Project Information

Project Title: **Evaluation of Health Status of an Infantry Battalion Following Deployment in Support of Operation Iraqi Freedom in 2004-2005.**

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1 Non-Technical Description/Summary

1.1 Problem

From October, 2004 through September, 2005, the 1st Battalion, 24th Infantry (1-24 IN) was assigned to the 1st Brigade, 25th Infantry Division "Lightning" Stryker brigade combat team (SBCT) and deployed in support of Operation Iraqi Freedom (OIF), serving in the vicinity of Mosul with Task Force Olympia. A previously conducted deployment and environmental health surveillance investigation by the Army Public Health Center (APHC) (2016) was unable to discern etiologic elements connecting the multitude of conditions and symptoms; deployment-associated environmental exposures which may have increased the risk of developing these conditions were not identified. The report focused on summarizing the health status of a small subset of 1-24 IN service members (SM); however, **a comprehensive comparative health status evaluation seeking to include all former members of the 1-24 IN who served in Iraq has not been conducted**.

1.2 Purpose

This proposal outlines APHC's intent to assess and compare the health status of members of the 1-24 Infantry Battalion who deployed to Iraq in 2004-2005. **The purpose of this initiative is to identify the frequency of post-deployment medical encounters for cancers, respiratory diseases, circulatory system diseases, and mental health disorders among soldiers and veterans that deployed to Iraq with the 1-24 IN**. The investigation is being conducted at the request of the Chief of Staff of the Army (CSA), Gen. Milley, who tasked APHC with investigating the health status of former members of the 1st Battalion, 24th Infantry. This charge was itself motivated by members of the 1-24 IN who voiced concern regarding the number among their ranks who have fallen ill, having developed lymphoma, leukemia, bile duct cancer, prostate cancer, Crohn's Disease, sleep apnea, asthma, depression, liver disorders, among others conditions and symptoms. This investigation will focus on cancer incidence, though a broad set of non-cancer diagnoses will also be evaluated in an attempt to mirror the

breadth of concerns raised among members of the 1-24 IN. In order to characterize the post-deployment health status of the 1-24 IN, the investigation includes the following objectives:

1. Identify the set of diagnoses affecting the 1-24 IN subsequent to their 2004-2005 deployment to Iraq;
2. Compare the frequency of post-deployment medical diagnoses and self-reported health conditions between those in the 1-24 IN who remain in service and those who have separated or retired from the Army and are Department of Veterans Affairs (VA) beneficiaries;
3. Compare the frequency of **self-reported health conditions** between former members of the 1-24 IN and a similar exposure group (SEG) consisting of other personnel in the 1 SBCT to subsets of Millennium Cohort Study (MCS) participants who either a) deployed to Iraq or Afghanistan between 2004 and 2005, or b) were stationed in Korea between 2004 and 2005 and did not deploy in support of Operations Iraqi or Enduring Freedom;
4. Compare the frequency of post-deployment **health conditions defined using administrative health data** and **self-reported health conditions** between former members of the 1-24 IN and SEG (i.e., the 1 SBCT) to SBCT that deployed prior to, and after, the 1 SBCT deployment in 2004-2005 and to SBCT personnel that deployed to another location in Iraq during the same time period as the 1 SBCT deployment.

APHC obtained a roster of the 1-24 IN (n=625) from the Defense Manpower Data Center (DMDC) as part of the previously conducted deployment and environmental health surveillance investigation. The accuracy and completeness of this roster will be assessed using a roster of the 1-24 IN obtained from Headquarters, Department of the Army G-1 (HQDA G-1).

APHC will obtain rosters of the remaining formerly deployed personnel to be compared in this investigation from HQDA G-1, except for MCS participants who will be identified by the Naval Health Research Center (NHRC). Health status for these individuals, other 1 SBCT personnel, and comparison SBCT personnel will be ascertained in two ways: 1) by mining outpatient and inpatient diagnosis and discharge codes (International Classification of Diseases, 9th Revision, ICD-9 CM codes) contained in the Defense Medical Surveillance System maintained by the Armed Forces Health Surveillance Branch (AFHSB) and the VA Health Data Repository (HDR) maintained by the VA Office of Public Health (OPH), and 2) by inviting former members of the 1 SBCT to complete a health survey designed to be directly comparable to surveys completed by participants in the MCS. Frequency of health conditions will be reported as cumulative incidence (proportions, risk differences, and relative risks) and incidence rates; relative rates will be estimated using multivariate Poisson regression.

