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

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#### **14. 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.

## **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**

### **Table of Contents:**

	Page Location
<b>Introduction:</b>	<b>2</b>
<b>Body:</b>	<b>2-3</b>
<b>Key Research Accomplishments:</b>	<b>4</b>
<b>Reportable Outcomes:</b>	<b>4-5</b>
<b>Conclusion:</b>	<b>5</b>
<b>References:</b>	<b>N/A</b>
<b>Appendices:</b>	<b>6-29</b>
<b>Supporting Data:</b>	<b>N/A</b>

## **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 1<sup>st</sup> and 2<sup>nd</sup> quarterly reports and were exempt from the 3<sup>rd</sup>.

**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 completed 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 Convention.

#### **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 not 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:

Gutierrez, P. M., Brenner, L. A., Wortzel, H., Harwood, J. E. F., Leitner, R., Rings, J., & Bartlett, S. (2012). Blister packaging medication to increase treatment adherence and clinical response: Impact on suicide-related morbidity and mortality. In J. Lavigne & J. Kemp (Eds.), *Frontiers in suicide prevention and research*. Hauppauge, NY: Nova Science Publishers, Inc.

#### **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

## **A1 VITA**

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### EDUCATION:

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Ph.D., Clinical Psychology	1997	University of Michigan	Ann Arbor, MI
M.A., Clinical Psychology	1994	University of Michigan	Ann Arbor, MI
B.A., Psychology	1991	Winona State University	Winona, MN

*Summa Cum Laude*

### 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).

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#### BOOK/CHAPTERS (7):

- Gutierrez, P. M., Brenner, L. A., Wortzel, H., Harwood, J. E. F., Leitner, R., Rings, J., & Bartlett, S. (2012). Blister packaging medication to increase treatment adherence and clinical response: Impact on suicide-related morbidity and mortality. In J. E. Lavigne (Ed.), *Frontiers in suicide risk: Research, Treatment and Prevention*. Hauppauge, NY: Nova Science Publishers, Inc.
- Brenner, L. A., Gutierrez, P. M., Huggins, J., & Olson-Madden, J. (2011). Suicide and traumatic brain injury. In A. L. Berman & M. Pompili (Eds.), *Medical conditions associated with suicide risk* (pp. 299-307). Washington, DC: American Association of Suicidology.
- Osman, A., Freedenthal, S., Fang, Q., Willis, J., Norizuki, T., & Gutierrez, P. M. (2011). The UTSA Future Disposition Inventory: Further analyses of reliability, validity, and potential correlates in non-clinical samples. In F. Columbus (Ed.), *Advances in Psychology Research (Chapter 3)*. New York: Nova Science Publishers.
- Gutierrez, P. M., & Brenner, L. A. (2011). Highlight section: Helping military personnel/Veterans and families manage stress reactions and navigate reintegration. In A. J. Palmo, W. J. Weikel, & D. P. Borsos (Eds.), *Foundations of mental health counseling, 4<sup>th</sup> Edition*. Springfield, IL: Charles C. Thomas Publisher, Inc.
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Jobes, D. A., Comtois, K. A., Brenner, L. A., & Gutierrez, P. M. (2011). Clinical trial feasibility studies of the Collaborative Assessment and Management of Suicidality (CAMS). In R. O'Connor, S. Platt, & J. Gordon (Eds.), *International handbook of suicide prevention: Research, policy, and practice*. Oxford, UK: John Wiley & Sons, Ltd.

Gutierrez, P. M., & Osman, A. (2008). *Adolescent suicide: An integrated approach to assessment of risk and protective factors*. DeKalb, IL: Northern Illinois University Press.

#### 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.

Goodman, M., Gutierrez, P. M., Bossarte, R., Rasmussen, A. M., Brenner, L., & Stanley, B. Research updates and new directions for suicide prevention in the Veterans Administration. Discussant for symposium presented at the American Psychiatric Association annual meeting, San Francisco, CA, May, 19, 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., Joiner, T., & Castro, C. Preventing suicide in the United States military: Research challenges and opportunities. Presented at the 14<sup>th</sup> European Symposium of Suicide & Suicidal Behavior, Tel Aviv-Jaffa, Israel, September 5, 2012.

