

THE UNITED STATES ARMY MEDICAL DEPARTMENT JOURNAL

FORCE HEALTH PROTECTION: THE PROVEN FORCE MULTIPLIER

July - September 2014

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Perspectives

COMMANDER'S INTRODUCTION

MG Steve Jones

FORCE HEALTH PROTECTION AND THE HUMAN DIMENSION

Baron Von Steuben introduced Force Health Protection to the United States Army at Valley Forge when he instructed regimental commanders that “the preservation of the Soldier’s health should be their first and greatest care.” Captains, lieutenants, and ensigns were given additional instructions on their role in supporting this new leadership responsibility. The concept has served the Army well since its introduction, and, with improved techniques, we saw significantly higher casualty survival rates and lower disease and nonbattle injury rates during the conflicts in Iraq and Afghanistan.

Joint Publication 4-02 defines Force Health Protection as “Measures to promote, improve, or conserve the behavioral and physical well-being of Service members to enable a healthy and fit force, prevent injury and illness, and protect the force from health hazards.”^{1(pGL-7)} Among other things, an October 31, 2006 change added a chapter on Force Health Protection^{1(pIV-1)} with subordinate core functional capabilities, the first of which is Casualty Prevention, which includes all measures taken by commanders, leaders, individual military personnel, and the healthcare system to promote, improve, or conserve the mental and physical well-being of military personnel. Additional core functional capabilities specified and detailed in *Joint Publication 4-02* are Preventive Medicine, Health Surveillance, Combat and Operational Stress Control, Preventive Dentistry, Vision Readiness, and Laboratory Services.

In his 1984 article in *Military Medicine*,² COL Ron Belamy stimulated critical thinking about our approach to combat casualty care. He stated:

Given optimal circumstances, such as in Vietnam, neither the application of sophisticated technologies designed to improve survival of traumatized patients in surgical intensive care wards or operating rooms, nor greater success in managing the common causes of postoperative death—sepsis and multiple organ failure—will have a significant impact on improving combat casualty care.

Rather, he insisted that improvement would come with “a renewed emphasis on field medical care.” That renewed emphasis was realized with implementation of the Combat Lifesaver Program, the 68W Combat Medic, and publication of Tactical Combat Casualty Care guidelines. We

taught Soldiers to apply tourniquets, open airways, and decompress a tension pneumothorax, and issued them the Improved First Aid Kit. Also, we taught tactical leaders their role in casualty management and evacuation.

The new approach to field medical care together with advances in Force Health Protection contributed to significantly increased survival rates after wounding on the battlefield over the past 12 years. Improved individual body armor with an increased area of coverage and greater ballistic protection decreased the incidence of thoracic and abdominal injuries. The flame-resistant Army Combat Shirt, Advanced Combat Helmet, and ballistic eye protection also provided additional personal protection. Vehicular armor evolved throughout the conflict from the improvised armor added to vehicles by units early in the war to up-armored HMMWVs* and MRAPs.† Each of these advances enhanced Soldier survivability.

While we should continue to seek technological advances such as improved surveillance for biological weapons, the human dimension of Force Health Protection deserves further attention. Just as critical thinking about care on the battlefield led to significant improvements in combat casualty care, critical thinking about the human factors that lead to casualties may significantly reduce their numbers. My analysis of casualties as Command Surgeon, Multinational-Force Iraq from 2005-2006 showed that service members were at greater risk of becoming a casualty during their first 90 days in theater. When these findings were forwarded up the chain of command, they prompted the Secretary of Defense to question whether shorter but more frequent tours in combat placed warfighters at an increased risk.

The Defense Advanced Research Projects Agency subsequently commissioned a study to identify critical fatality time periods, training, information, and equipment gaps.^{3,4} Researchers analyzed data on 1,770 US and 215 UK military fatalities in Iraq and Afghanistan from January 1, 2007 to September 1, 2009, and interviewed Soldiers and subject matter experts. They found that nearly 40% of fatalities occurred in the first 3 months of deployment, most often attributed to a lack of experience.

*High mobility multipurpose wheeled vehicle

†Mine resistant ambush protected vehicle

Loss of local intelligence when an old unit leaves and a lack of familiarity with the environment and enemy tactics were also cited as contributing factors. A second spike in fatalities occurred at the 6-month point in the tour which Soldiers attributed to complacency. A minor spike in Soldier fatalities noted at the 10-month mark was attributed to fatigue, complacency, and stale tactics.

The US Army Human Dimension Concept⁵ provides a framework to address the human factors of Force Health Protection. A better understanding of the cognitive, physical, and social components may lead to improvements in training and better communication of successful tactics, techniques, and procedures. Learning, training, repetition, and practice all affect cognition and the decision-making process. Initiatives to accelerate learning and compress the time it takes to accumulate experiential competence may shorten the high risk period early in a tour. Physical factors such as fatigue, sleep deprivation, dehydration, hunger, and stress from heat or cold affect decision-making in combat. Psychological factors including complacency, stress, boredom, motivation, and a sense of isolation affect decision-making as well. Recognition of these factors and actions to mitigate their effects may reduce casualty rates. Improved physical fitness, nutrition, and psychological fitness can help delay the onset of fatigue. A reduction in the use of energy drinks and long hours playing video games after missions will lead to better sleep, and more rested Soldiers. Improved social fitness with better self-discipline, valued relationships, and good communication with others will produce Soldiers who are more resilient and resistant to

stress. Application of the Human Dimension Concept has great potential for not only enhancing performance, but also improving health and fitness, and preventing injury and illness—the goal of Force Health Protection.

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EDITOR'S PERSPECTIVE

As a new century moves through its second decade, the world continues to present increasingly perplexing and dangerous challenges for stability and freedom. Threats continually ebb and flow, appearing, disappearing, relocating, shifting into different forms, and spreading. Military operations planners try their best to anticipate the nature and locations of these threats, and design strategies and doctrine to best counter them. A common thread across all planning is the certainty that future operations will continue to encounter serious threats unrelated to an anticipated military opponent, especially in undeveloped, remote areas throughout the world. In their article, COL Leon Robert and COL Mustapha Debboun address the variety and breadth of the threat posed by vector-borne diseases and how Army medical planners must tailor their efforts to support the regional-alignment model of building combat capacity and capability. Although the US military has an extensive, worldwide infrastructure involved in disease surveillance and research, experience has shown that there continue to be

gaps in data and information about resources for many locations where military operations may be required. This article discusses how those existing capabilities may take advantage of any locally-based resources, and the requirements for planning to work closely with other US and foreign government organizations, as well as nongovernmental organizations which are providing services in the regions.

