Award Number: W81XWH-09-1-0723

TITLE: Blister Packaging Medication to Increase Treatment Adherence and Clinical Response: Impact on Suicide-related Morbidity and Mortality

PRINCIPAL INVESTIGATOR: Peter M. Gutierrez, Ph.D.

CONTRACTING ORGANIZATION: Denver Research Institute
Denver, CO 80220

REPORT DATE: September 2013

TYPE OF REPORT: Annual

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

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Blister Packaging Medication to Increase Treatment Adherence and Clinical Response: Impact on Suicide-related Morbidity and Mortality

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Denver, CO 80220

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14. ABSTRACT  
Please see next page.

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Personnel; Regulatory approvals; Assessments; Quarterly reports, budget and tracking

16. SECURITY CLASSIFICATION OF:

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17. LIMITATION OF ABSTRACT  
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18. NUMBER OF PAGES  
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19a. NAME OF RESPONSIBLE PERSON  
USAMRMC

19b. TELEPHONE NUMBER (include area code)
ABSTRACT
Year one involved hiring and training staff, preparing all regulatory documents and submitting them for approval, initiating participant recruitment, baseline assessment, and follow-up. Year two focused on recruiting for and completing the feasibility phase of the study, and making necessary protocol amendments prior to the full-trial phase of the study. Year three focused on recruitment and data collection for the full trial phase. Year four continued to focus on recruitment and data collection including implementing a mass mailing to aid in the final recruitment push. We were also approved for a one year No Cost Extension.

14. ABSTRACT

15. SUBJECT TERMS
- Personnel
- Regulatory approvals
- Participant recruitment
- Assessments
- Quarterly reports, budget and tracking

16. SECURITY CLASSIFICATION OF:
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   b. ABSTRACT U
   c. THIS PAGE U

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19b. TELEPHONE NUMBER (Include area code)
Annual Report to Department of Defense

(Fiscal Year 2013: September 29, 2012-September 30, 2013)

"Blister Packaging Medication to Increase Treatment Adherence and Clinical Response: Impact on Suicide-related Morbidity and Mortality"

DoD Award: W81XWH-09-1-0723

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Introduction:

The focus of this study is to see if participants receiving outpatient care at the Denver VA Medical Center will have better treatment adherence and subsequently clinical outcomes as a result of having their medications placed into blister packs as opposed to standard pill bottle packaging. Previous research supports a range of benefits to blister packaging medications for at-risk patients (Llorca, 2008; Bosworth et al., 2005; Dolder, Lacro, & Jeste, 2003). Non-adherence, defined as "not having a prescription filled, not taking enough medication, taking too much medication, not observing the correct interval between doses, not observing the correct duration of treatment and taking additional non-prescribed medication" (Bosworth, Oddone, & Weinberger, 2005, p. 149), is a significant issue for those with psychiatric illness. Moreover, studies suggest that psychiatric symptoms interfere with adherence and partial adherence is associated with poorer psychiatric outcomes, including suicide. Specifically, those who are non-adherent are at 4-7 times greater risk of death (Llorca, 2008). Blister packaging, a structured means of dispensing medications (Bosworth et al., 2005) is expected to increase adherence, and decrease subsequent poor outcomes in the high risk population of psychiatric inpatients. Furthermore, this relatively simple intervention can be accomplished in any treatment setting and does not require any specialized training on the part of those administering the program. The specific aims of this study are to: examine if blister packaging medication significantly increases medication adherence; determine if Blister Packaging decreases self-poisoning behavior; determine if Blister Packaging medications decrease overall symptom distress; determine if Blister Packaging medications reduces additional negative medical and psychiatric outcomes; and finally to see if Blister Packaging medications reduces health care utilization.