Gutierrez, P. M., Castro, C., Fitek, D. J., Holloway, M., & Jobes, D. A. Status of DoD funded suicide research. Presented at the Annual DoD/VA Suicide Prevention Conference, Washington, DC, June 20, 2012.

Matarazzo, B., Gutierrez, P. M., & Silverman, M. M. The Self-Directed Violence Classification System: What it is and why it matters. Presented at the Annual DoD/VA Suicide Prevention Conference, Washington, DC, June 20, 2012.

Gutierrez, P. M., Fitek, D. J., Joiner, T., Holloway, M., Jobes, D., & Rudd, M. D. Status of Department of Defense funded suicide research. Featured Panel presentation at the American Association of Suicidology conference, Baltimore, MD, April 20, 2012.

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

Kemp, J., Thompson, C., Brown, G. K., Brenner, L. A., & Gutierrez, P. M. VA continuum of care for suicidal Veterans. Panel presentation at the American Association of Suicidology conference, Portland, OR, April 16, 2011.

- 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.
- Bahraini, N., Gutierrez, P. M., Brenner, L. A., Hedegaard, H., & Huggins, J. The Colorado Violent Death Reporting System (COVDRS): Exploring factors associated with suicide in VA and non-VA services utilizing Veterans. Presented at the American Association of Suicidology conference, Portland, OR, April 14, 2011.
- Marshall, J., Gutierrez, P. M., Lineberry, T., & Jobes, D. United States Army Medical Research and Materiel Command United States military suicide research activities: Activities and opportunities. Panel presentation at the DOD/VA Annual Suicide Prevention Conference, Boston, MA, March 15, 2011.
- Gutierrez, P. M., Bahraini, N., Basham, C. M., Brenner, L. A., Hedegaard, H., Denneson, L. M., & Dobscha, S. K. Lessons learned about veteran suicide from the Colorado and Oregon Violent Death Reporting Systems. Presented at the American Association of Suicidology conference, Orlando, FL, April 22, 2010.
- Gutierrez, P. M. Blister packaging medication to increase treatment adherence and clinical response: Impact on suicide related morbidity and mortality. Presented at the 2010 DoD/VA Suicide Prevention Conference, Washington, DC, January 12, 2010.
- Gutierrez, P. M. Theater of War. Plenary Panel member at the 2010 DoD/VA Suicide Prevention Conference, Washington, DC, January 12, 2010.
- Bahraini, N., Gutierrez, P. M., Brenner, L. A., Hedegaard, H., Chase, M., & Shupe, A. The Colorado violent death reporting system: Exploring factors associated with suicide in VA and non-VA services utilizing veterans. Presented at the Centers for Disease Control and Prevention's NVDRS Reverse Site Visit, Denver, CO, May 14, 2009.
- Leach, R. L., Breshears, R. E., Brenner, L. A., Homaifar, B. Y., Gutierrez, P. M., Gorgens, K. M., & Harwood, J. E. F. The utility of the Personality Assessment Inventory for predicting violence in veterans with traumatic brain injury. Presented at the Rehabilitation Psychology Conference, Jacksonville, FL, February 27, 2009.
- Gutierrez, P. M. Collaborative assessment and management of suicide (CAMS): A feasibility study. DoD/VA Annual Suicide Prevention Conference, San Antonio, TX, January 13, 2009.
- Gutierrez, P. M., Brenner, L. A., Homaifar, B. Y., & Olson-Madden, J. H. VA VISN 19 MIRECC research and clinical efforts at suicide prevention. Symposium presented at the American Psychological Association convention, Boston, MA, August 15, 2008.
- Brausch, A. M., & Gutierrez, P. M. Body image and disordered eating in adolescent suicidality. Presented at the American Association of Suicidology conference, Boston, MA, April 17, 2008.