As with the military threats mentioned above, the vectors that carry dangerous pathogens themselves appear, disappear, change, and spread, an increasingly serious problem in this modern world of ubiquitous modes of transportation. Current, accurate data concerning the presence and identification of such vectors in areas of concern are vital to those planning medical support for military operations. An example of the commitment and effort involved in gathering and maintaining such data is presented by Dr Leopoldo Rueda and his colleagues. Their article describes a biosurveillance project targeting mosquito species on the southern Japanese island of

Kyushu to update surveillance data and information from sites identified as having taxonomic and ecological importance. The article provides a detailed look at a biosurveillance project: the precollection research to better target collection areas; the multiyear collection effort itself; and the extensive work required to identify the collected specimens and then analyze the results against historical data.

Determination of the presence of pathogens among collected specimens of potential vectors is the critical step in the surveillance of an area to plan countermeasures against diseases. Such testing can be time consuming, and sometimes can only be performed at a laboratory distant from the area of concern. Dr Marty Soehnlen, CPT Stephen Crimmins, and their colleagues developed a method of standardized testing of surveillance samples using polymerase chain reaction methods which provides high-throughput and allows analysis of multiple pathogens from the same sample. They developed tests for 9 pathogens under international accreditation standards which can be performed at the US Army Public Health Command Region Europe Laboratory Sciences laboratory, but have universal Department of Defense application. Their detailed report should be of great interest to all those charged with providing surveillance of vector-borne diseases throughout not only military resources, but all other government disease management agencies as well.

Throughout most of recorded history, rabies has been known to mankind as a deadly, infectious disease. It has been a target for treatment and elimination from the dawn of medical science, yet today it is still present on every continent except Antarctica. It is found in many species of mammals, both feral and domesticated, in rural and urban environments. Although infections in humans is relatively rare in the United States, rabies poses a constant threat to military personnel involved in all types of deployed settings. As such, prompt and reliable identification of its presence is very important to preventive medicine and healthcare delivery personnel. Dr Kristen Voehl and LTC Greg Saturday have contributed an article describing a research study in which they evaluated a commercially available test kit which can be used in austere settings to confirm rabies infection in brain tissue. The results of their study, combined with that of their literature review, could result in another important tool for medical support units charged with protecting our troops from diseases and other environmental hazards.

Respiratory health has received increasing attention from researchers over the last century or so, as the relationship of damage to airborne hazards in the workplace,

smoking, and general air pollution has been proven and publicized. Military personnel can be exposed to a complex array of potential hazards and pollutants, sometimes highly concentrated, but more often present in lower concentrations which become an unnoticed, ever-present part of the environment. The Persian Gulf conflicts since 1991 have bought the concerns about respiratory health of Warfighters to an elevated level. Dr Joseph Abraham and his colleagues conducted an extensive, detailed study of medical treatment records concerning chronic obstructive pulmonary disease and associated conditions for active duty military personnel across the 13-year period of current combat operations in the Middle East and Afghanistan. They were seeking information on rates of the conditions, trends, and characteristics of the study population reflecting any trends. Their article is a clear description of the extensive data collected, the detailed data reduction performed, and the careful analysis of that data. The data is presented clearly and logically throughout the article. Some of the results were unexpected, others are not readily explainable. This study is a significant contribution to the body of research into respiratory health of our military personnel, and should generate further investigations.

Indicative of the level of concern regarding the respiratory health of military personnel who have served in combat theaters is language contained in the Dignified Burial and Other Veterans Benefits Improvement Act of 2012. That language directs the Department of Veterans Affairs to establish a registry to collect information regarding all potential exposures experienced by military personnel during deployments that might adversely affect their respiratory health. The article provided by Jessica Sharkey et al presents an excellent description of the purpose and parameters of the registry which is slated to be active before the end of 2014. Their article details the eligibility criteria and registration process for those wishing to enter the registry. There is also important information for military healthcare providers regarding the military healthcare system's perspective, responsibilities, and obligations to those requesting clinical assessments as part of the registration. This article is an excellent "heads up" for participants and caregivers alike concerning the impending availability of an important new aspect of healthcare for those who have served.

As has been noted in the pages of the *AMEDD Journal* time and again, military healthcare providers in deployed environments must always "expect the unexpected" when faced with confusing, conflicting, unfamiliar diagnostic indications. LTC Paul Kwon and Dr Jason Pickett relate such a situation in their excellent case study of a patient whose symptoms and diagnostic

PERSPECTIVES

indications were varied and complicated. She was eventually diagnosed as having Q fever, which was present as a coinfection with *mycoplasma pneumoniae*, a combination rarely addressed in medical literature. Further, she had no history of the typical risk factors associated with Q fever during her deployment. This article is a well-organized, detailed, and complete; a superb example of medical professionalism at its best.

Over the last 6 years, the Army Hearing Program has been addressed in several *Journal* articles, beginning with its conception, its implementation among garrison units, and how it was adopted in the deployed, combat environment. In this issue, MAJ Leanne Cleveland returns with an article that provides, among other things, an update on the level of understanding of the importance of hearing protection at the individual Soldier level, and how many have “tested” different hearing devices in combat, sometimes obtained at their personal expense. As part of the returning Soldier health assessments, she conducted a survey of returning troops to quantify their opinions of effectiveness of protective devices, as well as their preferences. The resulting data may be the first concerning protective devices to be collected from those who very recently experienced actual combat rather than a simulated test environment. The results of the surveys were then compared to the pre- and postdeployment audiograms to determine any correlation between those reporting use of protective devices, and those who did not. The information in this article should be of value to researchers, designers, and testers of protective hearing devices for the military, which will have broad civilian application as well.

The safety of the end user has long been a concern for developers of military equipment and weapons. In 1983, the Army formally established the Health Hazard Assessment Program, which had been operating under The Surgeon General since 1981, with the responsibility to evaluate and monitor development and procurement of all Army materiel systems, including weapons, equipment, clothing, etc. As manufacturing processes and the materials used have become more sophisticated and complex, the potential for toxicity in resulting products to have harmful effects on humans and other living things has become an ever more important factor. This is addressed by the Army’s Toxicity Clearance process which is detailed in the article by Dr Mohamed Mughal and his coauthors. They describe the formal investigative and clearance requirements involved for a manufacturer to obtain approval to use specific chemicals and other materials in products before introduction into the Army supply system. This is an interesting look at another important function performed by AMEDD professionals,

largely in the background, that is vital to protecting the health of our Soldiers every single day.