Several partnerships will be established to conduct this investigation. Within APHC, subject matter experts (SME) from Occupational and Environmental Medicine (OEM), Epidemiology and Disease Surveillance (EDS), and Health Risk Management (HRM), have contributed to the development of this proposal. Externally, APHC has partnered with the AFHSB to refine the design and analytic components of the investigation; AFHSB will also provide Department of Defense (DoD)-beneficiary medical encounter data for the project. Because 71% of the 1-24 IN has separated or retired from military service, this proposed evaluation will be conducted in partnership with the VA OPH. APHC will also partner with the Naval Health Research Center (NHRC) to compare health status among survey respondents from the 1 SBCT to MCS participants. The MCS is an ongoing DoD research project at the Deployment Health Research Department within NHRC (DMDC Reference Number 00-0019, RCS Number DD-

HA(AR)2106, OMB Approval Number 0720-0029, ASD/HA/TMA Protocol Number CDO-06-206, and Primary IRB Protocol Number NHRC.2000.0007). The HQDA G-1 will provide APHC with personnel rosters.

1.3 Goals, Outcomes, Deliverables

The overarching goal of the investigation is to better understand the post-deployment health status of soldiers and veterans who deployed to Iraq in 2004 with the 1-24 Infantry Battalion. The deliverables of this initiative will include an APHC information paper, a technical report, and summary presentations of the evaluation and its findings, including a presentation and brief to the CSA and TSG.

Per CSA's request, this initiative will be conducted rapidly, with initial results provided in an information paper summarizing the progress of the investigation, including any results obtained to be briefed by 08 June, 2016. A full report of the findings of this investigation will be written within 18 months of approval of this project by the APHC PHRB and other parties, as appropriate (e.g., MRMC IRB, VA OPH IRB, NHRC IRB).

2 Authority

2.1 References

2.1.1 This public health investigation is being conducted in response to a direct tasking from GEN Milley, CSA and LTG West, Army Surgeon General (SG). TASKER ID: 13943 TASKER TITLE: 1603189212 - CSA 39 PHC Deployment Ailments Update - 1/24 BN SBCT ORIGINATING AUTHORITY: OTSG

2.1.2 Department of Defense Instruction (DoDI) 6490.03, Deployment Health, establishes the requirement to identify and assess occupational and environmental health (OEH) hazards during deployments, to mitigate the short- and long-term health risk to the extent feasible in an operational environment, and to monitor and track health conditions that may result from those exposures.

2.1.3 In accordance with Army Regulation (AR) 40-5, Preventive Medicine, the APHC(P) will support comprehensive health surveillance for the Army and will review, interpret, and respond to assessment and surveillance data, to identify, prevent, and control newly identified or evolving health problems.

2.1.4 Data transfer agreement (DTA; February 2, 2013) signed by both the Deputy Secretary of the VA and the Under Secretary of Defense (Personnel and Readiness) (Appendix G).

2.2 Public Health Guiding Questions

To better understand the post-deployment health status of soldiers and veterans who deployed to Iraq in 2004 with the 1-24 Infantry Battalion, this project will address the following public health guiding questions:

1. What is the frequency of disease among the 1-24 IN following their 2004-2005 deployment to Iraq?

2. Is the post-deployment incidence of disease elevated among active duty and retired soldiers who deployed with the 1-24 IN relative to those who served with the 1-24 IN and who have since separated from service and are VA beneficiaries?

3. Is the post-deployment incidence of disease elevated among soldiers and veterans who deployed with the 1 SBCT relative to select MCS participants who either a) deployed to Iraq or Afghanistan between 2004 and 2005, or b) were stationed in Korea between 2004 and 2005 and did not deploy in support of Operations Iraqi or Enduring Freedom?