Body:

Statement of Work (updated with No-Cost Extension)

Task 1. Project Start-up (months 1-3) Completed

1a. Hire research assistant, pharmacy technician, and pharmacist (month 1)
   - All study personnel were hired by January 2010 (month 4)
1b. Train staff (month 2)
   - All study personnel were trained by April 2010 (month 7)
1c. Orient inpatient staff to study logistics (month 3)
   - Accomplished by month 7

Task 2. Participant recruitment (months 4-51): In Progress

2a. Introducing study to appropriate patients receiving care at the Denver VA Medical Center (VAMC) (months 4-51)
2b. Securing consent to participate (months 4-51)
2c. Recording contact information (months 4-51)
2d. Creating participant data base (month 4)
Task 3. Baseline assessment (months 4-51): In Progress

3a. Administering assessment protocol to all participants (months 4-51)
3b. Entering baseline assessment data (months 4-51)

Task 4. Preparing year one quarterly reports (months 3, 6, 9, 12) completed

- We submitted our 1st and 2nd quarterly reports and were exempt from the 3rd.

Task 5. Follow-up assessments (months 5-57): In Progress

5a. Setting up appointments or making phone calls to administer follow-up assessments to each participant at one month intervals post-baseline (months 5-57); Giving participants cash and having them sign a receipt indicating that payment was received or mailing checks to participants following each completed assessment (months 5-57)
5b. Reviewing participants' VA medical records for clinic visits and in-patient admissions on a monthly basis (months 5-57)
5c. Entering follow-up assessment data (months 5-57)

Task 6. Preparing year two quarterly reports (months 15, 18, 21, 24) completed

Task 7. Data analyses (months 57-60)

Task 8 Preparing year three quarterly reports (months 27, 30, 33, 36): Completed

Task 9. Preparing final report (months 59-60)

Overall project timeline:

Year 1 — Complete Task 1; initiate Tasks 2-5
- Task 1 accomplished by month 7; tasks 2-5 initiated by month 11.
Year 2 — Complete Tasks 4 and 6; Continue Tasks 2, 3, and 5
Year 3 — Continue Tasks 2, 3, and 5; Complete Task 8
Year 4 — Continue Tasks 2, 3, and 5
Year 5 — Complete Tasks 2, 3, 5, 7, and 9

Recruiting participants is ongoing as are baseline and follow-up assessment. To-date we have recruited 255 participants. Some of the participants have competed the full year of study enrollment and other participants are over half way through completing the year-long follow-up assessments. In order to help facilitate recruitment, we submitted documents so that we could run a query through the national VA database. A query was generated to identify Veterans who meet study criteria and are receiving mental health care through the Denver VA Medical Center. This query generated approximately 1,800 Veterans who meet the criteria for the study. We are sending the mailing out in three batches. The first mailing is sent out from the Chief of the Mental Health Service, Dr. Herbert Nagamoto (the Service Chief), to those who are potentially eligible. The mailing includes a patient information sheet and a recruitment letter in addition to a “Refusal to Participate” card so that Veterans can opt out of participating in the study. Each “Refusal to Participate” card will have a
randomly assigned unique identifier so that study staff can track those that are returned. If we do not hear back from participants in response to the initial mailing, we will contact them again with two additional mailings to see if they would be interested in participating. We plan on recruiting new participants through December of 2013 and continue conducting follow-up assessments through July of 2014.

**Key Research Accomplishments:**

- Finished recruiting participants for the feasibility phase of the study.
- Recognized important procedural issues that would be helpful to fix and received regulatory approval on these minor modifications.
- Began recruiting for the full-phase trial of the study.
- Baseline and follow-up assessments underway.
- Participants completing study participation.
- Getting approval to send out a mass mailing
- No-Cost extension approved.

**Reportable Outcomes:**

Insufficient data have been collected to test study hypotheses. The study was accepted to present preliminary psychometric data for the Self-Harm Behavior Questionnaire (SHBQ; Gutierrez, Osman, Barrios & Kopper, 2001) at the 2013 APA Annual Conversion.