History is replete with examples of best-intended, consensus actions proving fruitless because someone does not follow the plan. Since 1899, a series of international laws, treaties, pronouncements, and unilateral actions have been intended to eliminate chemical and biological weapons, with the inevitable result that those weapons continue to exist under control of the most dangerous of lawless regimes and tyrants. However, since the notion that the problem was solved was conveyed by the cooperating governments, interest in those weapons waned in both academic and official circles. As a result, people truly knowledgeable in chemical and biological warfare and associated subjects became more difficult to find. A number of events over the last 30 years has exposed and reestablished the vital need for this area of expertise. In their article, CDR (Ret) David Claborn and Dr Keith Payne describe a fellowship and graduate program of study in Countering Weapons of Mass Destruction now offered by Missouri State University in cooperation with the National Defense University in the Washington, DC area. This is an important and very informative article about a proactive approach to dealing with a real-world threat with potentially disastrous ramifications. Sadly, this threat will likely not be truly eliminated any time soon, if ever.

Regular readers of the *AMEDD Journal* are familiar with MAJ (now retired) Joseph Topinka’s contributions, along with those of his colleagues, of excellent articles focused on various legal topics and considerations specifically related to military medicine. For this issue, he has submitted an article providing an overview of public health law. This article is written as an introduction for military medical personnel and other leaders to convey the breadth and depth of legal considerations that pertain when working within the public health sector. It is an interesting, easy read, and definitely eye-opening as the reader begins to understand how integral and important a basic understanding of the law is to successfully functioning in the various areas of public health.

Among the many changes resulting from the 2005 Base Realignment and Closure Commission recommendations was the consolidation of all enlisted basic and most specialty medical training into a single Medical Education and Training Campus (METC) at Fort Sam Houston, Texas. The METC became fully operational in September 2011. One of the consolidated specialty areas taught at METC is the Public Health Specialist Program, which graduates Army and Navy Preventive Medicine Specialists and Technicians (respectively).

MAJ Colacicco-Mayhugh and her coauthors have provided a detailed description of that program, and how it has already been revised to optimize both resources and schedule based on initial experience teaching a multi-service curriculum. Their article provides excellent insight into the dedication and high level of expertise and professionalism that is involved in the design, delivery, evaluation, and revision cycle necessary to ensure that students receive only the best training possible. The future health and readiness of many military members may directly depend on the knowledge and skills imparted to these new Soldiers and Sailors.

Throughout history, militaries have always faced the Gordian knot of how to satisfy the ever increasing requirements their governments/leaders place on them, while simultaneously receiving ever decreasing resources with which to accomplish those tasks. Today's environment is no different. Politics, economic factors, shifting priorities, new and resurfacing threats, and many other factors result in unpredictable financial resources which must be divided into many parts. In most cases, the amount of available funds is finite, so competition for a share of those funds can be intense. Usually that competition hinges on the value to the organization realized from the committed funding, the classic return on investment (ROI). The government data source for typical personnel costs does not cover all of the categories affecting the true amount of medical costs, thus degrading the suitability of the data for use in evaluating preventive medicine program initiatives. Cindy Smith and her coauthors have provided a detailed description of a tool developed within the Army Institute of Public Health which draws specific, relevant data into analysis to calculate a more accurate and realistic ROI for prevention programs. This excellent article is, in essence, a tutorial for use of the analysis tool, clearly explaining the process in a straightforward manner. This powerful analysis tool should be of great interest and utility to all preventive medicine program developers in Army medicine.

In recent years, the news coverage of the relief responses to large scale disasters have increasingly focused on the apparent disorganization and inability to coordinate within and among government organizations involved in the efforts. While the news organizations overemphasize these problems for the ratings benefits of hyping the latest, biggest scandal, the basic difficulties that are highlighted in such reports do in fact reflect the complexity of public health systems of virtually every scale, even the seemingly benign and routine functioning within a military installation. As Anna Courie and her coauthors clearly describe, the public health systems in both the civilian communities and on military

installations share the same characteristic of dependence on various, distinct resources and components which are themselves responsible to disparate organizations and authorities. This fragmented structure wastes resources, causes confusion, is error prone, and is obviously slow and ponderous in functioning and reacting to public health issues. The Army has adopted a structure across its installations called the community health promotion council (CPHC) to manage the Army Public Health System. The Army Public Health Command has established a standard model for the CPHC to ensure a coordinated approach to managing public health responsibilities and functions. The standard CPHC has been implemented in 12 of the larger Army installation in the United State, while 14 others have CPHC processes but have not as yet received the additional resources necessary to adopt the standard model. Ms Courie et al investigated the relative effectiveness of the public health systems aboard installations with standard CPHC processes versus those without the features of the standard model. Their well-researched article carefully develops the foundation for the CPHC approach, and details the results of their study. This is an interesting, informative look at the complexity and broad range of concerns, both tangible and perceptive, that are involved in managing an effective public health system.

Lean Six Sigma (LSS) is a well-known process improvement, problem-solving methodology that is used by activities within the US Army, including those within AMEDD. Although best known for its success within business and manufacturing, it has also proven valuable in use with knowledge-based processes. Dr Eren Youmans Watkins and her colleagues applied LSS to a public health surveillance function within the Army's Behavioral Social Health Outcomes Program, specifically the report of the suicide behavior surveillance data. Their article clearly details the application of the LSS methodology as a carefully designed, step-by-step process to define the project, measure the existing process parameters, analyze the data, determine the points of substandard performance and the causes, develop and incorporate changes to improve the processes, and measure and document the resulting performance. For this project, the total number of labor hours (baseline) required to produce each report was 448. Following the project, the number of hours was 199. Also, it was determined that a quarterly report was not seen to be necessary by its users, so the report is now produced annually, resulting in additional savings. This article presents an excellent introduction to LSS for those unfamiliar with it. It demonstrates how even a seemingly straightforward process reveals much room for improvement once the components are identified and analyzed in detail.

