MEMORANDUM FOR SGSP
ATTN: MAJ SHAOPING MO SUMNER

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval


2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.

3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are a 59 MDW staff member, we can forward your request for funds to the designated Wing POC at the Chief Scientist’s Office, Ms. Alice Houy, office phone: 210-292-8029; email address: alice.houy.civ@mail.mil.

4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

*Warrior Medics — Mission Ready — Patient Focused*
PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

INSTRUCTIONS

USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON AF E-PUBLISHING

1. The author must complete page two of this form:
   a. In Section 2, add the funding source for your study (e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE); SGS O&M; SGS R&D; Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRDP); NIH; Congressionally Directed Medical Research Program (CDMRP); Grants; etc.)
   b. In Section 2, there may be funding available for journal costs, if your department is not paying for figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form, if you need publication funding support.

2. Print your name, rank/rank, sign and date the form in the author’s signature block or use an electronic signature.

3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g. case report, QA/QI study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box.

4. Attach a copy of your abstract, paper, poster and other supporting documentation.

5. Save and forward, via email, the processing form and all supporting documentation to your unit commander, program director or immediate supervisor for review/approval.

6. On page 2, have either your unit commander, program director or immediate supervisor:
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7. Submit your completed form and all supporting documentation to the CRD for processing (59crdpubspres@us.af.mil). This should be accomplished no later than 30 days before final clearance is required to publish/present your materials. If you have any questions or concerns, please contact the 59 CRD/Publications and Presentations Section at 292-7141 for assistance.

8. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations, 502 ISG/JSAC (Ethics Review) and Public Affairs (59 MDW/PA) for review and then forward you a final letter of approval or disapproval.

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10. If your manuscript is accepted for scientific publication, please contact the 59 CRD/Publications and Presentations Section at 292-7141. This information is reported to the 59 MDW/C. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DTIC). See 59 MDW 41-108, Presentation and Publication of Medical and Technical Papers, for additional information.

11. The Joint Ethics Regulation (JER) DoD 5500.07-R, Standards of Conduct, provides standards of ethical conduct for all DoD personnel and their interactions with other non-DoD entities, organizations, societies, conferences, etc. Part of the Form 3039 review and approval process includes a legal ethics review to address any potential conflicts related to DoD personnel participating in non-DoD sponsored conferences, professional meetings, publication/presentation disclosures to domestic and foreign audiences, DoD personnel accepting non-DoD contributions, awards, honoraria, gifts, etc. The specific circumstances for your presentation will determine whether a legal review is necessary. If you (as the author) or your supervisor check "NO" in block 17 of the Form 3039, your research or technical documents will not be forwarded to the 502 ISG/JSAC legal office for an ethics review. To assist you in making this decision about whether to request a legal review, the following examples are provided as a guideline:

   For presentations before professional societies and like organizations, the 59 MDW Public Affairs Office (PAO) will provide the needed review to ensure proper disclaimers are included and the subject matter of the presentation does not create any cause for DoD concern.

   If the sponsor of a conference or meeting is a DoD entity, an ethics review of your presentation is not required, since the DoD entity is responsible to obtain all approvals for the event.

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NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement:

"The views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components"

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"The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402."

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"The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication No. 80-23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended."
**PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS**

1. **TO:** CLINICAL RESEARCH
2. **FROM:** (Author's Name, Rank, Grade, Office Symbol)
   Shaoping Mo Sumner, Major/O-4, SGSP
3. **GME/GHSE STUDENT:** YES NO
4. **PROTOCOL NUMBER:** C.207.024e

5. **PROTOCOL TITLE:** (NOTE: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.)
   Assessing Medication Adherence in Patients with Rheumatoid Arthritis (RA)

6. **TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED:**
   Assessing Medication Adherence in Patients with Rheumatoid Arthritis (RA)

7. **FUNDING RECEIVED FOR THIS STUDY?** YES NO FUNDING SOURCE:

8. **DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES:** YES NO

9. **IS THIS MATERIAL CLASSIFIED?** YES NO

10. **IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.?** YES NO NOTE: If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.