- 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.
- Breshears, R. E., Brenner, L. A., & Gutierrez P. M. Predictive validity of the Personality Assessment Inventory in veterans with traumatic brain injury. Presented at the Rehabilitation Psychology Conference, Tucson, AZ, March 13, 2008.
- King, C. A., Gutierrez, P. M., & Jobes, D. A. Looking back – looking ahead: American suicidology at mid-life. Plenary panel presentation at the American Association of Suicidology conference, New Orleans, LA, April 12, 2007.
- Mazza, J. J., Reynolds, W. M., & Gutierrez, P. M. Screening for youth suicidal behavior revisited. Panel presentation at the American Association of Suicidology conference, New Orleans, LA, April 12, 2007.
- Schumacher, M., Quinnett, P., & Gutierrez, P. M. QPRT suicide risk assessment and management course utility. Panel presentation at the American Association of Suicidology conference, New Orleans, LA, April 12, 2007.
- 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.
- Rudd, M. D., Berman, L., Silverman, M. M., Gutierrez, P. M., & Schumacher, M. Warning signs for suicide: Theory, research, and clinical applications. Panel presented at the American Association of Suicidology conference, Seattle, WA, April 30, 2006.
- Freedenthal, S. L., & Gutierrez, P. M. Adolescents' disclosures of suicidality: Who knows? Presented at the American Association of Suicidology conference, Seattle, WA, April 30, 2006.
- Gutierrez, P. M. Shneidman Award Presentation – An integrated approach to assessing risk and protective factors for adolescent suicide. Presented at the American Association of Suicidology conference, Broomfield, CO, April 15, 2005.
- Schumacher, M., & Gutierrez, P. M. Bipolar spectrum traits and suicide risk. Presented at the American Association of Suicidology conference, Broomfield, CO, April 15, 2005.
- Gutierrez, P. M., & Osman, A. Prediction of adolescent suicide reattempts. Presented at the Kansas Conference in Clinical Child and Adolescent Psychology, Lawrence, KS, October 22, 2004.
- Gutierrez, P. M., & Konick, L. C. Evaluation of school-based suicide prevention programs. Presented at the Suicide Prevention: Advancing the Illinois Strategic Plan conference, Springfield, IL, September 23, 2004.

- Williams, J. E., Osman, A., Barrios, F., Kopper, B. A., & Gutierrez, P. M. Reliability and validity of the Inventory for Suicide Ideation – 30. Presented at the American Psychological Society conference, Chicago, IL, May 28, 2004.
- Hovey, J. D., Freedenthal, S., Gutierrez, P. M., & Fernquist, R. Career development strategies in suicide research #1: Working with a mentor. Panel presented at the American Association of Suicidology conference, Miami, FL, April 15, 2004.
- Conwell, Y., Silverman, M., Gutierrez, P. M., Konick, L. C., & Muehlenkamp, J. J. Career development strategies in suicide research #3: Publishing your findings. Workshop presented at the American Association of Suicidology conference, Miami, FL, April 16, 2004.
- Konick, L. C., & Gutierrez, P. M. Suicide risk in college students: A test of a model. Presented at the 2004 American Association of Suicidology conference, Miami, FL, April 16, 2004.
- Brausch, A. M., & Gutierrez, P. M. 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.
- Muehlenkamp, J. J., Swanson, J., & Gutierrez, P. M. 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.
- Kaplan, M., Schultz, D., Gutierrez, P. M., Sanddal, N., & Fernquist, N. Suicide research: Working with a mentor. Panel presentation at the American Association of Suicidology annual conference, Santa Fe, NM, April 24, 2003.
- Konick, L. C., & Gutierrez, P. M. Is spirituality a moderator of risk for suicide? Presented at the American Association of Suicidology annual conference, Santa Fe, NM, April 25, 2003.
- Watkins, R. L., & Gutierrez, P. M. Exposure to peer suicide in college students. Presented at the American Association of Suicidology annual conference, Santa Fe, NM, April 25, 2003.
- Gutierrez, P. M., Osman, A., Watkins, R. L., Konick, L. C., Muehlenkamp, J. J., & Brausch, A. M. Development and validation of the Suicide Resilience Inventory - 25 (SRI-25) in clinical and nonclinical samples. Presented at the Kansas Conference in Clinical Child Psychology, Lawrence, KS, October, 19, 2002.
- Konick, L. C., Brausch, A. M., Gutierrez, P. M., & Pawlowski, C. CBT in depressed kids: What factors moderate treatment effectiveness? Presented at the Kansas Conference in Clinical Child Psychology, Lawrence, KS, October, 19, 2002.
- Hovey, J. D., Gutierrez, P. M., & Jha, A. Measuring cultural risk factors in suicide research. Panel presented at the American Association of Suicidology annual conference, Atlanta, GA, April 19, 2001.
- Gutierrez, P. M., Osman, A., Barrios, F. X., & Kopper, B. A. The Self-Harm Behavior Questionnaire. Presented at the American Association of Suicidology annual conference, Atlanta, GA, April 21, 2001.