**Data from APA Poster:**

N=205

The internal consistency reliability estimate (i.e., coefficient alpha) for the SHBQ total score was .93, and the subscale alphas ranged from .96 - .98 (SHB=0.98, SHA=0.97, SHT=0.96, SHI=0.96). We used the SHBQ total score cut-off of 22 to predict membership in suicidal versus non-suicidal groups based on the suicidality scale of the M.I.N.I.. This resulted in sensitivity of .52 [95% CI (0.43, 0.62)] and specificity of 0.96 [95% CI (0.90, 0.99)]. We then ran a logistic regression with current suicidality (Y/N on M.I.N.I. Suicide scale) as the outcome and SHBQ score as the predictor, the area under the curve (AUC) was 0.90, 95% CI (0.86, 0.95). With a cut-off of 9 sensitivity = 0.87 (95% CI 0.80, 0.93) and specificity = 0.85 (95% CI 0.76, 0.92). With a cut-off of 10 Sensitivity = 0.86 (95% CI 0.79, 0.92) and specificity = 0.88 (95% CI 0.78, 0.94).

Assessment of the SHBQ’s psychometric properties when used with high-risk Veterans suggests that it is a valid and reliable measure of self-directed violence. Although the published cut-off score (based on adult psychiatric inpatients) yielded acceptable specificity, the sensitivity was unacceptably low for a measure of suicide risk. However, follow-up analyses indicated that a more conservative cut-off score of 9 performs much better and would yield reasonable results in clinical settings. While additional analyses regarding other
psychometric properties such as convergent and divergent validity need to be conducted, we are encouraged about the potential for this measure in research and clinical settings with Veterans at high risk of self-directed violence.

A book chapter describing the background for the study, methodological overview, and potential impact of the findings has been published:


ABSTRACT:

Medication overdoses account for substantial numbers of cases of self-directed violence (SDV) in several segments of the United States (US) population. The purpose of the study described in this chapter is to determine if medication administration via blister packaging is associated with an increase in treatment adherence and a decrease in intentional overdoses among a high risk population of patients either discharged from psychiatric inpatient units or receiving care in outpatient mental health or substance abuse clinics. As such the research aims of the project to be described are as follows: 1) To explore whether blister packaging medication decreases overall symptom distress; 2) To explore whether blister packaging medication reduces additional negative medical and psychiatric outcomes (e.g., emergency department admissions, psychiatric hospitalizations); and 3) To explore whether blister packaging medication reduces health care utilization (e.g., clinic visits). If hypotheses are supported, findings from this study will provide evidence that this means of dispensing prescription medications decreases suicide risk through two mechanisms. Specifically, it is expected that increasing adherence will result in a decrease in symptoms reported as well as overall psychological distress. This alone would be expected to decrease an individual’s suicide risk. Also, creating appropriate means restriction should result in reduced morbidity and mortality resulting from intentional and accidental overdoses. The theoretical and empirical background, rationale, methods, and measures described in this chapter should help clinicians to appreciate the potential utility of blister packaging medications for their high-risk patients and provide researchers with a promising line of study in the realm of suicide means restriction.

Conclusion:

Participant recruitment for the feasibility phase of the clinical trial is complete. Necessary changes to the protocol based on those findings have been made and approved by all regulatory bodies. Full trial recruitment and data collection are underway. Interest from the field in the project is strong, and information about this work is being disseminated.

References:

N/A
Appendices:

A1. Peter Gutierrez, Ph.D. CV  
Appendix Pages: 7-27

A2. Most Recent Changes  
Appendix Pages: 28-29
VITA

DATE: 9-4-13

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1055 Clermont Street
Denver, Colorado 80220

PHONE: 303-378-5562

E-MAIL: peter.gutierrez@va.gov

EDUCATION:

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<th>Degree</th>
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<td>Ph.D., Clinical Psychology</td>
<td>1997</td>
<td>University of Michigan</td>
<td>Ann Arbor, MI</td>
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<td>M.A., Clinical Psychology</td>
<td>1994</td>
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<td>B.A., Psychology</td>
<td>1991</td>
<td>Winona State University</td>
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<td><strong>Summa Cum Laude</strong></td>
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AREAS OF SPECIALIZATION AND RESEARCH INTERESTS:

Suicide risk factors, assessment, and prevention. Young adult suicidality. Cultural validity of assessment tools and suicide risk models. Scale development and psychometric evaluation.

