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AWARD NUMBER: W81XWH-16-1-0581

TITLE: Development, Reliability, and Equivalence of an
Alternate Form for the CQ Duty Performance-based Measure

PRINCIPAL INVESTIGATOR: Mary Vining Radomski

CONTRACTING ORGANIZATION: Allina Health
Minneapolis, MN 55407

REPORT DATE: October 2018

TYPE OF REPORT: Annual

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

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REPORT DOCUMENTATION PAGE

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1. REPORT DATE Oct 2018			2. REPORT TYPE Annual		3. DATES COVERED 30 Sep 2017 - 29 Sep 2018	
4. TITLE AND SUBTITLE Development, Reliability, and Equivalence of an Alternate Form for the CQ Duty Performance-based Measure					5a. CONTRACT NUMBER	
					5b. GRANT NUMBER W81XWH-16-1-0581	
					5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Mary Vining Radomski E-Mail: mary.radomski@allina.com					5d. PROJECT NUMBER	
					5e. TASK NUMBER	
					5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Allina Health System 800 E. 28 th Street Minneapolis, MN 55407-3723					8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012					10. SPONSOR/MONITOR'S ACRONYM(S)	
					11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited						
13. SUPPLEMENTARY NOTES						
14. ABSTRACT Previous research demonstrated that the recently-developed Charge of Quarters Duty Test (CQDT), a performance-based assessment of executive function, can be reliably administered and distinguishes between known-groups of healthy control soldiers and those with traumatic brain injury. As such, the CQDT shows promise in helping to inform readiness to return to duty and need for rehabilitation. However, performance based assessments that involve multitasking such as the CQDT, cannot be repeated as a post-treatment outcome measure due to learning effects. Therefore, an equivalent alternate form is needed. <u>Research Question #1.</u> Can an expert team of military, Veterans Administration, and civilian rehabilitation researchers and clinicians develop an equivalent alternate form of the CQD that is experienced as novel by SM with mTBI? <u>Research Question #2.</u> To what extent can 2 independent raters achieve acceptable levels of inter-rater reliability in scoring subject performance of CQD-Original (CQD-O) and CQD-Alternate Form (CQD-AF)? <u>Research Question #3.</u> To what extent is the CQD-AF equivalent to the CQD-O based on a) difference of paired scores for both forms of the CQD and b) correlation between participants' performance of neurocognitive measures of executive functioning and each version of the CQD?						
15. SUBJECT TERMS mild traumatic brain injury; implementation intentions; executive function; metacognitive strategy instruction						
16. SECURITY CLASSIFICATION OF: U			17. LIMITATION OF ABSTRACT Unclassified	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC	
a. REPORT Unclassified	b. ABSTRACT Unclassified	c. THIS PAGE Unclassified			19b. TELEPHONE NUMBER (include area code)	

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1. INTRODUCTION: Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

Many Service Members (SM) experience concussion (also known as mild traumatic brain injury [mTBI]) as a result of military combat and training, motor vehicle crashes, and sports-recreational activities. After mTBI, SM may experience an array of sensorimotor and cognitive problems, including difficulty with executive functions. Executive functions refer to higher order thinking abilities that enable goal-directed behavior, particularly in novel situations where people lack well-learned behaviors to draw upon. Because there are evidence-based cognitive rehabilitation interventions that can improve executive functioning, it is important to identify SM with mTBI with executive dysfunction who should be referred to these services before resuming high-consequence activities such as military duty. Unfortunately, executive dysfunction often goes undetected because traditional neurocognitive measures are designed to evaluate single domains rather than integrated functioning and the high levels of structure inherent in these assessments fail to adequately challenge the impaired functions. Performance-based assessment requires the patient to perform tasks that simulate the demands of everyday activities while the examiner uses behaviorally-based metrics to quantify functioning. **Performance-based measures designed to incorporate multitasking appear to be particularly sensitive to detecting deficient executive functions.** Existing performance-based involving multitasking have demonstrated sensitivity to executive dysfunction but the nature of the task components may lack face validity for SM with mTBI and their superiors, especially as related to readiness for return to duty.