4. Is the post-deployment incidence of disease elevated among soldiers and veterans of the 1 SBCT relative to soldiers and veterans who deployed in support of Iraqi Freedom with SBCT either before or after the 1 SBCT deployment in 2004-2005 and, additionally an SBCT that deployed during the same time period (2004-2005), but to other locations in Iraq?

Questions 1, 2, and 3 will leverage both administratively collected healthcare encounter data and self-reported health survey data. Question 4 will be addressed using only administratively-collected healthcare encounter data for DoD and VA beneficiaries. At a minimum, these questions will address the following sets of health conditions:

- **Cancers**
- **Chronic respiratory diseases**
- **Diseases of the circulatory system**
- **Mental health conditions**

3 Project Plan

3.1 Objective(s)

The overall goal of this investigation is to characterize the burden of disease among members of the 1-24 IN following their deployment to Iraq in 2004-2005. To meet this goal and the corresponding public health guiding questions, the investigation will address the following specific objectives:

1. Identify the set of diagnoses affecting 1-24 IN subsequent to their 2004-2005 deployment to Iraq;

2. Estimate the frequencies of post-deployment select sets of medical conditions between former members of the 1-24 IN who remain in service and compare them to the corresponding frequencies among those who have separated from the Army and are VA beneficiaries;

3. Compare the frequencies of self-reported health conditions between former members of the 1-24 IN and SEG (i.e., the 1 SBCT) to subsets of MCS participants who either a) deployed to Iraq or Afghanistan between 2004 and 2005, or b) were stationed in Korea between 2004 and 2005 and did not deploy in support of Operations Iraqi or Enduring Freedom;

4. Estimate the frequencies of select sets of post-deployment health conditions between members of the 1-24 IN and SEG (i.e. the 1 SBCT) and compare them to the frequencies observed among personnel from other SBCT deployed in support of OIF either before, or after the 2004-2005 1 SBCT deployment and to an SBCT deployed in support of OIF during the same 2004-2005 time period, but to a different location.

3.2 Data Protection Plan

To conduct this surveillance project, APHC and collaborating investigators will utilize fully-identified medical encounter and survey data (PHI) in combination with demographic, occupation, and deployment history data (PII). APHC will use an in-house troop tracker database to identify Unit Identification Code (UIC) corresponding to the 1st SBCT and suitable comparison populations. Soldiers that served in units corresponding to these UICs will then be identified by APHC using a DMDC Joint Manpower Information System (JMIS) data feed. After creating a master key file containing an anonymous identifier variable and PII, APHC will create a master roster of individuals to be included in the assessment that contains the anonymous identifier variable and PII variables (SSN, name, DOB, UIC) to be distributed to the following collaborating investigators:

- AFHSB, who will search for and retrieve medical encounter data from Defense Medical Surveillance System (DMSS) for DoD beneficiaries. AFHSB will provide APHC with health ICD-9 diagnoses codes for inpatient and outpatient medical encounters occurring after October 2004 to present (~APR 2016) among former 1 SBCT personnel and for DoD beneficiaries identified in SEG and comparison populations, as appropriate.
- VA OPH, who will search for and retrieve medical encounter data from VA HDR for VA beneficiaries. VA OPH will provide APHC with health ICD-9 diagnoses codes for inpatient and outpatient medical encounters occurring after October 2004 to present (~APR 2016) among former 1 SBCT personnel and for VA beneficiaries identified in SEG and comparison populations, as appropriate.
- Army Medical Command Headquarters (MEDCOM HQ), who will identify current contact information using the LexisNexis database for individuals that have separated from service and provide this information back to APHC.
- APHC will provide NHRC with de-identified survey response data to compare with responses of male MCS participants who had deployed in support of OIF or OEF anytime between the years 2004 and 2005 and those stationed in Korea during that time period.