The Growing Challenges of Vector-Borne Diseases to Regionally-Aligned Forces

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ABSTRACT

The long-term strategic focus of US foreign policy has pivoted to the Pacific, but tensions in the Middle East require constant attention in the present. As our current role in Afghanistan diminishes, we must seize the opportunity to refocus on the new priority of regionally-aligned forces. The short-term reality requires first re-establishing core warfighting competencies of a smaller Army and then building the capacity of forces focused on regional alignment. The continuing threat of vector-borne and other infectious diseases will present growing challenges to US forces focused on regional alignment and engagement. Greater understanding of these threats, host nation vulnerabilities and capabilities, and the regional presence of international and nongovernmental organizations will enable US forces to respond and engage more effectively and appropriately to accomplish assigned missions and future contingencies. Effective vector surveillance and control has a longstanding and proven record of preventing, reducing, and eliminating vector-borne diseases and must remain a focus of regionally-aligned forces. Operational readiness of armed forces continues to rely heavily on vector surveillance and control, and on personal protection strategies. Regionally-aligned forces must also work closely with the US Department of State and US Agency for International Development, international governments, governmental and nongovernmental organizations, and private organizations operating in the region and know how to effectively interact with these diverse organizations. In addition, a working knowledge of a host country's public health policy, capabilities and economic realities will be essential. Teamwork with previously unfamiliar groups and organizations will be an essential component of working in regional environments and can present unfamiliar tasks for traditionally-trained military units.

Global factors are interacting together to fundamentally change the worldwide vector-borne disease threat and the corresponding public health landscape. These challenges are predicted to become increasingly problematic in the future. Specific challenges such as climate change, rapid urbanization of megacities, lack of clean drinking water, poor sanitation and health, and the growing threat of emerging and reemerging vector-borne diseases will certainly present an increasing challenge for military entomologists and public health professionals. In addition, these challenges will almost certainly place increasing demands on regionally-aligned US forces in terms of operational requirements, available manpower, and resource consumption.

In 2012, the Chief of Staff of the Army announced that future Army forces must be tailored to meet local requirements, must be rapidly deployable and scalable from squad to corps level.¹ The changing strategic environment necessitates organizing the Army for regional conditions in an effort to align forces regionally to specific combatant commanders, such as those in Europe, the Pacific, and in Africa. In addition, regionally-aligned forces will require intimate integration with regional allies and multinational forces. This overall effort seeks

to increase specialized regional expertise and cultural awareness so US forces will be better prepared to meet present and future regional requirements. Through the regional alignment of forces, we will meet both these imperatives, ensuring that our Army remains globally responsive and regionally engaged.

As regional alignment of forces begins, Department of Defense (DoD) planners and military forces worldwide continue to face numerous challenges from vector-borne diseases. Not only must military healthcare systems continually adapt to emerging and re-emerging diseases to protect US forces, but they must operate in developing countries that either cannot or will not address continuing high mortality from infectious diseases.² These countries have little or no surge capacity (ie, numbers of hospital beds, medical supplies, adequate distribution systems, and measures for managing public panic) in case of an influenza pandemic, bioterrorist attack, or even a regional outbreak of a vector-borne disease. Governments will increasingly rely on regionally-aligned US forces to assist and manage unexpected healthcare emergencies as they develop. Thus, there is an urgency to continually improve joint adaptability, versatility, and training to cope with uncertainty and complexity

in military preventive medicine and public health as it relates to infectious disease surveillance and control.³

CHALLENGES AHEAD

United States forces will continue to face challenges in remote lands ranging from regular and irregular wars, humanitarian relief and reconstruction, to sustained global engagement. The challenge to force health protection (FHP) planners and leaders is best summarized by the FHP problem statement below.

The problem that faces the joint force is to determine how to more effectively provide health protection to a force that will operate in a complex and diverse operational environment; confront a range of traditional and new adversaries and threats; employ and integrate new technologies; and collaborate with other organizations, agencies, nations and cultures.^{4(p15)}

The importance of this problem statement is reinforced by the Director-General of the World Health Organization who warns that emerging diseases have become a much larger menace in a world characterized by high mobility and unstable economies.⁵ Also, climate change, widespread land-use change, globalization of trade and travel, and social upheaval are driving the emergence and changing patterns of zoonotic (animal diseases transmissible to humans under natural conditions) and vector-borne diseases (infectious diseases transmitted host-to-host by another animal, usually an arthropod) worldwide.

Throughout history, zoonotic diseases and vector-borne diseases have severely reduced the fighting strength of armies and changed the course of military operations. Since World War I, these infectious diseases are no longer the main causes of morbidity and mortality among military personnel. However, even with modern medicine and therapeutics, zoonotic and vector-borne infectious diseases continue to be an important threat to US forces both in the United States and worldwide.⁶ Continual progress in modern medicines, hygiene, and vector control has lessened the effects of some vector-borne diseases (eg, plague, yellow fever, and epidemic typhus) while others such as malaria and dengue fever remain a military concern and new potential threats continue to emerge, West Nile encephalitis and chikungunya fever, for example.⁷ As neither effective medication nor vaccines are available for some of these diseases, vector control remains pivotal. Therefore, operational readiness of armed forces continues to rely heavily on vector surveillance and control, and on personal protection strategies. Without aggressive application of both vector control and personal protection strategies, these diseases may again have the same devastating effect on

service member health and military readiness as they did in the past.

THE GLOBAL CHALLENGE OF VECTOR-BORNE DISEASES

The global challenge of infectious diseases cannot be underestimated; nearly half of the world's population is at risk from at least one type of vector-borne pathogen.⁸ Vectors like mosquitoes, ticks, and fleas transmit parasites, viruses, or bacteria between people or between animals and people. Because of the increasing threat of vector-borne diseases, the World Health Organization (WHO) selected vector-borne diseases as the theme of the 2014 World Health Day.⁸ Numerous publications and workshops have reviewed the relationship between global change and vector-borne diseases and have provided specific recommendations for detection and control capabilities, improving and coordinating surveillance, diagnosis, and response to disease outbreaks.⁹⁻¹¹

Vector-borne diseases account for 17% of the estimated global burden of all infectious diseases.¹² Every year more than one billion (10^9) people are infected and more than one million people die from vector-borne diseases, including malaria, dengue, schistosomiasis, leishmaniasis, Chagas disease, yellow fever, lymphatic filariasis, and onchocerciasis.¹¹ Forty percent of the world's population is at risk from dengue virus; there are an estimated 390 million dengue infections each year in over 100 countries. Dengue is the world's fastest growing vector-borne disease, with a 30-fold increase in disease incidence over the last 50 years. Southeast Asia and Latin America are especially affected, but dengue also occurs in Africa, where cases are less often diagnosed. Malaria is a vector-borne disease that is one of the most severe public health problems worldwide. It is a leading cause of death and disease in many developing countries, where young children and pregnant women are the groups most affected. The WHO estimates that in 2012, there were 207 million cases of malaria resulting in 627,000 deaths.¹¹