Previous research demonstrated that the recently-developed Charge of Quarters Duty Test (CQDT), a performance-based assessment of executive function, can be reliably administered and distinguishes between known-groups of healthy control soldiers and those with traumatic brain injury. As such, the CQDT shows promise in helping to inform readiness to return to duty and need for rehabilitation. However, performance based assessments that involve multitasking such as the CQDT, cannot be repeated as a post-treatment outcome measure due to learning effects. Therefore, an equivalent alternate form is needed.

Research Question #1. Can an expert team of military, Veterans Administration, and civilian rehabilitation researchers and clinicians develop an equivalent alternate form of the CQD that is experienced as novel by SM with mTBI?

Technical Objective #1: Develop an alternate form of the CQD.

Research Question #2. To what extent can 2 independent raters achieve acceptable levels of inter-rater reliability in scoring subject performance of CQD-Original (CQD-O) and CQD-Alternate Form (CQD-AF)?

Technical Objective #2: Assure rater agreement across 2 raters.

Research Question #3. To what extent is the CQD-AF equivalent to the CQD-O based on a) difference of paired scores for both forms of the CQD and b) correlation between participants' performance of neurocognitive measures of executive functioning and each version of the CQD?

Technical Objective #3: Evaluate equivalence of CQD-AF.

2. KEYWORDS: Provide a brief list of keywords (limit to 20 words).

Mild traumatic brain injury symptom complex
Executive function
Performance-based assessment
Multitasking
Alternate form

3. ACCOMPLISHMENTS: The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Table 1. Goals, milestones, and status

As of 9-29-18	Estimated, Updated Timeline	Status	% of Study Activities Completed
STUDY PART 1			
Technical Objective 1: Develop a CQD-AF			
Subtask 1: Establish contracts and critical documents for all participating institutions, contracts, and consultants	Oct. -Nov. 2016	Completed	100%
Subtask 2: Obtain Allina Health IRB and ORP/HRPO approval to conduct study	Dec. 2016 – May 2018	Completed	100%
Develop and submit research protocol to the Allina Health IRB for Part 1 (<i>CQD-AF development</i>) (formal data collection for all technical objectives to occur only at CKRC)	Nov. – Dec. 2016	Completed	100%
Once approved by the Allina Health IRB, submit protocol to USAMRMC Office of Research Protections for Part 1, as needed.	May 2017	Completed	100%
Order supplies: CQD-O test materials, camcorder	Nov. 2016	Completed	100%
Create study database for Part 1	Feb.-May. 2017	Completed	100%
Subtask 3: Characterize CQD-O			
Finalize CQD-O task analysis methodology	Nov. 2016 – Jan. 2017	Completed	100%
CQD-O document review; administration of CQD-O for experiential analyses	Nov. 2016 – Jan. 2017	Completed	100%
Recruit volunteers at CKRI; video-record performance of CQD-	July 2017	Completed	100%
Hierarchical and cognitive task analyses based on video-recorded performance of CQD-O	August 2017	Completed	100%
Subtask 4: Specify an optimal CQD-AF			
Team work groups generate, develop options for CQD-AF	Oct. – Nov. 2017	Completed	100%
Identify 2 best CQD-AF options; reduce to practice and informally administer (no formal data collection)	December 2017	Completed	100%
Team consensus meeting to select optimal version of CQD-AF for subsequent evaluation and to finalize Phase 2 protocol	January 2018	Completed	100%
Further testing and refinement of CQD-AF in preparation for Phase 2	January – March 2018	Completed	100%
STUDY PART 2			