- Gutierrez, P. M., Collura, D., & Watkins, R. A case for regular suicide risk screening in high schools. Presented at the Kansas Conference in Clinical Child Psychology, Lawrence, KS, October 14, 2000.
- Osman, A., Gutierrez, P. M., Kopper, B. A., Barrios, F. X., Breitenstein, J. L., & Silich, N. Validity and utility of the Adolescent Psychopathology Scale (APS) with adolescent psychiatric inpatients. Presented at the Kansas Conference in Clinical Child Psychology, Lawrence, KS, October 13, 2000.
- Kopper, B. A., Gutierrez, P. M., Osman, A., & Barrios, F. X. Helping kids stay alive: The Reasons for Living Inventory - Adolescents. Presented at Western Psychological Association Annual Convention, Portland, OR, April 14, 2000.
- Gutierrez, P. M., Rodriguez, P. J., & Foat, N. K. A model of late adolescent suicidality. Presented at the American Association of Suicidology annual conference, Houston, TX, April 15, 1999.
- Gutierrez, P. M., Osman, A., Kopper, B. A., & Barrios, F. X. Quality of risk assessment with common measures. Presented at the American Association of Suicidology annual conference, Bethesda, MD, April 18, 1998.

#### POSTER PRESENTATIONS (53):

- Davidson, C. L., Babson, K. A., Hostetter, T. A., Crowley, K. J., Forster, J. F., Gutierrez, P. M. (2013, November). *Exploring the relationship between physical activity and suicide risk among Veterans in the Behavioral Risk Factor Surveillance System Questionnaire*. Poster to be presented at the 2013 Association of Behavioral and Cognitive Therapies Suicide and Self-Injury Special Interest Group, Nashville, TN.
- 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.
- Leitner, R., Gutierrez, P. M., Brenner, L., Wortzel, H., Forster, J. E., & Huggins, J. Psychometric properties of the Self-harm Behavior Questionnaire in Veterans. Presented at the American Psychological Association conference, Honolulu, HI, July 31, 2013.
- Dwyer, M. M., Soberay, K., Hanson, J., & Gutierrez, P. M. Military suicide research consortium (MSRC). Presented at the American Association of Suicidology conference, Austin, TX, April 26, 2013.

- Rings, J. A., Gutierrez, P. M., Harwood, J. E. F., & Leitner, R. Examining prolonged grief symptomatology and its relationship to self-directed violence among Veterans. Presented at the Veterans Affairs Mental Health Conference. Baltimore, MD, August 23, 2011.
- Rings, J. A., Gutierrez, P. M., & Harwood, J. E. F. Prolonged grief disorder and its relationship to self-directed violence among Veterans: Preliminary findings. Presented at the Departments of Defense and Veterans Affairs Suicide Prevention Conference. Boston, MA, March 15, 2011.
- Huggins, J., Homaifar, B.Y., Skopp, N.A., Reger, M., Gahm, G., Gutierrez, P., & Brenner, L.A. Suicide prevention through the transformation of data into information. Presented at the Departments of Defense and Veterans Affairs Suicide Prevention Conference. Boston, MA, March 15, 2011.
- Bethhauser, L. M., Allen, E., Brenner, L. A., & Gutierrez, P. M. Centrality of intimate relationships on failed belongingness and perceived burdensomeness in returning combat Veterans. Presented at the International Association for Relationship Research, Lawrence, KS, November, 2009.
- Bahraini, N., Gutierrez, P. M., Brenner, L. A., Huggins, J., Hedegaard, H., Shupe, A., & Chase, M. The Colorado violent death reporting system: Exploring factors associated with suicide in VA and non-VA services utilizing veterans. Presented at the American Psychological Association conference, Toronto, Ontario Canada, August 6, 2009.
- Brausch, A. M., & Gutierrez, P. M. Psychosocial factors related to non-suicidal self-injury in adolescents. Presented at the American Association of Suicidology annual conference, San Francisco, CA, April 17, 2009.
- Ballard, E. D., Jobes, D., Brenner, L., Gutierrez, P. M., Nagamoto, H., Kemp, J., et al. Qualitative suicide status form responses of suicidal veterans. Presented at the American Association of Suicidology conference, Boston, MA, April 18, 2008.
- Bahraini, N., Gutierrez, P. M., Brenner, L. A., Staves, P., Cornette, M., & Bethhauser, L. Pain tolerance and links to increased suicide risk. Presented at the American Association of Suicidology conference, Boston, MA, April 18, 2008.
- Cornette, M. M., DeBoard, R. L., Clark, D. C., Holloway, R. H., Brenner, L., Gutierrez, P. M., & Joiner, T. E. Examination of an interpersonal-behavioural model of suicide: Toward greater specificity in suicide risk prediction. Presented at the International Association for Suicide Prevention conference, Dublin, Ireland, August 31, 2007.
- Brenner, L. A., Gutierrez, P. M., Cornette, M., Staves, P. J., & Bethhauser, L. M. Veterans' experiences of habituation to painful stimuli, perceived burdensomeness and failed belongingness. Presented at the American Psychological Association conference, San Francisco, CA, August 19, 2007.