PROFESSIONAL EXPERIENCE:

7/1/09- Associate Professor, University of Colorado School of Medicine, Department of Psychiatry.

6/9/08- Licensed Clinical Psychologist, Colorado #3203.

2008- Clinical/ Research Psychologist, Denver VA Medical Center, Mental Illness Research and Education Clinical Center.

2008-2009- Visiting Associate Professor, University of Colorado Denver School of Medicine, Department of Psychiatry.

2007-2008- Research Psychologist, Denver VA Medical Center, Mental Illness Research and Education Clinical Center.
2006-2008  Adjoint Associate Professor, University of Colorado Denver School of Medicine, Department of Psychiatry.

2006-2007  Research Consultant, Denver VA Medical Center, Mental Illness Research and Education Clinical Center.

2002-2007  Associate Professor, Northern Illinois University, Department of Psychology.

2002-2006  Assistant Chair, Northern Illinois University, Department of Psychology.

1996-2002  Assistant Professor, Northern Illinois University, Department of Psychology.

1995-1996  University of Michigan, University Center for the Child and Family, Psychology Intern (APA Accredited through University’s Captive Consortium).

1993-1995  University of Michigan Medical Center, Division of Child and Adolescent Psychiatry, Department of Psychiatry, Psychology Intern (APA Accredited through University’s Captive Consortium).

PUBLICATIONS (77):


BOOK/CHAPTERS (7):


PAPER PRESENTATIONS (51):

Gutierrez, P. M., Joiner, T., Blatt, A., & Castro, C. United States military suicide prevention research: Navigating challenges and capitalizing on opportunities. Presented at the International Academy of Suicide Research World Congress on Suicide, Montreal, Quebec, Canada, June 12, 2013.


Gutierrez, P. M. Alcohol and suicide: A deadly cocktail or misinterpretation of data? Plenary address presented at the American Association of Suicidology conference, Austin, TX, April 26, 2013.


Gutierrez, P. M. Navigating IRBs as a suicide researcher. Presented at the American Association of Suicidology conference, Baltimore, MD, April 19, 2012.

Gutierrez, P. M., & Lineberry, T. United States Army Medical Research and Materiel Command United States military suicide research: Activities and opportunities. Panel presentation at the American Association of Suicidology conference, Portland, OR, April 14, 2011.


Gutierrez, P. M. Redefining diversity: The chronically suicidal veteran as one example. Presidential address at the American Association of Suicidology conference, Boston, MA, April 17, 2008.


Gutierrez, P. M. Change is good: What the past 40 years tell us about the future. Presidential address at the American Association of Suicidology conference, New Orleans, LA, April 12, 2007.

Gutierrez, P. M. Suicide in the young adult population. Presented at the Department of Veterans Affairs Employee Education System’s Evidence-Based Interventions for Suicidal Persons conference, Denver, CO, February 8, 2007.


Schumacher, M., & Gutierrez, P. M. Bipolar spectrum traits and suicide risk. Presented at the American Association of Suicidology conference, Broomfield, CO, April 15, 2005.


Does this magazine make me look fat? Media’s impact on body image, depression, and eating. Presented at the Midwestern Psychological Association Conference, Chicago, IL, May 1, 2004.

Differences between self-injury and suicide on measures of depression and suicidal ideation. Presented at the Midwestern Psychological Association annual meeting, Chicago, IL, May 9, 2003.

Suicide research: Working with a mentor. Panel presentation at the American Association of Suicidology annual conference, Santa Fe, NM, April 24, 2003.