Subtask 2: Obtain Allina Health IRB and ORP/HRPO approval to conduct study			
Develop and submit research protocol to the Allina Health IRB for Part 2 (<i>CQD-AF validation</i>) (formal data collection for all technical objectives to occur only at CKRC)	April 2018	Completed	100%
Once approved by the Allina Health IRB, submit protocol to USAMRMC Office of Research Protections for Part 2, as needed.	June 2018	Completed (submitted, waiting HRPO approval)	90%
Create study database for Part 2	October 2019	Not started	0%
Technical Objective 2: Assure rater agreement across 2 raters			
Subtask 1: Recruit and consent up to 14 participants (full data set on minimum of 10)	October – December 2018	Not started	0%
Subtask 2: Administer CQD-O and CQD-AF to up to 14 participants to verify interrater reliability with 2 raters			
Technical Objective 3: Evaluate equivalence of CQD-AF			
Subtask 1: Recruit and consent up to 46 participants (full data set on minimum of 34)	November – April 2019	Not started	0%
Subtask 2: Administer CQD-O, CQD-AF, and neurocognitive measures to up to 46 volunteers			
Subtask 2: Assure protocol fidelity and adherence to all IRB requirements	September 2018–April 2019	Not started	0%
Enter data into study database.	October 2018 – April 2019	Not started	0%
Major Task: Data Analysis & Dissemination			
Perform all analyses according to specifications, share output and finding with all investigators	April – Sept. 2019	Not started	0%
Work with data core and dissemination of findings (abstracts, presentation, publications, DOD)			

Projected Quarterly Enrollment

	Year 1				Year 2				Year 3			Total
	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	
Target Enrollment (per quarter)												
Courage Kenny Research Center (<i>Target</i>)	-	-	2	-	-	8		12	20	20	8	70
Target Enrollment - Cumulative	-	-	2	-	-	10		22				
Courage Kenny Research Center (<i>Actual</i>)			2			7	0	0				
Actual Enrollment - Cumulative			2			9	9	9				

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Technical Objective 1: Develop a CQD-AF

Subtask 4: Specify an optimal CQD-AF

Achievement: We used a systematic process to develop the procedures for the Maintenance Office Duty Test (MODT) as a potential CQD-O alternate form.

In Year 1, the research team used a systematic process to specify the cognitive and sensorimotor demands of the CQDT (the original version of the test). In Year 2, these findings were used to inform a test development process in which 2 sub-teams were each charged with designing at least 2 alternate form options, 4 total (multitasking contexts: fuel-check maintenance office; briefing scenario; camping; standing up a FOB market). Each of these options were subjected to task analysis using the same framework used in analyzing the CQD-O and the Burgess definition of multitasking. During an all-team TCON on December 4, 2017, all 4 options were presented and evaluated; the team determined that Fuel-check Maintenance and Camping CQD-AF options offered the most potential as logistically feasible, reasonable face validity, and potential equivalence with the CQD-O. Those 2 test scenarios were reduced to practice and 2 participants' performances of both test options were videorecorded and analyzed by the research team.

On January 8, 2018, the entire team participated in an all-day work session to evaluate the 2 best CQD-AF options and select the one with the most promise for equivalence. Team members used experiential task analyses, observation, and discussion to come to consensus on the alternate form to advance to equivalence testing – the Maintenance Office Duty Test (MODT). Subsequently, 5 occupational therapists performed both CQDT and MODT, rating challenge associate with various tasks domains. Results were used to finalize MODT refinements; experiential analyses suggesting that CQDT and MODT have similar task challenges (see Figures 1 & 2).

Figure 1. Demand impressions: Close agreement on the Concentration and Time-Related dimensions with respect to comparative demands for the two test versions; wide variation among rater impressions for Ease & Frustration, Memory, and Supplies/Materials dimensions; intermediate levels of rater agreement for Planning, Problem Solving, Instructions.

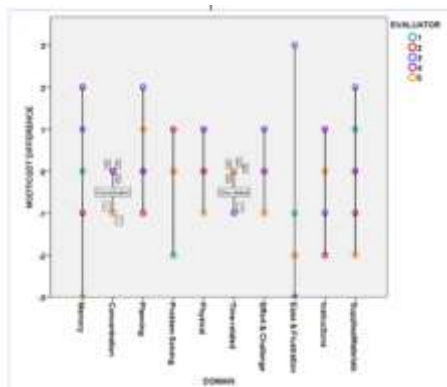


Figure 2. Krippendorff's alpha rater agreement results for CQDT and MODT suggest moderate rater agreement of comparative demands.