Global trade, rapid international travel, and environmental changes such as climate change and urbanization are causing vectors and vector-borne diseases to spread beyond borders. At the same time, the world is facing a severe shortage of entomologists and vector control experts.¹¹ Very few African countries have entomology programs at the undergraduate university level, and some countries have few trained entomologists. Many national and local governments, especially in Africa and Asia, are reducing their financial commitments to vector-borne disease surveillance, control, and treatment. This has resulted in the silent increase in

THE GROWING CHALLENGES OF VECTOR-BORNE DISEASES TO REGIONALLY-ALIGNED FORCES

vector-borne disease morbidity and mortality in these areas. These realities will place increased burden on regionally-aligned US forces as they engage and reengage with regional allies and threats.

More closely related to the present and future challenges to surveillance and control of zoonotic and vector-borne diseases are global threats in sanitation and health, especially the most daunting challenges in megacities.^{13,14} The number of these megacities with populations in excess of 10 million people is projected to reach 27 by 2015.¹⁵ These cities will not only pose significant military and public health threats to deployed forces, but will certainly be characterized by growing lawlessness, increasing poverty, and decreasing essential services. Public health emphasis to eliminate insect vectors and control associated diseases must grow away from “blanket” application of pesticides to more integrated and sustainable approaches. These integrated approaches must include sound environmental management practices, community education and participation, mobilizing community resources, and minimal reliance on routine pesticidal spraying.¹¹

DoD FORCE HEALTH PROTECTION FOR REGIONALLY-ALIGNED FORCES

Department of Defense Joint Force Health Protection (JFHP) Concept of Operations (CONOPS) strategic guidance highlights the need for improving joint warfighting through JFHP transformation and incorporating that transformation into the respective military services’ operational level JFHP in support of regionally-aligned forces.¹⁶ In 2011, the FHP CONOPS⁴ was published as part of the overarching Health Readiness CONOPS.¹⁷ The FHP CONOPS creates a roadmap for significantly improving Military Health System joint interoperability and mission effectiveness. The FHP CONOPS supports rigorous assessment and analysis of force health protection-related capabilities through analysis of existing and new requirements, capability gaps, and shortfalls. Subsequently, follow-on recommendations will be made for appropriate materiel and nonmateriel solutions to be presented and adjudicated as part of broader DoD joint capabilities.

Regionally-aligned forces will increasingly rely on early warning health protection detection systems, including the capability to establish fixed in-theater, early warning of infectious disease trends and characterization that will require the capability of access to Level IV and V diagnostic laboratories. The full and appropriate use of these diagnostic facilities will certainly necessitate advanced training of military preventive medicine personnel so they fully understand the requirements and capabilities of rapid diagnostic labs.

Regionally-aligned forces will also require a full understanding of the capabilities of overseas DoD regional research and surveillance laboratories. There are Naval Medical Research Units in Phnom Penh, Cambodia (NAMRU-2), Cairo, Egypt (NAMRU-3) and Lima, Peru (NAMRU-6). In addition, the Walter Reed Army Institute of Research has Special Foreign Activity laboratories in Nairobi, Kenya (US Army Medical Research Unit-Kenya); Sembach, Germany (USAMRU-Europe); and Bangkok, Thailand (US Army Medical Component of the Armed Forces Research Institute of Medical Sciences (USAMC-AFRIMS)) with satellite laboratories located in rural Thailand and Nepal. The missions of these laboratories include prevention of psychiatric battle casualties, disease surveillance, vector studies, arboviral transmission, basic research, and vaccine and drug development for enteric diseases (infectious diarrhea), malaria, tropical viral diseases, and HIV/AIDS to increase the operational readiness of forward-deployed service members.

The overseas laboratories continuously conduct disease surveillance as part of the Armed Forces Health Surveillance Center’s Global Emerging Infections Surveillance and Response System which performs surveillance for emerging infectious diseases that could affect the US military. This mission is accomplished by orchestrating a global portfolio of surveillance projects, capacity-building efforts, outbreak investigations, and training exercises. Because overseas laboratories interact with host nation medical systems at national and local levels on a frequent (often daily) basis, they have a deep understanding of population health trends, needs, and capabilities.

Regionally-aligned forces necessarily work closely with the US Department of State, US Agency for International Development, international governments, nongovernmental organizations (NGOs), and private organizations operating in the region; so they must understand how to effectively interact with these diverse organizations. In addition, a working knowledge of the host country’s public health policy, capabilities, and economic realities is essential. The provincial reconstruction teams partnering with the Afghan government to implement the Afghan Ministry of Public Health National Malaria Strategic Plan is an example of implementing the planning considerations for foreign internal defense missions that will also apply in future regionally-aligned missions.³ This knowledge and associated skills are not learned in traditional military operational or training environments.

Thus, military and specialty-specific training must include not only traditional military preventive medicine and sanitation topics but be expanded to include country

and region-specific information, to include cultural awareness and rudimentary language skills. This expanded skill set will not be learned from existing training courses and programs. New training opportunities must be afforded military preventive medicine personnel to familiarize them with how to interact with and synergize the efforts of host nation assets, other governmental agencies, NGOs, and international military partners. This training should start with initial entry training and be a continual process.

A GLIMPSE INTO THE FUTURE?

The WHO recently established the integrated vector management (IVM) strategy, a rational decision-making process to optimize use of resources, as an innovative platform for combating vector-borne diseases. The strategy is based on the premise that effective control is not the sole responsibility of the health sector but of a wide range of public and private agencies, including local communities. Five key attributions have been identified as being critical to the IVM strategy: (1) advocacy; social mobilization and legislation; (2) collaboration with the health sector and with other sectors; (3) integrated approach; (4) evidenced-based decision making; and (5) capacity building. The ultimate goal is to prevent the transmission of vector-borne diseases such as malaria, dengue, Japanese encephalitis, leishmaniasis, schistosomiasis, and Chagas disease.¹⁸ It has been recently suggested that this new IVM be used for rational decision-making and sustainable vector control in Southern Sudan and an archetype for other similar postconflict environments.¹⁹

The signing of the 2005 Comprehensive Peace Agreement in South Sudan marked the end of decades of civil war and left the country with enormous infrastructure, human and financial resource constraints, and a weak healthcare system facing a huge burden of several vector-borne diseases.²⁰ The implementation of IVM, more specifically in South Sudan, will require an explicit understanding of spatio-temporal patterns of vector-borne diseases and complicating factors that incorporates and integrates all necessary information, such as geographic information system tools. Establishing a viable IVM strategy will face formidable challenges: environmental, sociocultural, socioeconomic, technical, and programmatic, to name a few. Challenges will be exacerbated by instability, a weak (almost nonexistent) healthcare system, limited access to health services, a paucity of entomological and epidemiological information, and extremely limited skilled personnel to implement the vector control program.

