

AWARD NUMBER: W81XWH-15-1-0506

TITLE: Mental Health Disorders, Suicide Risk, and Treatment
seeking among Formerly Deployed National Guard
and Reserve Service Member seen in Non-VA Facilities

PRINCIPAL INVESTIGATOR: Joseph A. Boscarino, PhD, MPH

CONTRACTING ORGANIZATION:
Geisinger Clinic
Danville PA, 17822

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5012

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6. AUTHOR(S) Joseph A. Boscarino, PhD, MPH, Stuart N Hoffman, DO, Thomas G. Urosevich, OD, MS, FAO, H. Lester Kirchner, PhD, Johanna C. Hyacinthe, MS, Richard E. Adams, PhD, Charles R. Figley, PhD E-Mail: jaboscarino@geisinger.edu						5d. PROJECT NUMBER		
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14. ABSTRACT The focus of the proposed study is to assess the prevalence of and risk factors for mental health disorders, variations in service use and treatment seeking among National Guard and Reserve service members seen in non-VA facilities following deployments, compared to other service members. Of the 1,343 veterans surveyed to date, 5% were female, 45% were under 64 years old, 78% were married, 96% were white race, 41% reported multiple warzone deployments, and 27% were National Guard and Reserve veterans. The prevalence of current PTSD was 7% (95% CI = 5.7-8.5). Preliminary analyses indicated that PTSD, depression, mental health service use, alcohol misuse, suicidal thoughts, and stressful life events were more common among National Guard and Reserve veterans, compared to other era veterans (p-values < 0.05). However, other era veterans were more likely to rate themselves to be in "fair" or "poor" health and to have a service-connected disability (p-values < 0.05). Nevertheless, multivariable analyses that adjusted for demographic variables, level of combat exposure, current life stressors, and current social support, found no differences in mental health status and mental health service use among the veteran groups. Preliminary analyses suggest that while deployed National Guard and Reserve GWOT service members tended to have a higher prevalence of mental health disorders and mental health service use, when the data were adjusted for demographic factors and potential confounders, there were few differences between these veteran groups. Further research is planned.								
15. SUBJECT TERMS PTSD, DEPLOYED VETERANS, MENTAL HEALTH DISORDERS, SERVICE USE, TREATMENT OUTCOMES, NATIONAL GUARD AND GWOT RESERVE VETERANS								
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1. INTRODUCTION:

The focus of the current study is to assess the prevalence of and risk factors for mental health disorders, variations in service use, and outcomes among National Guard and Reserve service members following warzone deployments. This study is important because the majority of veterans have private and/or other health insurance coverage and often receive their care from non-VA institutions. The knowledge gained from studying National Guard and Reserve veterans in non-VA healthcare systems is highly relevant. The availability of healthcare options for veterans will likely increase in the future through the Affordable Healthcare Act (ACA) and other sources. Most veterans are not seen in VA facilities. The Geisinger Clinic, the community partner for the current study, is a large, non-profit integrated healthcare organization located in Pennsylvania. This system serves more than 2.6 million residents throughout 44 counties in central and northeast Pennsylvania. It has more than 21,000 employees, including a 1,100-member multi-specialty group practice, ten hospital campuses, a 467,000-member health plan, and is one of the largest employers in the state. The knowledge gained from studying veterans in non-VA healthcare systems is important for the monitoring the quality of care, diagnostic screening, and for outcomes research. Currently, Geisinger has over 35,000 current and former service members who use this system for their healthcare. Many of these patients currently are or were former members of the National Guard or the Reserves.