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12. **HAVE YOUR ATTACHED RESEARCH/TECHNICAL MATERIALS BEEN PREVIOUSLY APPROVED TO BE PUBLISHED/PRESENTED?**

13. **EXPECTED DATE WHEN THE CRAD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC**

14. **59 MDW PRIMARY POINT OF CONTACT** (Last Name, First Name, M.I., email)
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15. **DUTY PHONE/PAGER NUMBER**
    916-3455; pager 210-228-6002

16. **AUTHORSHIP AND CO-AUTHOR(S)** List in the order they will appear in the manuscript.

   **LAST NAME, FIRST NAME AND M.I.** | **GRADE/RANK** | **SQUADRON/GROUP/OFFICE SYMBOL** | **INSTITUTION (If not 59 MDW)**
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Shaoping Mo Sumner | O-4/Major | 59 CSPS | 59 MDW
Annabel L Schumaker | GS | BAMC Army | USARMY MEDCOM
Thomas Shank | O5 (retired) | N/A | Pfizer

17. **IS A 502 ISG/JAC ETHICS REVIEW REQUIRED (JER DOD 5500.07-R)?** YES NO

18. **AUTHOR’S PRINTED NAME, RANK, GRADE**
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20. **DATE**
   03/15/2017

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22. **APPROVING AUTHORITY’S SIGNATURE**
   BOUCHARD JOHN A 1392707685

23. **DATE**
   03/20/2017
Presentation of IRB approved research with appropriate disclaimers. Approved.
Assessing Medication Adherence in Patients with Rheumatoid Arthritis (RA)

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BACKGROUND

- Rheumatoid Arthritis (RA) is a symmetric, erosive, synovial autoimmune disease
- There are 1-3 million Americans suffering from RA of whom 70% are women
- People with RA have higher risk of developing heart disease and stroke
- Oral Disease Modifying Anti-Rheumatic Drugs (DMARDs) are the most used RA medications
- Compliance with DMARDs is a significant healthcare issue affecting many patients, especially those with chronic diseases and prolonged drug therapy
- Non-adherence rates to DMARDs in RA patients are reported to be up to 60% for correct dosing
- There are different methods to measure how adherence patients are to their medication regimen
- Patient questionnaires/research reports are thought to be simple, inexpensive, and the most useful method in the clinic setting
- The Morisky Medication Adherence Scale (MMAS) was developed to assess medication adherence intent and has been validated in several common disease but not in RA
- There are several variations of the MMAS but we used the MMAS-8 which has eight questions
- The Compliance-Questionnaire-Rheumatology (CQR) is a rheumatology-specific instrument measuring patient compliance to drug regimens
- CQR identifies factors that contribute to suboptimal patient compliance and could be used to predict future compliance in patients with RA
- CQR is validated in RA but is difficult to score which limits its usefulness in the clinic setting
- The average time to complete the CQR is approximately 12 minutes, compared to less than 1 minute to complete the MMAS-8

OBJECTIVES

- The primary objective is to determine if there is a correlation between the CQR19, CQRS, and the MMAS-8
- The secondary objective is to assess if there is a potential medication adherence issue in patients with RA taking oral DMARDs

METHODS

DMARD drugs included in this study

- In this study, patients with RA were asked if they were currently taking one of the following oral DMARD medications: methotrexate, hydroxychloroquine (Plaquenil®), leflunomide (Arava®), sulfasalazine (Azulfidine®), and/or minocycline (Minocin®)

Hypothesis

- There is a correlation between the CQR19 and the MMAS-8. The research study would also estimate the extent of medication adherence in patients with RA taking oral DMARDs

Study population

- Inclusion criteria: anyone that is 18 years old and over with a diagnosis of RA, treated with an oral DMARD, treated for RA at the BAMC Rheumatology Clinic, able to read English, and has no cognitive disability

METHODS (Cont.)