- Fang, Q., Choma, K., Salvatore, A., Mack, T., Bailey, J., & Gutierrez, P. M. Validation of the Pain Distress Inventory using an adolescent inpatient sample. Presented at the Kansas Conference in Clinical Child and Adolescent Psychology, Lawrence, KS, October 19, 2006.
- Brausch, A. M., & Gutierrez, P. M. Adolescent gender differences in reasons for living. Poster presented at the American Association of Suicidology conference, Seattle, WA, April 30, 2006.
- 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., Gutierrez, P. M., Williams, J. E., & Barrios, F. X. Suicide Resilience Inventory-25: Validation with normal and adolescent psychiatric inpatients. Poster presented at the 2005 APA conference, Washington, DC.
- Kopper, B. A., Osman, A., Barrios, F. X., Gutierrez, P. M., & Williams, J. E. The Beck Depression Inventory-II with nonclinical and inpatient adolescents. Poster presented at the 2005 APA conference, Washington, DC.
- Brausch, A. M., & Gutierrez, P. M. Ethnic differences in body image, affect, and eating behaviors and the impact of media exposure. Presented at the Association for the Advancement of Behavior Therapy conference, New Orleans, LA, November 11, 2004.
- Muehlenkamp, J. J., & Gutierrez, P. M. Validation of the Self-Harm Behavior Questionnaire in adolescents. Presented at the Association for the Advancement of Behavior Therapy conference, New Orleans, LA, November 11, 2004.
- Linden, S., Osman, A., Barrios, F. X., Kopper, B. A., Williams, J. E., & Gutierrez, P. M. Structure of the Adolescent Psychopathology Scale (APS) clinical subscales in psychiatric inpatients. Presented at the Association for the Advancement of Behavior Therapy conference, New Orleans, LA, November 11, 2004.
- Osman, A., Williams, J. E., Barrios, F. X., Kopper, B. A., Gutierrez, P. M., Linden, S. C., & Carlson, N. Development of cutoff scores for the Beck scales in adolescent psychiatric inpatients. Presented at the Kansas Conference in Clinical Child and Adolescent Psychology, Lawrence, KS, October 21, 2004.
- Osman, A., Barrios, F. X., Gutierrez, P. M., Kopper, B. A., Williams, J. E., Carlson, N., & Koser, K. Reliability and validity of the Multidimensional Anxiety Scale for Children and the Children's Depression Inventory. Presented at the Kansas Conference in Clinical Child and Adolescent Psychology, Lawrence, KS, October 21, 2004.
- Osman, A., Gutierrez, P. M., Barrios, F. X., Kopper, B. A., Linden, S. C., Carlson, N., & Koser, K. The Reynolds Adolescent Depression Scale 2: Reliability and validity. Presented at the Kansas Conference in Clinical Child and Adolescent Psychology, Lawrence, KS, October 21, 2004.