2. KEYWORDS: PTSD, DEPLOYED VETERANS, MENTAL HEALTH DISORDERS, SERVICE USE, TREATMENT OUTCOMES, NATIONAL GUARD AND GWOT RESERVE VETERANS

3. ACCOMPLISHMENTS:

- **What were the major goals of the project?**

YEAR 1

Major Goal 1: Study Start, Instrument/Protocol Finalization, Local IRB, DoD IRB Approval

Subtask 1: Convene initial study meetings with study group (+1 month)
Subtask 2: Review and update study instruments and protocol from pilot study, pilot test revised protocol (+1/2 months)
Subtask 3: Submit revised protocol to Geisinger Clinic's IRB and obtain approval (+2 months)
Subtask 4: Submit protocol for DoD's IRB review (approval pending) (+3 months)
Milestone: Finalize study protocol/instruments received required IRB approvals (+3/4 months)

Major Goal 2: Survey Data Collection, Baseline EHR Data Collection, DNA Collection, Data Cleaning, Preliminary Data Analyses

Subtask 1: Pull baseline electronic health record (EHR) data from Geisinger's Information Technology (IT) Systems, including veteran status data, outpatient, inpatient and emergency department data
Subtask 2: Conduct survey data collection
Subtask 3: Collect DNA Samples by Mail
Subtask 4: Conduct preliminary data analyses
Milestones Achieved: Survey data collected, baseline EHR data collected, DNA collected, preliminary analyses being completed

YEAR 2

Major Goal 3: Bio-bank DNA, Complete Genotyping, Merge Survey, EHR, and Genotype Data, Complete Analyses for Study Aim 1 (Prevalence Study) and for Aim 2 (PTSD Study), Prepare Manuscripts for Review

Subtask 1: Complete genotyping of selected study SNPs
 Subtask 2: Merge genotype data into survey and EHR datasets
 Subtask 3: Continue analyses related to study Aims 1 and 2
 Subtask 4: Convene team conference on site to review study results
 Subtask 4: Prepare and submit manuscripts for peer review
 Subtask 5: Complete and review preliminary genetic analyses
 Subtask 6: Prepare manuscripts for internal review and peer review submission

Milestones Achieved: DNA Bio-banked, complete genotyping, merge survey, EHR, and genotype data, complete analyses for study Aims 1 and 2, prepared & subcommittee manuscripts for peer review

YEAR 3

Major Goal 4: Complete Follow-up EHR data pull from Geisinger IT Systems, Merge Follow-up Data, Complete Analyses for Study Aim 3 (Effectiveness) and for Aim 4 (Genetics), Prepare Final Manuscripts for Review and Submission, Convene Final Conferences and meetings

Subtask 1: Conduct Follow-up data pull from Geisinger's EHR IT Systems, using outpatient, inpatient, ED data
 Subtask 2: Merge and clean/code data/ and run preliminary analyses
 Subtask 3: Complete analyses for Aims 3 and 4
 Subtask 4: Prepare final manuscripts for review and submission
 Subtask 5: Prepare and submit proposals for additional genetic and follow-up research funding
 Subtask 6: Prepare documentation/datasets for bio-banking and data-sharing of study data
 Subtask 6: Complete follow-up EHR data pull from Geisinger IT Systems, merge follow-up data, Completed analyses for Aims 3 and 4, Prepare Final manuscripts for review and submission, convene final conference meeting, prepare documentation and datasets for data sharing.

Yearly Patient Enrollment

Table 1. (planned)	Year 1*			
Target Survey Enrollment (per quarter)	Q1	Q2	Q3	Q4
Geisinger Site	1500	200	100	0
Target Enrollment (cumulative)	1500	1700	1800	1800

- **What was accomplished under these goals?**

YEAR 1

Major Goal 1:

Quarter 1 -

Hired 2 personnel essential to the execution of the study. Conducted initial meetings with the study team via in person and phone conferences. Updated the current veteran registry database, preparing for the data pull to recruit potential participants via mail for study survey phase. Revised the phone survey, correcting issues identified in the original pilot conducted in 2012. Submitted protocol and supporting documents to Geisinger Clinic and Department of Defense (DoD) for Institutional Review Board (IRB) approval. Prepared and submitted the application for a National Institute of Mental Health (NIMH) certificate of confidentiality (CoC), providing additional protection for the information collected, while also enhancing the likeliness of a service member participating. Worked with Kent State's and Tulane's IRB staffs to allow them to cede to Geisinger's IRB as the lead IRB on the study.