	Alpha	LL95%CI	UL95%CI	Units	Observers	Samples
CQDT	.4486	.2964	.5867	10	5	10,000
MODT	.4607	.3279	.5849	10	5	10,000

Technical Objective 2: Assure rater agreement across 2 raters and Technical Objective 3: Evaluate equivalence of CQD-AF

Subtask 2: Obtain Allina Health IRB and USAMRMC HRPO approval to conduct Part 2 of the study

Achievement: The Allina Health IRB approved the Part 2 protocol on June 7, 2018

In March 2018, the research finished the process of specifying the Part 2 protocol. The protocol was submitted to the Allina Health IRB on May 14, 2018 and approved on June 7, 2018. The protocol was submitted to USAMRMC HRPO on June 13, 2018. On July 13, 2018, Dr. Effiong (HRPO Human Subjects Protection Scientist) emailed requests related to the protocol; Dr. Radomski responded to all requests on July 24, 2018. Dr. Radomski contacted Dr. Effiong in August and September regarding project status and did not receive replies. On September 17, 2018, Dr. Radomski was contacted by Ms. Jacqueline Kiwanuka (HRPO Human Subjects Protection Scientist), who was assuming responsibility for protocol review at HRPO.

During the 4th quarter of Year 2 and as we waited for HRPO approval, we assembled all data collection materials and supplies; set up testing spaces. Data collectors practiced administering all measures to prepare for actual data collection.

Dr. Radomski submitted a request for a No Cost Extension on August 31, 2018.

Goals not met:

As of the end of Year 2 (September 29, 2018), the project was not yet approved by HRPO. However, approval was granted on October 9, 2018. In part because of IRB/HRPO delays, we were not able to commence Part 2 participant recruitment and data collection in Year 2.

Dissemination

- Results of Part 1 of the study were presented as part of a short course at the American Occupational Therapy Association’s Annual Meeting – April 19, 2018 (see Section 6 of this report).
- Dr. Radomski participated in an IPR at Fort Detrick on April 12, 2018.

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

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. “Training” activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. “Professional development” activities result in increased knowledge or skill in one’s area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Nothing to report.

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to report.

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

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

Goals and objectives	Planned activities for the next quarter
Technical Objective 2: Assure rater agreement across 2 raters	
Subtask 1: Recruit and consent up to 14 participants (full data set on minimum of 10)	-Create study database -Commence recruitment and participant enrollment
Subtask 2: Administer CQDT and MODT and neurocognitive measures on to up to 14 participants to verify interrater reliability with 2 raters	-Collect full data sets on at least 10 participants using 2 raters in order to assure rater agreement in scoring CQDT and MODT

4. IMPACT: Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

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

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to Report.

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report.

What was the impact on technology transfer?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report.

What was the impact on society beyond science and technology?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report.

5. **CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:

Changes in approach and reasons for change

Describe any changes in approach during the reporting period and reasons for these changes.

Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing to report

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

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

The USAMRMC HRPO approval took longer than anticipated, especially for a minimal risk study for which all data collection will occur within Allina Health. The longer than expected process was made more challenging because of Dr. Effiong’s lack of responses to Dr. Radomski’s inquiries (later explained by the fact that at some point during the Summer of 2018, he left HRPO). This process was in contrast to our past work with USAMRMC that was notably more efficient and collaborative.

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Nothing to report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

None.

Significant changes in use or care of vertebrate animals.

N/A

Significant changes in use of biohazards and/or select agents

N/A

6. PRODUCTS: List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state “Nothing to Report.”

- **Publications, conference papers, and presentations**
Report only the major publication(s) resulting from the work under this award.

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report

Books or other non-periodical, one-time publications. Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: Author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).

Nothing to Report

Other publications, conference papers, and presentations. Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.

Radomski, MV. Translating Post - 911 Era Military and Veteran Occupational Therapy Research to Civilian Practice: Development, Reliability, and Equivalence of an Alternate Form for the CQ Duty Performance-based Measure. American Occupational Therapy Association Annual Conference. Salt Lake City, UT: April 19, 2018.

- **Website(s) or other Internet site(s)**

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

None.

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.

Nothing to report.

- **Inventions, patent applications, and/or licenses**

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

None.

- **Other Products**

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment, and/or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *biospecimen collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

None.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate “no change.”