POSTER PRESENTATIONS (53):


Soberay, K., Dwyer, M., Hanson, J., Ribeiro, J., Gronau, K., Gutierrez, P. M., & Maner, J. Exploring the MSRC common data elements: The relationship between TBI, severe insomnia, and suicidal behaviors in military populations. Presented at the American Psychological Association conference, Honolulu, HI, August 1, 2013.

Pease, J., Soberay, K., Dwyer, M., Gronau, K., & Gutierrez, P. M. Thwarted belonging makes a modest contribution to suicidal ideation after controlling for universalism and relationships. Presented at the American Psychological Association conference, Honolulu, HI, August 1, 2013.


Dwyer, M. M., Soberary, K., Hanson, J., & Gutierrez, P. M. Military suicide research consortium (MSRC). Presented at the American Association of Suicidology conference, Austin, TX, April 26, 2013.


Swanson, J. D., & Gutierrez, P. M. Gender, social support, and student suicidality. Poster presented at the American Association of Suicidology conference, Seattle, WA, April 30, 2006.


Kopper, B. A., Osman, A., Linehan, M. M., Barrios, F. X., Gutierrez, P. M., & Bagge, C. L. Validation of the Adult Suicide Ideation Questionnaire and the Reasons for Living Inventory in an adult psychiatric inpatient sample. Presented at the annual convention of the American Psychological Association, Boston, MA August 22, 1999.


Gutierrez, P. M., & Hagstrom, A. H. Uses for the Multi-Attitude Suicide Tendency Scale. Presented at the American Association of Suicidology annual conference, Bethesda, MD, April 17, 1998.


GRANTS AND AWARDS:

10/12-9/14 Department of Veterans Affairs National Center for Patient Safety; Co-investigator (PIs Robert Bossarte, Ph.D. & Ira Katz, MD); $569,222 for Patient Safety Center of Inquiry.

3/11-2/13 Department of Defense, Military Operational Medicine Research Program, grant; Consultant (PI Steven Vannoy, Ph.D., MPH); $1,354,386 for Development and Validation of a Theory Based Screening Process for Suicide Risk.

3/11-3/15 Department of Defense, Military Operational Medicine Research Program, grant; Co-Investigator; $3,400,000 for A Randomized Clinical Trial of the Collaborative Assessment and Management of Suicidality vs. Enhanced Care as Usual for Suicidal Soldiers.

9/10-9/15 Department of Defense, Military Operational Medicine Research Program, grant; Principle Investigator; jointly with Thomas Joiner, Ph.D., Florida State University; $13,635,864 (additional $13,635,864 going to FSU) for Military Suicide Research Consortium.

9/09-9/13 Department of Defense, Military Operational Medicine Research Program, grant; Principle Investigator; $1,173,408 for Blister Packaging Medication to Increase Treatment Adherence and Clinical Response: Impact on Suicide-related Morbidity and Mortality.
5/09-5/10 Colorado TBI Trust Fund Education grant; $8427 to support the hosting of a conference of national experts in suicide safety planning and TBI rehabilitation.

5/08-5/09 Colorado TBI Trust Fund Education grant; $5,000 to support the hosting of a conference of national experts in assessment of TBI and suicide risk and the role of executive dysfunction in linking the two problems.

2005 Shneidman Award for Significant Contributions to Suicide Research, American Association of Suicidology

2003 Outstanding Young Alumni, Winona State University

PROFESSIONAL SERVICE:

1/12- Department of Psychiatry Faculty Promotions Committee

1/12- Editorial Board Member, Archives of Suicide Research, Barbara Stanley, Ph.D., Editor-in-Chief

4/09- Associate Editor, Suicide and Life-Threatening Behavior, Thomas Joiner, Ph.D., Editor-in-Chief.

4/09-4/11 Past-president, Board position, of the American Association of Suicidology.


5/07-10/08 Member of the International Advisory Board for the Australian National Study of Self Injury (ANESSI), Professor Graham Martin, Director.

4/07-4/09 President of the American Association of Suicidology.