Quarter 2 -

Convened on-site study meeting with all investigators to discuss the study objectives, design, statistical analysis, timetable, anticipated

issues, and publications planned. Baseline EHR veteran status data was pulled from Geisinger's IT systems. Identified shortage in cohort of Guard and Reserve service members and implemented additional recruitment strategy within Geisinger patient population to increase sample size. Commenced survey data collection. Sent out DNA collection kits via mail. Began preliminary survey data analyses.

Quarter 3-

Held monthly meetings with all investigators to discuss preliminary data, status of recruitment efforts, and publications planned. Implemented additional recruitment strategy within Geisinger patient population to increase sample size of Guard and Reserve service members whereby we directly contacted patients via a study-specific email directing them to the MyGeisinger.org survey. This additional step was approved by DoD. Continued survey data collection. Began receiving DNA samples which have been sent to lab to be genotyped and bio banked. Continued preliminary data analyses. Had poster to the accepted for the Society of Federal Health Professionals conference. Submitted two posters to the Health Care Research Network (HCSRN) annual conference. Also began preparing several manuscripts that will be submitted during the next quarter.

Yearly Patient Enrollment

Table 1. (actual)	Year 1*			
	Q1	Q2	Q3	Q4
Target Survey Enrollment (per quarter)				
Geisinger Site	0	131	658	1422
Target Enrollment (cumulative)	1500	1700	1800	1800

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

Nothing to Report.

- **How were the results disseminated to communities of interest?**

Nothing to Report.

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

We plan to complete survey data and DNA collection, and complete genotyping for this study. A community outreach is also planned including a town hall meeting with local and regional veterans.

4. IMPACT:

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

Nothing to Report.

- **What was the impact on other disciplines?**

Nothing to Report.

- **What was the impact on technology transfer?**

Nothing to Report.

- **What was the impact on society beyond science and technology?**

Nothing to Report.

5. CHANGES/PROBLEMS: *The were no substantive changes submitted to the Department of Defense during the last reporting period.*

However, problems faced include:

- **Changes in approach and reasons for change:** After conducting the EHR data pull screening by phone, it was discovered that the sample size for veterans who have served in the National Guard or Reserves during or after 2001 in the Global War on Terror and were actually deployed was smaller than anticipated. To address this issue we have directly contacted patients utilizing a study specific e-mail to direct them to a brief online eligibility survey for patients within Geisinger who may have been missed in the veteran's database. This eligibility survey is available on MyGeisinger.org and patients can voluntarily take the survey which screens them for study eligibility. This eligible sample is reviewed to avoid duplication and new patients are then enrolled in the study. This additional recruitment step was approved by the Geisinger IRB. We also recruited additional National Guard/Reserve veterans by e-mailing patients in top 20 populated veteran zip-codes to direct them to the MyGeisinger.org survey. Both of these additional recruitment steps were sent to the HRPO contact and it was determined that additional approval was not needed by the DoD.
- **Actual or anticipated problems or delays and actions or plans to resolve them.**

1. Recruiting additional National Guard/Reserve veterans to reach our originally planned sample size.

Action to be taken:

- We have reached out to leaders of student veteran organizations at over 30 colleges and universities in the central and northeastern PA areas to help with recruitment of the National/Guard Reserve cohort. Leader of these organizations will direct students who are Geisinger patients to the Mygeisinger.org website so they can be screened for enrollment into the study.
 - We also plan to have a Town Hall meeting to increase community awareness about study and to facilitate recruitment.
2. Poor quality DNA samples submitted by participant or DNA samples not returned.

Action to be taken:

- Re-contacting participants via phone and mail with additional instructions to a request another sample.