Name:	Mary Vining Radomski
Project Role:	PD/PI
Researcher Identifier (e.g. ORCID ID):	0000-0003-0600-4494
Nearest person month worked:	1

Contribution to Project:	Dr. Radomski contributed the following: -Developed and submitted the Part 2 IRB protocol to Allina Health and USAMRMC -Worked with study coordinator to set up team TCONs, facilitated meetings and distributed minutes -Contributed to development of CQD-AF options -Worked with statistician to analyze and interpret experiential analyses
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Funding Support:

This grant

There were no other individuals who contributed at least one person month over the past year. This is anticipated to change in Year 2 of the study.

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

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to report

What other organizations were involved as partners?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:

Organization Name:

Location of Organization: (if foreign location list country)

Partner’s contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner’s facilities for project activities);*
- *Collaboration (e.g., partner’s staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner’s staff use each other’s facilities, work at each other’s site); and*
- *Other.*

Nothing to report.

Development, Reliability, and Equivalence of an Alternate Form of the CQ Duty Performance-based Measure

ERMS/Log Number: BA150325

W81XWH-16-1-0581

PI: Mary Vining Radomski, PhD, OTR **Org:** Allina Health/Courage Kenny Research Center **Award Amount:** \$247,961.00



Study Aims

Technical Objective #1: Develop an alternate form of the CQD.

Technical Objective #2: Assure rater agreement across 2 raters in administering the CQDT-Original (CQDT-O) and CQDT-Alternate Form

Technical Objective #3: Evaluate equivalence of CQDT-AF based on a) difference of paired scores for both forms of the CQDT and b) correlation between participants' performance of neurocognitive measures of executive functioning and each version of the CQDT .

Approach

This study involves 2 parts. In part 1, a team of rehabilitation research experts from military, VA, civilian sectors will conduct task analyses of the CQDT-O in order to characterize key demands. Based on the results, the team will develop 2 workable CQDT-AF, conduct similar task analyses, and select the option that appears to be equivalent to the CQDT-O. In part 2, up to 60 individuals (some with a history of mild TBI) will be recruited. Inter-rater agreement will be evaluated by 2 raters on the first 10-15 subjects. All subjects will perform CQDT-O, CQDT-AF, and neurocognitive measures to assess construct validity.



Performance-based measures that involve multitasking appear to be sensitive to deficient executive functions that can occur with TBI; this type of test can't be repeated due to practice effects. The CQD Test (CQDT), part of the recently developed *Assessment of Military Multitasking Performance*, was found to be reliable and differentiate between healthy controls and SM with mild TBI. **If we succeed in developing an equivalent alternate form, the CQDT may be used to both identify executive dysfunction and quantify treatment outcomes in SM with mTBI.**

Accomplishments (Yr 2, Q8): Obtained all materials and supplies needed for Part 2 data collection; set up data collection spaces; practiced data collection procedures; responded to HRPO requests; waited for HRPO notification to proceed with data collection; submitted request for NCE.

Timeline and Cost

Activities	CY	16	17	18	19
Establish contracts; prepare for task analyses; submit Part 1 protocol to Allina IRB		█	█		
Develop CQDT-AF			█	█	
Conduct validation study on CQDT-AF				█*	
Data analysis and dissemination				█*	
Estimated Budget (\$K)		\$10	\$40	\$80	\$110

*We requested a NCE on 8-31-18.

Updated: 10/25/18

Goals/Milestones

CY16 Goal – Study kick off

- Functionality tests of integrated firmware and software
- Development and submission of Part 1 protocol to Allina IRB
- Obtain approval from Part 1 protocol to USAMRMC HRPO

CY17 Goals – Develop CQD-AF

- Conduct task analyses to characterize CQD-O
- Develop CQD-AF options

CY18 -19 Goal – Complete validation study; analyze/report findings

- Select best CQDT-AF option to subject to validation
- Part 2 protocol approved by AH 6-7-18 and by HRPO 10-9-18
- Begin subject enrollment, data collection for validation study (part 2)
- Complete subject enrollment, data collection for validation study
- Analyze data
- Report findings

Comments/Challenges/Issues/Concerns: N/A

Budget Expenditure to Date

Projected Total Expenditure: \$247,961.00

Actual Expenditure to date: \$ 99,315