3/06-3/07 Reviewer for National Registry of Evidence-based Programs and Practices, Substance Abuse and Mental Health Services Administration.

4/05-4/07 President-Elect of the American Association of Suicidology.

2/04-4/09 Consulting Editor and Editorial Board member, Suicide and Life-Threatening Behavior, Morton M. Silverman, M.D., Editor-in-Chief.

11/02-6/06 Member, Illinois Suicide Prevention Strategic Planning Task Force, Illinois Department of Public Health.

3/02-1/06 Member, American Association of Suicidology Institutional Review Board.
4/00-4/03 Director, Research Division, American Association of Suicidology.


1998-2002 Member, North Central Association Outcomes Endorsement Team for Auburn High School, Rockford, IL.

7/98-4/00 Chair, Publications Committee, American Association of Suicidology.

1998-2006 Director, Adolescent Risk Project, Auburn High School, Rockford, IL. Combined research and suicide risk screening project.

1997-2006 Faculty Associate of the Center for Latino and Latin-American Studies at Northern Illinois University.

MEMBERSHIP IN PROFESSIONAL ORGANIZATIONS:

2010- International Academy for Suicide Research, Fellow

2007- Colorado Psychological Association

2003-2010 International Academy for Suicide Research, Associate Member

1999- APA Div. 12, Section VII, Clinical Emergencies and Crises


1997-2007 Midwestern Psychological Association

1996- American Association of Suicidology
COMIRB

Project Title: Blister Packaging Medication to Increase Treatment Adherence and Clinical Response: Impact on Suicide-Related Morbidity and Mortality

Describe the Change

Check ALL that apply:

- Application Form
- Protocol
- Consent Form Revision
- Assent Form Revision
- VA Consent Form(s)
- Advertisement/Revised Advertisement
- Documents Used with Subjects
- Personnel Change
- Performance Site Change
- Project Title Change
- Investigational Brochure or Package Insert
- Other Description of Change (please include a list of and include a copy of all attached documents):

Descriptions of Change (please include a list of and include a copy of all attached documents):

- Protocol Changes
- Updated COMIRB Application and Attachments
- Updated Recruitment Letters Sent to Participants
  - To help facilitate recruitment, we are submitting documents so that we can run a query through the national VA database. A query will be generated to identify Veterans who have Major Affective Disorder, PTSD, Bipolar Disorder or Schizophrenia and are receiving mental health care through the Denver VA Medical Center. A mailing will then be sent out from the Chief of the Mental Health Service, Dr. Herbert Nagamoto (the Service Chief), to those who are potentially eligible. Those being sent mailings are aware that they are receiving mental health care at the Denver VA thus have a treatment relationship with the mental health staff. The mailing will include a patient information sheet and a recruitment letter in addition to a “Refusal to Participate” card so that Veterans can opt out of participating in the study. Each “Refusal to Participate” card will have a randomly assigned unique identifier so that study staff can track those that are returned. If we do not hear back from participants in response to the initial mailing, we will contact
them again with two additional mailings to see if they would be interested in participating. This process was modeled on PI: Dr. Battaglia's previously approved study; COMIRB #08-0556.

- Personnel Changes

**Forms that are being changed:**

1. **Protocol**
   a. Updated the version date
   b. Updated language

2. **COMIRB Application**
   a. Updated the version date
   b. Updated study personnel
   c. Updated language

3. **Attachments coinciding with the COMIRB Application**
   a. **Attachments we use:** C, D, F, J, L, M, O
   b. Updated the version date

4. **Recruitment Documents**
   a. Updated Chart Extraction/Screening Form
   b. Updated Recruitment Flyer for Clinics
      i. We also used this flyer to create a 4X6 recruitment card to hand out
   c. Updated Recruitment Flyer for Inpatient Unit Admission Packets
   d. Deleted Staff Flyer for Inpatient Unit Staff—will no longer use

5. **Personnel Change:**
   **Add:**
   Herbert Nagamoto

   **Delete:**
   Mishalynda Brigham