- **Changes that had a significant impact on expenditures**

Nothing to Report

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

Nothing to Report

- **Significant changes in use or care of human subjects:**

Nothing to Report

- **Significant changes in use or care of vertebrate animals:**

Nothing to Report

- **Significant changes in use of biohazards and/or select agents:**

Nothing to Report

6. PRODUCTS:

- **Publications, conference papers, and presentations**
Journal publications.
Nothing to Report
- **Books or other non-periodical, one-time publications.**
Nothing to Report
- **Other publications, conference papers, and presentations.**
Presented Poster based on Pilot Study: Mental Health Disorders and Treatment seeking among Veterans in Non-VA Facilities: Results and Implications from the Veterans' Health Study. Annual Meeting of the International Society of Traumatic Stress Studies, New Orleans, LA, November 5, 2015.
Upcoming Poster Presentation: Mental Health Disorders and Treatment seeking among Formerly Deployed National Guard and Reserve Service Members. Annual Meeting of the Society of Federal Health Professionals Annual Meeting, National Harbor, MD, November 29' 2016
Pending Abstract Submission: Alcohol Misuse among Formerly Deployed U.S. Service Members seen Non-VA Facilities: Results from the Veterans' Cohort Study. 2017 Health Care Systems Research Network Conference, San Diego, CA, March 21, 2017
Pending Abstract Submission: Post-Deployment Mental Health Status and Obesity among a Multi-generational Sample of U.S. Veterans. 2017 Health Care Systems Research Network Conference, San Diego, CA, March 21, 2017
- **Website(s) or other Internet site(s)**
Nothing to Report
- **Technologies or techniques**
Nothing to Report
- **Inventions, patent applications, and/or licenses**
Nothing to Report
- **Other Products**
Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

- **What individuals have worked on the project?**

Name:	Joseph A. Boscarino
Project Role:	<i>Principle Investigator, Geisinger Clinic</i>
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	12
Contribution to Project:	<i>Wrote study application, secured study funding, directs overall study, monitors study progress and budget, prepares study presentations and manuscripts for dissemination.</i>
Funding Support:	N/A
Name:	Charles Figley
Project Role:	<i>Co-Investigator, Tulane University</i>

Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	11
Contribution to Project:	Conference calls and personal meeting with PI to discuss study measurements, data analysis, conceptual focus, coordination of IRB approval with Tulane University's IRB, and review of data collection instruments for current study.
Funding Support:	N/A
Name:	Richard Adams
Project Role:	<i>Co-Investigator, Kent State University</i>
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	11
Contribution to Project:	Contribution to Project: Conference calls with Study PI to discuss planned study measurements, data analysis, conceptual focus of study, coordination of IRB approval with Kent State's IRB, and review of data collection instruments planned for current study. Began writing paper examining psychosocial factors that impact deployed veterans.
Funding Support:	N/A
Name:	Thomas Urosevich
Project Role:	<i>Co-Investigator, Geisinger Clinic</i>
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	11
Contribution to Project:	Conference calls with Study PI to discuss planned study measurements, data analysis, conceptual focus of study, identification of key genotypes for study, and identification of key TBI measures to be used in study.
Funding Support:	N/A
Name:	Stuart Hoffman
Project Role:	<i>Co-Investigator/Neuroscience Consultant</i>

Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	11
Contribution to Project:	Contribution to Project: Meetings with Study PI to discuss planned study measurements, data analysis, conceptual focus of study, identification of key genotypes for study, and identification of key neurological and sleep disturbance measures to be used in study.
Funding Support:	N/A
Name:	H. Lester Kirchner
Project Role:	<i>Co-Investigator, Geisinger Clinic</i>
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	11
Contribution to Project:	Contribution to Project: Consulted with Study PI regarding biostatistics, study database, and data dictionary planned for study, and met with study staff assigned to project.
Funding Support:	N/A
Name:	Xin Chu
Project Role:	<i>Genetic Consultant, Geisinger Clinic</i>
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	10
Contribution to Project:	Ordered Inventory of needed supplies and assays for study and overseeing the genotyping and bio-banking of DNA being collected for study.
Funding Support:	N/A
Name:	Johanna Hyacinthe
Project Role:	<i>Project Manager, Geisinger Clinic</i>
Researcher Identifier	N/A

