERDSP has been filed and reviewed by our ISSO, addressing security of all sensitive data within this study. Further, to minimize risk, all VA sensitive research data for this protocol, including participant data and PHI, will be stored on a secure VA server behind the necessary VA firewalls. In addition, data recorded digitally over the course of the study will be saved in a secure folder behind the VA firewall. Only approved study staff and administrators will have access to this secure data folder. This is in accordance with the Minneapolis Research Service Data Security Plan. The PI will ensure that all data storage locations will be kept current in the Minneapolis VAHCS Data Inventory database. In order to preserve privacy only de-identified, anonymized dataset will be created and shared with study colleagues for analysis. The PI will provide oversight for the security of the data and conduct of the study. Study records will be maintained in a secure location (locked cabinets in locked offices and secure wing, and electronically behind as listed above) and destroyed according to VA Federal Records requirements in VHA Record Control Schedule (RCS 10-1) which is currently 6 fiscal years following the closure of the study.

Inclusion of Women, Minorities, and Children – Children will not be included in this study because it is focused on Veterans, who must be adults to have served in the military. We will not target Veterans of specific sex or race for this study. Our population of patients in Minneapolis is largely Caucasian males. In future multi-site studies, we will try to engage other sites that have more diversity.

Hazards
We do not have any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

Project Timeline

Action	Year 1				Year 2				Year 3				Year 4			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Recruitment for all Aims																
Aim 1a																
Veteran Focus groups																
Hardware redesign																

Aim 1b																
Clinician Focus groups																
Software redesign																
Aim 2																
Clinician education																
In-Patient Pilot																
Aim 3*																
Out-Patient Pilot																
Analysis/Dissemination																

*The Merit funding is for a 4-year study, started in April 2020. We are purposefully staging IRB approvals due to the wide variations in data management between Aims. We have prior approval for Phase 1 & 2. Given that, we are now submitting this protocol, adding Phase 3 (Aim 3) for approval.

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