At APHC, all datasets containing PII or PHI will be saved and stored on an APHC secure drive in a directory accessible only by APHC project staff. Read and write access to the primary and derivative analytic datasets will be restricted by Common Access Card (CAC) to the APHC project personnel and for whom drive access has been granted.

All data files containing PII and PHI will be transferred between APHC and partnering organizations using the AMRDEC SAFE Web Application (https://safe.amrdec.army.mil/SAFE/). Data linkage will be conducted by APHC, VA OPH, AFHSB, and NHRC. The SAFE website is designed to provide its customers an alternative way to securely send files instead of using email. Key files linking the assigned subject identification numbers with personal identifiers (SSNs) will be maintained by the organizations from which the data are to be sourced (VA-OPH, AFHSC, and NHRC) and transferred only via AMRDEC SAFE.

APHC will not distribute datasets containing personnel identifiers with PII elements other than those required by collaborating investigators to identify appropriate medical and survey records (i.e. name, DOB, SSN). Prior to returning datasets containing PII and PHI via AMRDEC SAFE, the collaborating organizations will strip datasets of PII contained in the original roster sent by APHC.

After the data transfers, datasets containing PHI will be saved to APHC's secure drive.

Infantry identified as having deployed with the 1 SBCT will be invited to complete a health survey. This post-deployment health survey was designed by APHC to closely mirror relevant portions of the MCS survey instrument. Individuals who agree to participate in the survey and sign an informed consent document will have the option of completing the survey online using a secure APHC survey website (Verint web survey software), or using a hardcopy survey which will be returned to APHC via certified mail in an envelope with postage provided to the participant by APHC. Participation in the survey is completely voluntary. However, APHC will take the following steps to maximize participation: An APHC investigator will attempt to contact all individuals who do not complete and return the survey, beginning 14 days after the initial invitation to participate was mailed. The first follow-up contact will be via an email sent to all individuals who have not returned a completed survey. This email will include a telephone number to call if the potential respondent has questions about participation in the survey. The email will also include an invitation to call if the individual would prefer to complete the survey telephonically. In the absence of an email or phone response indicating an intention to complete the survey, this initial reminder email will be followed one day later by a telephone call. If an APHC investigator is able to make contact with a potential respondent via telephone, the investigator will offer to allow the individual to complete the questionnaire over the phone. In the event that the investigator is not able to contact the individual, a second email will be sent to the individual that includes 1) the fact that the call was attempted, 2) a contact number to use if the individual would like to complete the survey telephonically, and 3) a specified time that the investigator will call again. This time will be no more than two days from the time the email is sent, and will be a different time of day from the previous call. These steps will be repeated eight times over the course of one month (twice per week), before the individual is deemed a potential "non-responder". A letter will then be mailed to potential non-responders, indicating that we had attempted to contact the individual by letter, phone and email, and once again inviting them to complete the survey. All of the paperwork initially sent to the individual will be included in this letter. The letter will also include an invitation for the individual to call APHC to complete the survey telephonically. Letters, emails and telephone correspondence attempts will be logged in a Microsoft Excel Workbook. Responses to paper-based surveys and surveys delivered telephonically will be entered into the online Verint survey application by APHC staff. After a quality control check by a second data entry personnel, the paper-based surveys will be destroyed using a government-approved cross-cut paper shredder.

The Verint Public Health survey software is a commercial web-based product. It is used by APHC to build surveys collect/evaluate responses, view statistical reports, and export responses to databases. The types of personal information collected include: Name, Birth Date, Race, Ethnicity/Gender, Medical Information, and Contact Information. The Privacy Act System of Records Notice (SORN) Identifier for the Verint Survey Builder Software is A0040-5 DASG. The authority provided in the PIA is as follows: 10 U.S.C. 3013, Secretary of the Army; 5 U.S.C. 7902, Safety Programs; 29 U.S.C. 668, Programs of Federal Agencies; 29 CFR 1910, Occupational Safety and Health Standards; Army Regulation 40-5, Preventive Medicine; E.O. 12223, Occupational Safety Health Programs for Federal Employees; and E.O. 9397 (SSN). The Privacy Act Impact Assessment (PIA) is included below.