(e.g. ORCID ID):	
Nearest person month worked:	10
Contribution to Project:	Application and document preparation, regulatory compliance, budgeting, and operational management of study.
Funding Support:	N/A
Name:	James Pitcavage
Project Role:	<i>Former Project Manager, Geisinger Clinic</i>
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	3
Contribution to Project:	Application and document preparation, regulatory compliance, budgeting, and operational management of study.
Funding Support:	N/A
Name:	Brielle Evans
Project Role:	<i>Current Research Assistant, Geisinger Clinic</i>
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2
Contribution to Project:	Mailings of incentives, DNA kits, consent forms, etc. and over all tracking of patient participation. Assists with the daily operations of study.
Funding Support:	N/A
Name:	Melinda Hatt
Project Role:	<i>Former Research Assistant , Geisinger Clinic</i>
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	4

Contribution to Project:	Mailings of incentives, DNA kits, consent forms, etc. and over all tracking of patient participation. Assists with the daily operations of study.
Funding Support:	N/A
Name:	Jared Pajovich
Project Role:	<i>Former Research Assistant, Geisinger Clinic</i>
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	11
Contribution to Project:	Completion of Certificate of Confidentiality application, Mailings of incentives, DNA kits, consent forms, etc. and over all tracking of patient participation. Assists with the daily operations of study.
Funding Support:	N/A

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

Nothing to Report

- **What other organizations were involved as partners?**

Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS

▪ QUAD CHART:

Mental Health Disorders, Suicide Risk and Treatment seeking among Formerly Deployed National Guard and Reserve Service Member seen in Non-VA Facilities

Log Number: PT140183; Study preparation & set-up phase; Study recruitment & data collection phase

Award Number: W81XWH-15-1-0506

PI: Joseph A. Boscarino, PhD, MPH Org: Geisinger Clinic, Danville, PA

Award Amount: \$ 2,261,852



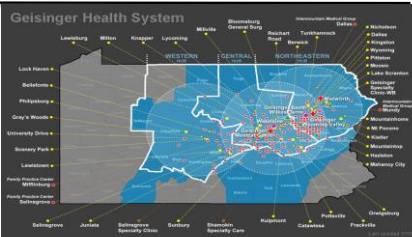
Study Aims
Aim 1: To estimate the prevalence of and risk factors for mental health disorders, substance use disorders, TBI, and suicide among National Guard and Reserves personnel who have returned from recent combat.
Aim 2: To identify protective factors for the onset and course of posttraumatic stress disorder (PTSD) and related disorders among service members after combat operations.
Aim 3: To assess the outcome of interventions received by National Guard and Reserves members during/after recent combat operations, including brief interventions.
Aim 4: To conduct genetic research related the risks for mental disorders, including the development of a DNA repository and research panel for future studies related to the genetics and consequences of PTSD and related disorders.

Method
 A cohort study that includes multivariable analyses of diagnostic interviews with 900 deployed National Guard/Reserve veterans and 900 deployed veterans from other service areas, plus longitudinal clinical data from electronic health record (EHR) and DNA samples from Geisinger Clinic veterans.

Timeline and Cost

Activities	CY	15	16	17	NA
Setup, IRB, recruit, data collection					
Merge survey, EHR data, DNA					
Conduct data analyses					
Complete analyses & disseminate					
Estimated Budget (\$K)		\$857K	\$804K	\$601K	--

Updated: 10-12-16 (JH)