The potential for using IVM to integrate successful vector control in South Sudan is enormous. However, the

realities of lack of essential physical infrastructure, financial research and technical expertise, and resources are daunting. Even if successful, the IVM process will be slow and will require a sustained national and international commitment. A version of this model was used in Afghanistan by provincial reconstruction teams, agribusiness development teams, and civil affairs units to develop the Afghan Ministry of Public Health National Malaria Strategic Plan, 2008-2013,²¹ and implement this plan to rebuild the nation-wide Afghanistan malaria control infrastructure.³ This mission required a detailed, advanced knowledge of how other governmental agencies (ie, Department of State and US Agency for International Development), international governments, NGOs, and private organizations were operating in Afghanistan, and how to effectively interact with these diverse organizations. In addition, a working knowledge of the host country's public health policy, capabilities, and economic realities is essential

Military force health protection planners would be well-advised to use the current and future IVM efforts in South Sudan as a case study for future contingency threats to regionally-aligned forces. If successful, IVM may serve as a global strategic framework for prevention and control of vector-borne diseases when engaging and assisting regional international and national partners and allies.

SUMMARY

Regionally-aligned US forces will certainly face new and unforeseen challenges, such as emerging and re-emerging vector-borne diseases. These diseases will have increasingly negative effects on human health in developing countries and growing mega-cities.

The challenges will require traditional preventive medicine training and prevention measures. However, new skills such as increased coordination and cooperation with host nation assets, other governmental agencies, NGOs, and international military partners will be required. These skills must be learned through increased didactic training opportunities and field training experiences. Department of Defense and US Army force health protection doctrine and training must continually adapt to these future challenges.

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Mosquito Biosurveillance on Kyushu Island, Japan, with Emphasis on *Anopheles* Hyrcanus Group and Related Species (Diptera: Culicidae)

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ABSTRACT

This report includes the distribution records of the *Anopheles* (*Anopheles*) Hyrcanus Group and associated species in Kyushu Island, Japan, based on our field collections from various localities of 4 prefectures (Fukuoka, Kumamoto, Nagasaki, Saga), primarily from 2002-2013. The status of common and potential mosquito vectors, particularly *Anopheles* species, in Japan are noted.

Mosquito-borne disease agents can pose a threat to humans, particularly to deployed troops, both in foreign environments and, if imported, domestically. Gaps exist in the fundamental knowledge regarding mosquito vector species, specifically concerning the species complex in subgenera *Anopheles*, *Aedes*, and *Culex* from central Japan. These 3 subgenera include major vector species that are responsible for transmitting malaria, dengue, Japanese B encephalitis, as well as other pathogenic microorganisms in many parts of the world, particularly in Asia. *Anopheles* Hyrcanus Group consists of several species that are vectors of malaria, filariasis and other mosquito-borne diseases in the Oriental and Palearctic regions. Currently, about 30 species have been described and named.¹⁻³ In 2004, about 27 species were listed in the Hyrcanus Group, with 6 species placed in the Lesteri Subgroup, 4 in the Nigerrimus Subgroup, and 17 in the unassigned subgroup.³ In their 2013 review of the malaria vectors in the Greater Mekong subregion, Hii and Rueda⁴ created the new Sinensis Subgroup that contains those previously unassigned species (*An. sinensis* Wiedemann, *An. pullus* Yamada, other 6 species). Recently, there is more focus on *Anopheles* Hyrcanus Group in Asia, primarily to clarify the taxonomy of the species complex and to update the distribution records of vectors and related species.⁴⁻¹⁰ Although several *Anopheles* mosquito publications exist, they were not updated to include recent discoveries, taxonomic records, and related pertinent collection data from central Japan.¹¹⁻¹⁴ In 2005, Rueda and others⁵ noted five species of *An. Hyrcanus* Group occurring in Japan, namely: *An.*

sinensis, *An. engarensis* Kanda and Ogama, *An. yatsu-shiroensis* Miyazaki, *An. sineroides* Yamada, and *An. lesteri* Baisas and Hu. In 2013, Imanishi¹⁵ recorded for the first time *An. belenrae* Rueda from Hokkaido, Japan. *Anopheles pullus* and *An. kleini* Rueda, the primary malaria vectors in South Korea, have never been collected in Japan.¹⁶ Known and potential vectors of malaria in the Hyrcanus Group include *An. sinensis*, *An. lesteri*, *An. belenrae*, *An. kleini*, and *An. pullus*.¹⁶

The purpose of our study was to strengthen mosquito-borne disease biosurveillance capability in Japan by acquiring biogeographic vector data from sites identified as having taxonomic and ecological importance, thereby enhancing the knowledge base associated with potential malaria vectors, and incorporating this information as a component of already in-place mosquito surveillance programs, including the Walter Reed Biosystematics Unit's VectorMap/MosquitoMap, and the US Army Public Health Command Regions – North and Pacific mosquito surveillance training programs.

MATERIALS AND METHODS

Mosquito Field Collection and Identification

Specimen collections were conducted from 2006-2013 from various areas within Kumamoto, Fukuoka, Saga and Nagasaki Prefectures, on Kyushu Island, Japan (Figure 1). Additional specimens were previously collected by Dr Motoyoshi Mogi from 1984-2005 from localities in Saga and Nagasaki Prefectures. These prefectures were selected because the taxonomic records

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for the *Anopheles Hyrcanus* Group were unclear or had conflicting information regarding previously reported and described species from this region. The Hyrcanus Group includes all known malaria vector species in Japan^{5,14} and it is essential to clarify the taxonomy of the group, including geographic distribution records of the group species. The mosquito taxonomic classification used in this paper follows that of Knight and Stone.¹⁹

Depending on the habitats (rice paddies, irrigation ditches, permanent and temporary pools, other standing water areas (Figures 2 and 3)), larvae were collected using a standard larval dipper (350 ml, 13 cm diameter) or a white plastic larval tray (25×20×4 cm) (BioQuip, Rancho Dominguez, CA). Each habitat within a location was surveyed for up to one hour or until about 100 larvae were collected. The latitude and longitude of each location was recorded using a hand-held global positioning system (GPS) unit (Garmin International, Olathe, KS) set to the WGS84 datum. Sampling locations were photographed using a digital camera to assist in verifying the accuracy of the habitat description.