- Muehlenkamp, J. J., & Gutierrez, P. M. Are self-injurious behaviors and suicide attempts different points on the same continuum? Presented at the Suicide Prevention: Advancing the Illinois Strategic Plan conference, Springfield, IL, September 23, 2004.
- Brausch, A. M., Swanson, J., & Gutierrez, P. M. Parent marital status, depression and suicide. Presented at the American Association of Suicidology conference, Miami, FL, April 16, 2004.
- Konick, L. C., Gutierrez, P. M., Muehlenkamp, J. J., Watkins, R. L., Ward, K. E., & Haase, K. Development of the Spiritual Attitudes and Beliefs Inventory: Phase II. Presented at the Midwestern Psychological Association annual meeting, Chicago, IL, May 8, 2003.
- Konick, L. C., Gutierrez, P. M., & Watkins, R. L. Adult Suicidal Ideation Questionnaire psychometrics. Presented at the American Association of Suicidology annual conference, Santa Fe, NM, April 25, 2003.
- Gutierrez, P. M., & Muehlenkamp, J. J. Understanding differences between self-injurious behavior and suicide attempts in high school students. Presented at the Kansas Conference in Clinical Child Psychology, Lawrence, KS, October, 18, 2002.
- Gutierrez, P. M., Osman, A., Brausch, A. M., Muehlenkamp, J. J., Watkins, R. L., & Konick, L. C. Reliability and validity of the Beck scales in the assessment of suicide-related behaviors in adolescent psychiatric inpatients. Presented at the Kansas Conference in Clinical Child Psychology, Lawrence, KS, October, 18, 2002.
- Gutierrez, P. M., Osman, A., Watkins, R. L., & Muehlenkamp, J. J. Potential racial differences in adolescent suicide risk. Presented at the Kansas Conference in Clinical Child Psychology, Lawrence, KS, October, 18, 2002.
- Osman, A., Gutierrez, P. M., Kopper, B. A., Barrios, F. X., Boyle, T., & Duncan, A. The Inventory of Suicide Orientation - 30: Further validation with adolescent inpatients. Presented at the Kansas Conference in Clinical Child Psychology, Lawrence, KS, October, 18, 2002.
- Osman, A., Linden, S., Gutierrez, P. M., Barrios, F. X., Kopper, B. A., & Forman, K. Validity of the Adolescent Psychopathology Content Scales (APS) in Pediatric Medical Institute for Children (PMIC) inpatients. Presented at the Kansas Conference in Clinical Child Psychology, Lawrence, KS, October, 18, 2002.
- Konick, L. C., Wrangham, J. J., Gutierrez, P. M., Blacker, D., Watkins, R. L., Aalders, G., Giannerini, J., Miller, M. J., Rapp, J. M., Shayne, L. E., & Ward, K. E. Development of the Spiritual Attitudes and Beliefs Inventory (SABI). Presented at the annual meeting of the Midwestern Psychological Association, Chicago, IL, May 2, 2002.
- Gutierrez, P. M., Wrangham, J., Konick, L., Osman, A., & Barrios, F. X. Does ethnicity influence adolescent suicide risk? Presented at the American Association of Suicidology annual conference, Bethesda, MD, April 12, 2002.