- Geisinger Health System**
- Goals/Milestones**
- CY15 Goals – Study preparation, and set-up, IRB phase**
- Hired 2 personnel key to study operation
 - Conducted initial meeting, updated veteran registry, and revised phone survey
 - Submitted protocol and supporting documents to Geisinger & DoD IRB and National Institute of Mental Health (NIMH) for Certificate of Confidentiality
 - Received Geisinger/DoD IRB approval & Certificate of Confidentiality from NIMH
- CY16 Goals – Recruit study subjects from Geisinger Clinic**
- Conducted EHR data pull for veterans status and demographics
 - Began survey interviewing and collection of DNA
 - Conducted preliminary data analyses
 - Prepared abstract to submit to Military Medicine and began writing manuscripts
 - Began genotyping of selected SNPs
 - Presenting findings at regional & national conferences
 - Merge & clean data, complete analyses
 - Extract relevant clinical data from EHR.
 - Extract DNA & genotype candidate genes for PTSD/addiction disorders, etc.
 - Presenting findings at regional & national conferences
- CY17 Goals – Complete data analyses & disseminate results**
- Submit papers for publication to key medical journals
 - Comments/Challenges/Issues/Concerns
 - Delayed timeline due to coding IRBs and survey time of >60 minutes
 - Increasing sample size of National Guard/Reserve cohort

9. APPENDICES :

Mental Health Disorders and Treatment seeking among Formerly Deployed National Guard and Reserve Service Members

Joseph A. Boscarino, PhD, MPH;¹ Stuart N Hoffman, DO;¹ Thomas G. Urosevich, OD, MS, FAAO;¹ H. Lester Kirchner, PhD;¹ Johanna C. Hyacinthe, MS;¹ Jared V. Pajovich, BA;¹ Richard E. Adams, PhD;² Charles R. Figley, PhD³
¹Geisinger Clinic, ²Kent State University, ³Tulane University

Study Objective: Our objective was to assess the prevalence of mental health disorders and treatment seeking among deployed National Guard and Reserve service members seen in non-VA Facilities.

Methods: We surveyed a random sample of veterans who were patients in a large non-VA hospital system located in Central and Northeastern Pennsylvania to assess their mental health status and service use. The study included veterans from three cohorts: Vietnam, Gulf War, and Global War on Terror (GWOT) veterans. Our hypothesis was that deployed National Guard and Reserve GWOT veterans would have a higher prevalence of mental disorders, substance misuse, and mental health treatment seeking than deployed veterans from other eras.

Results: Of the 731 veterans surveyed, 39.9% were GWOT National Guard and Reserve veterans, 6.8% were female, 64% were under 64 years old, 75.7% were married, 95.7% were white, and 45% reported multiple warzone deployments. Overall, 26.7% of veterans had a mental health visit in the past year, 23.5% reported using psychiatric drugs, and 48.7% used the VA system in the past year. Current mental health disorders among veterans included alcohol misuse (14.6%), depression (10.1%), generalized anxiety (11.4%), and PTSD (10.4%). Altogether, 29% of veterans reported a concussion during military service and 42.7% reported current difficulty sleeping. Bivariate analyses indicated that current depression, mental health service use, alcohol misuse, generalized anxiety, and recent stressful life events were more prevalent among National Guard and Reserve GWOT veterans, compared to other era veterans (p-values < 0.05). However, other era veterans were more likely to report "fair" or "poor" health status and to report a service-connected disability (p-values < 0.05). Nevertheless, multivariable analyses that adjusted for age, gender, education, combat exposure, current life stressors and current social support, found no significant differences in mental health status or service use between these veterans.

Conclusion: Our analyses suggested that while deployed National Guard and Reserve GWOT service members tended to have a higher prevalence of mental health disorders and service use than other veterans, when the data were adjusted for demographic factors and potential confounders, there were no significant differences found between these veteran groups.

Funding: U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND (USAMRMC), PRINCIPAL INVESTIGATOR: Joseph A. Boscarino, PhD, MPH, Psychological Health and Traumatic Brain Injury Research Program (PHTBIRP) - Community Partners in Mental Health Research, Award # W81XWH-15-1-0506.

Learning Objectives:

Attendees will learn the prevalence of mental health disorder among service members seen in non-VA facilities.

Attendees will be able to describe the mental health disorders among service members seen in non-VA facilities.

Attendees will be able to identify risk factors for mental health disorders among service members seen in non-VA facilities.

To be Presented at: The AMSUS 2016 Federal Health Conference, Gaylord National Convention Center, National Harbor, MD, November, 29 to December 2, 2016.