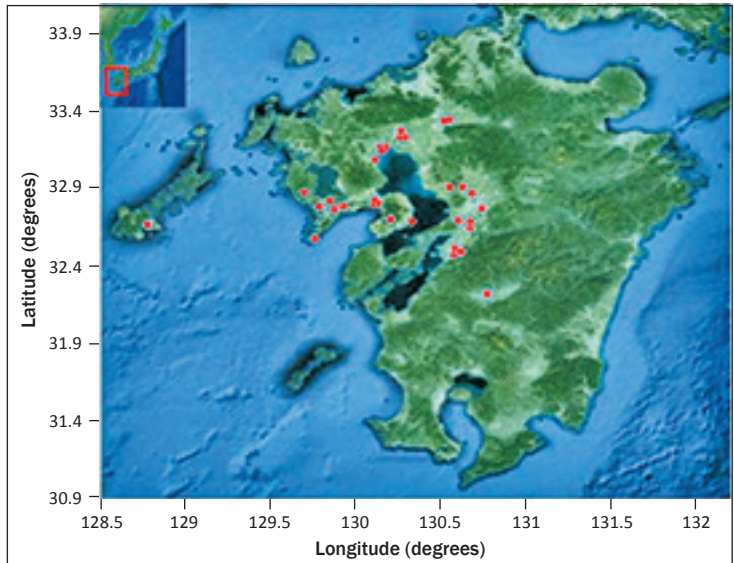


Figure 1. Mosquito collection sites on Kyushu Island (right) and Fukuoka Island (left), Japan.

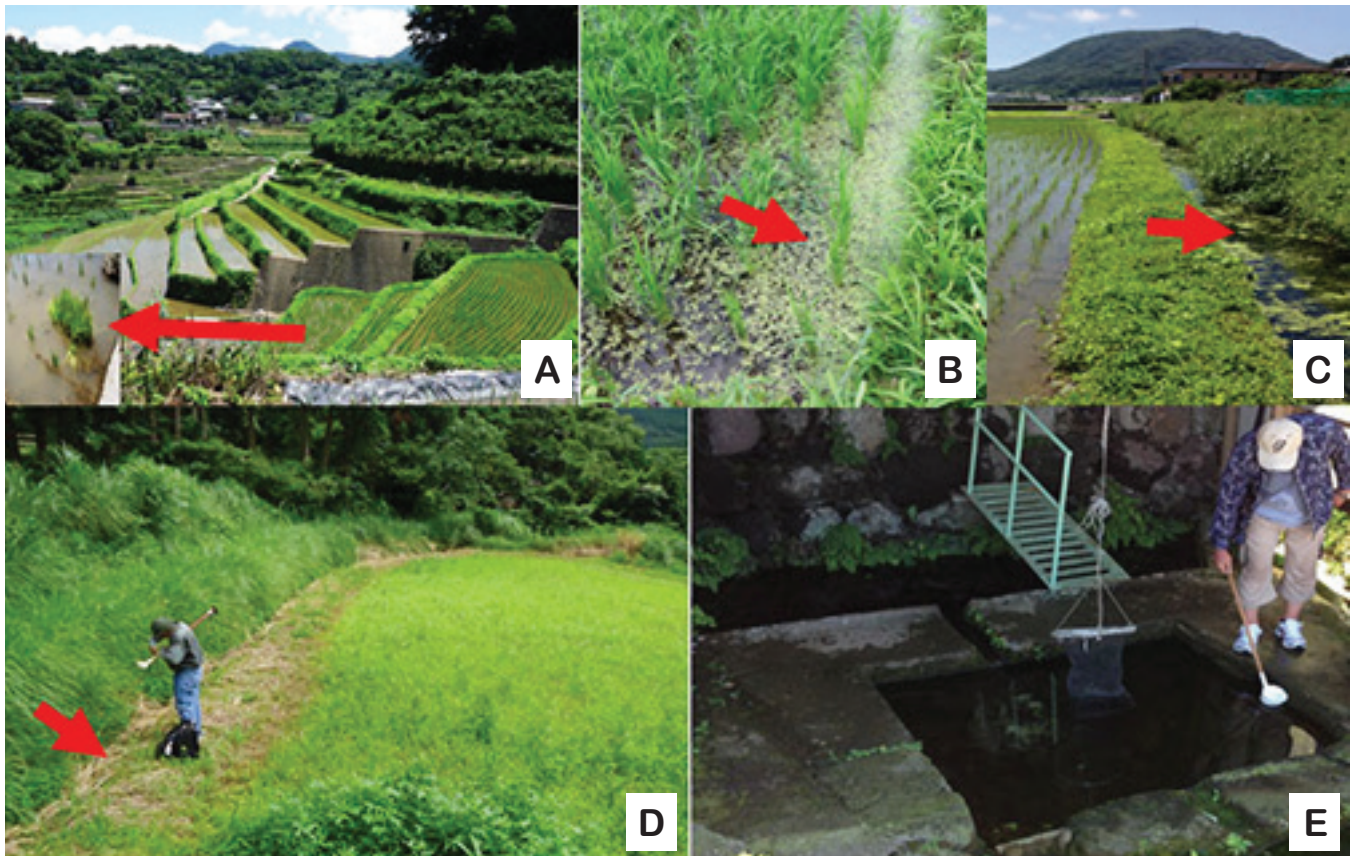


Figure 2. Larval habitats of *Anopheles* (*Anopheles*) species in the Nagasaki Prefecture, Kyushu Island: (A) rice paddies with terraces, with closeup of rice seedlings; (B) rice paddy, with closeup of rhizobium rice plants; (C) irrigation ditch; (D) drainage ditch, partially covered by dried grasses (Fukuoka Island); (E) water well.