- Wrangham, J., Gutierrez, P. M., Osman, A., & Barrios, F. X. Validation of the PANSI with minority young adults. Presented at the American Association of Suicidology annual conference, Bethesda, MD, April 12, 2002.
- Konick, L. C., Brandt, L. A., & Gutierrez, P. M. School-based suicide prevention programs: A meta-analysis. Presented at the American Association of Suicidology annual conference, Bethesda, MD, April 12, 2002.
- Gutierrez, P. M., Osman, A., Kopper, B. A., & Barrios, F. X. Use of the Multi-Attitude Suicide Tendency Scale with minority individuals. Presented at the meeting of the Midwestern Psychological Association, Chicago, IL, May 4, 2001.
- Valentiner, D., Gutierrez, P. M., Deacon, B., & Blacker, D. Factor structure and incremental validity of the Anxiety Sensitivity Index for Children in an adolescent sample. Presented at the annual meeting of the Society for Research in Child Development, Minneapolis, MN, April 21, 2001.
- Gutierrez, P.M., Rodriguez, P. J., & Garcia, P. Minority suicide risk. Presented at the American Association of Suicidology annual conference, Los Angeles, CA, April 13, 2000.
- Kopper, B. A., Gutierrez, P. M., Osman, A., Barrios, F. X., Baker, M. T., & Haraburda, C. M. Reasons for Living Inventory for Young Adults: Psychometric properties. Presented for Division 17 - Counseling Psychology - at the annual convention of the American Psychological Association, Washington, DC, August 5, 2000.
- Kopper, B. A., Gutierrez, P. M., Osman, A., Barrios, F. X., & Bagge, C. L. Assessment of suicidal ideation in college students. Presented for Division 17 - Counseling Psychology - at the annual convention of the American Psychological Association, Washington, DC, August 5, 2000.
- Gutierrez, P. M., Rubin, E. C., & Blacker, D. A preliminary investigation of the role of suicide exposure and attitudes about death on adolescent suicidal ideation. Presented at the Midwestern Psychological Association annual conference, Chicago, IL, May 4, 2000.
- Martin, H., & Gutierrez, P. M. The role of mediating factors on the long-term relationship between early parental death and later depression and anxiety. Presented at the Midwestern Psychological Association Annual Conference, Chicago, IL, May 4, 2000.
- Kopper, B. A., Osman, A., Gilpin, A. R., Panak, W. F., Barrios, F. X., Gutierrez, P. M., & Chiros, C. E. The Multi-Attitude Suicide Tendency Scale: Further validation with adolescent psychiatric inpatients. Presented at the annual convention of the American Psychological Association, Boston, MA August 22, 1999.
- 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.

- Osman, A., Bagge, C. L., Barrios, F. X., Gutierrez, P. M., & Kopper, B. A. Receiver operating characteristic curve analyses of the Beck Depression Inventory - II in adolescent psychiatric inpatients. Presented at the Kansas Conference in Clinical Child Psychology, Lawrence, KS, October 9, 1998.
- Osman, A., Bagge, C. L., Gutierrez, P. M., Kopper, B. A., & Barrios, F. X. Validation of the Reasons for Living Inventory for Adolescents (RFL-A) in a clinical sample. Presented at the Kansas Conference in Clinical Child Psychology, Lawrence, KS, October 9, 1998.
- Kopper, B. A., Osman, A., Hoffman, J., Gutierrez, P. M., & Barrios, F. X. Reliability and validity of the BDI-II with inpatient psychiatric adolescents. Presented at Division 12 - Clinical Psychology - at the annual convention of the American Psychological Association, San Francisco, CA, August 16, 1998.
- 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.
- Gutierrez, P., & Williams, J. Children's understanding of death. Presented at the Midwestern Psychological Association annual meeting, Chicago, IL, May, 3, 1991.

#### 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.
- 3/09-12/09 U. S. Army Suicide Reduction and Prevention Research Strategic Planning Workgroup, Soldier Identification and Case Management Expert Lead.
- 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.
- 4/99- Ad hoc reviewer for *Psychiatry Research*; *Journal of Personality Assessment*; *American Journal of Public Health*; *Internal Journal of Circumpolar Health*; *Death Studies*; *Social Problems*; *Journal of Adolescent Research*; *Child Abuse and Neglect*; *British Journal of Clinical Psychology*; *Journal of Clinical and Consulting Psychology*; *Journal of Abnormal Psychology*; *International Journal of Psychology*; *Archives of Suicide Research*; *American Journal of Orthopsychiatry*; *Journal of Mental Health Counseling*; *Crisis*.
- 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
- 1998-2013 APA Div. 53, Society of Clinical Child and Adolescent Psychology
- 1997-2007 Midwestern Psychological Association
- 1996- American Association of Suicidology

A2

Change Form - PAM 013

COMIRB

Date: May 29, 2013 Protocol #: 10-0214 PI Name: Peter M. Gutierrez, Ph.D.  
Contact Person: Rebecca Leitner Phone #: (303) 399-8020 ext. 2404  
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
  - o 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