Exclusion criteria: Patients not meeting the inclusion criteria

Sample size: An 80% power was used to detect a correlation coefficient of 0.2. Based on the validation studies for the CQR and MMAS, we estimated that between 10% and 20% of surveys will be unanswerable. The estimated sample size for this study is 102

Data collection methods and processing: At the time of check-in for a routine appointment in the Rheumatology Clinic, patients were invited to participate in a survey. Patients were provided a questionnaire containing both the MMAS-8 and CQR19. The CQR and MMAS were used to assess medication adherence in the treatment of RA patients. The CQR and MMAS were compared to assess whether the shorter MMAS could be used to routinely assess medication adherence in patients taking oral DMARDs for RA. The completed surveys were collected in designated drop boxes located at the clinic front desk. At the end of each business day, the primary investigator (PI) collected the completed surveys from up to 7 weeks

Statistical Analysis

- The data were evaluated using descriptive statistics to describe the patient population and adherence testing to determine whether we should use Pearson or Spearman correlation. Spearman correlation was used to assess the relationship between the two adherence predictors on continuous scores. Chi-square tests were used to compare how CQR19, CQRS, and MMAS placed patients into adherence groups. The CQR19 places patients into low and high medication taking and dosing compliance groups, the CQRS places patients into low and high medication adherence groups, and MMAS places patients into low adherence (scores <6), medium adherence (scores of 6 or 7), and high adherence (scores of 8 or 9). Descriptive Statistics

Data were collected on 66 patients, but not all patients provided complete data and analyzed using Stata version 14. The descriptive statistics are presented below

PRELIMINARY RESULTS

Descriptive Statistics

Before inferential testing, the variables were evaluated to ensure that the assumptions for each test were met. We intended to use Pearson correlation to compare the continuous adherence predictor variables which requires that the variables be normally distributed. Since none of the CQR19 or CQRS predictors were normally distributed, Spearman correlations were employed to determine the strength of association between these variables. These results are provided below

Spearman Correlations for Adherence/Compliance Predictor Scores

Before conducting any inferential testing, the assumptions for the tests were met. We intended to use Pearson correlation to compare the continuous adherence predictor variables which requires that the variables be normally distributed. Since none of the CQR19 or CQRS predictors were normally distributed, Spearman correlations were employed to determine the strength of association between these variables. These results are provided below

PRELIMINARY RESULTS (Cont.)

Chi-Square Tests of Independence (All Adherence/Compliance Groups)

DISCUSSION

- This is a preliminary analysis because the data collection has not been completed
- The CQR19 performance in our patient population was similar to that which was described in the validation study
- The CQRS high adherence predictor was moderately correlated with CQR19 dosing compliance
- The MMAS was very weakly correlated with both the CQR19 and CQRS
- Both the CQR19 and CQRS were similar in their ability to place patients into adherence groups
- Neither the CQR19 nor CQRS were similar to the MMAS in their ability to place patients into adherence groups

CONCLUSION

- Based on the preliminary analysis, the MMAS was not able to place patients into adherence groups in a way that was similar to the CQR19; we would not recommend replacing the CQR19 with the MMAS
- The CQRS was able to predict adherence as well as both of the CQR19 compliance measures (taking and dosing) and could be used in the clinic setting

REFERENCES

5. The findings described in this report represent the views of the authors and do not necessarily reflect the views of the Department of Defense, the Department of the Army, the Office of the Secretary of Defense, or the United States Government. The views expressed are those of the authors (presenters) and do not reflect the official policies or positions of the Department of the Army or the Department of Defense. This did not constitute or represent the views of the Department of the Army or the Department of Defense.

State Corp., State Statistical Software Release 14, College Station, TX; State Corp. LP.