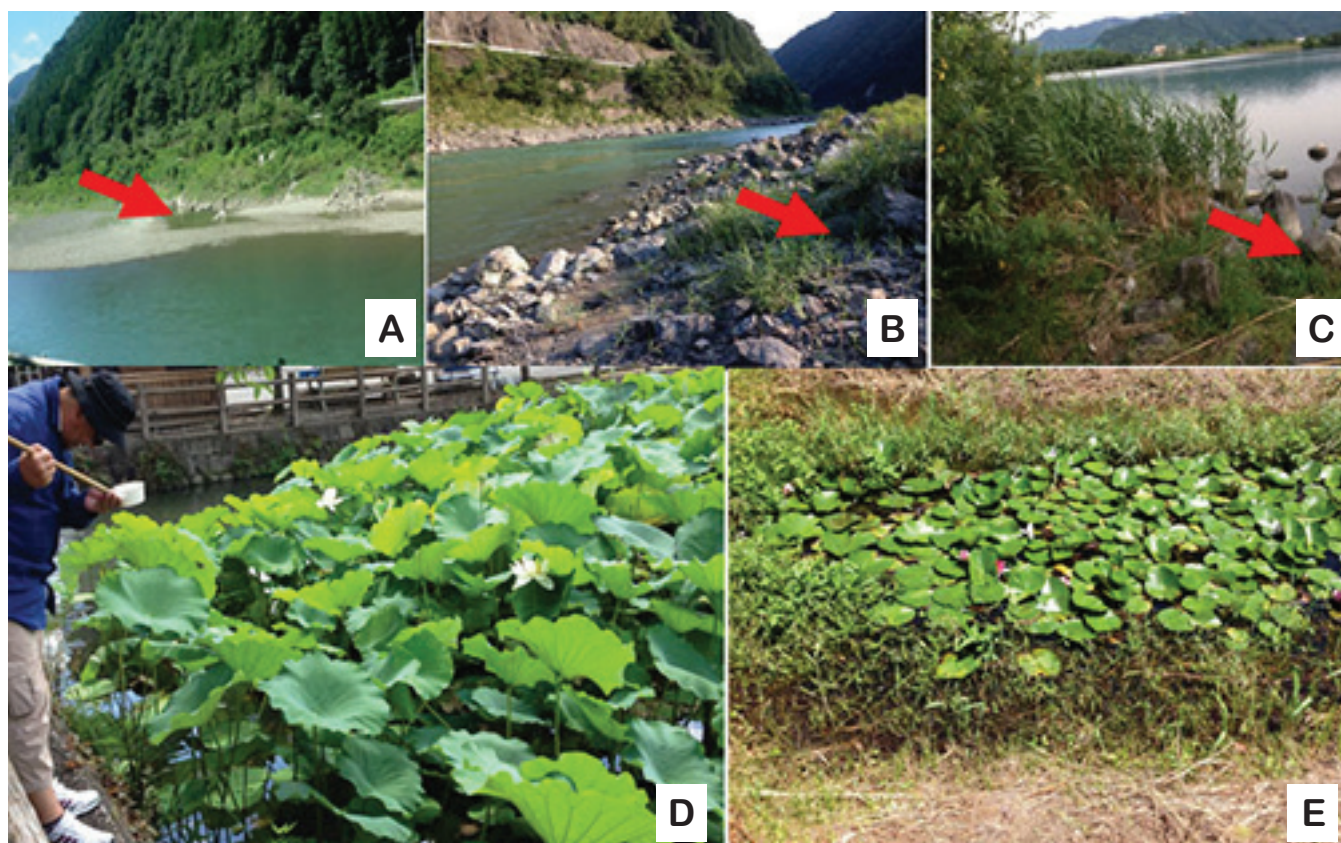


Figure 3. Larval habitats of *Anopheles* (*Anopheles*) species on Kyushu Island: (A) stream margin with small pool (arrow) (Kumamoto Prefecture); (B) stream margin with small water pockets (arrow) (Kumamoto Prefecture); (C) river margin with water pockets (arrow) (Yatsushiro, Kumamoto Prefecture); (D) lotus field (Nagasaki Prefecture); (E) hill or road side ditch with water lilies and grasses (Nagasaki Prefecture).

Collected larvae were placed in plastic Whirl-Pak bags (118 ml, 8×18 cm) (BioQuip, Rancho Dominguez, CA) and filled approximately $\frac{1}{2}$ full with water from the collection site. The Whirl-Pak was then tightly closed to retain air, placed in a cooler, and brought to the laboratory where the larvae were directly preserved in 100% ethanol for molecular identification. The remaining larvae were individually link-reared to adult stage, as morphological voucher specimens for this work (Figure 4). Emergent adults were pinned on paper points, each given a unique collection number, and identified using diagnostic morphological characters (Figure 5).

DNA Isolation and Sequencing

For molecular species identification, DNA was isolated from individual larvae, pupae, and adults (1 or 2 legs per adult) by phenol-chloroform extraction, and the PCR amplification protocol, cycling conditions, and direct sequencing were carried out using standard protocol.¹⁷ A fragment of rDNA ITS2 was amplified using the primers 5.8S (5'-ATCACTCGGCTCGTGATCG-3') and 28S (5'-ATGCTTAAATTTAGGGGGTAGTC-3').¹⁸ The PCR products were directly sequenced using Big Dye 3.0 (Applied Biosystems, Inc (ABI), Foster, CA) with

an ABI 3100 sequencer. Sequences were edited using Sequencer (v4.8, Gene Codes Corporation, Ann Arbor, MI) and aligned in Clustal X. Sequences of *An. Hyrcanus* Group species (*An. sinensis*, *An. lesteri*) are those of previous studies using the primers therein.^{17,18} Voucher specimens and collection records will be deposited in the US National Museum of Natural History (USNMNH) of the Smithsonian Institution, Suitland, MD.

RESULTS

The summary of collection localities and larval habitats for *Anopheles* species (primarily *An. sinensis* and *An. lesteri*) from 4 prefectures (Fukuoka, Kumamoto, Nagasaki, Saga) of Kyushu Island, Japan, are presented in the Table (page 18). The map of Kyushu, with collection sites of mosquitoes, is shown in Figure 1. Prior to 2013, larvae of *An. sinensis* were collected from various habitats either alone or in association with the following *Aedes* or *Culex* species: *Cx. (Culex) tritaeniorhynchus* Giles larvae (in rice fields, irrigation ditches, marsh and drainage areas, ground pits or depressions) in Nagasaki and Kumamoto Prefectures. Aside from *An. sinensis*, no *Anopheles* species were collected from any larval habitats in association with *Aedes* or *Culex* species. In 2013,

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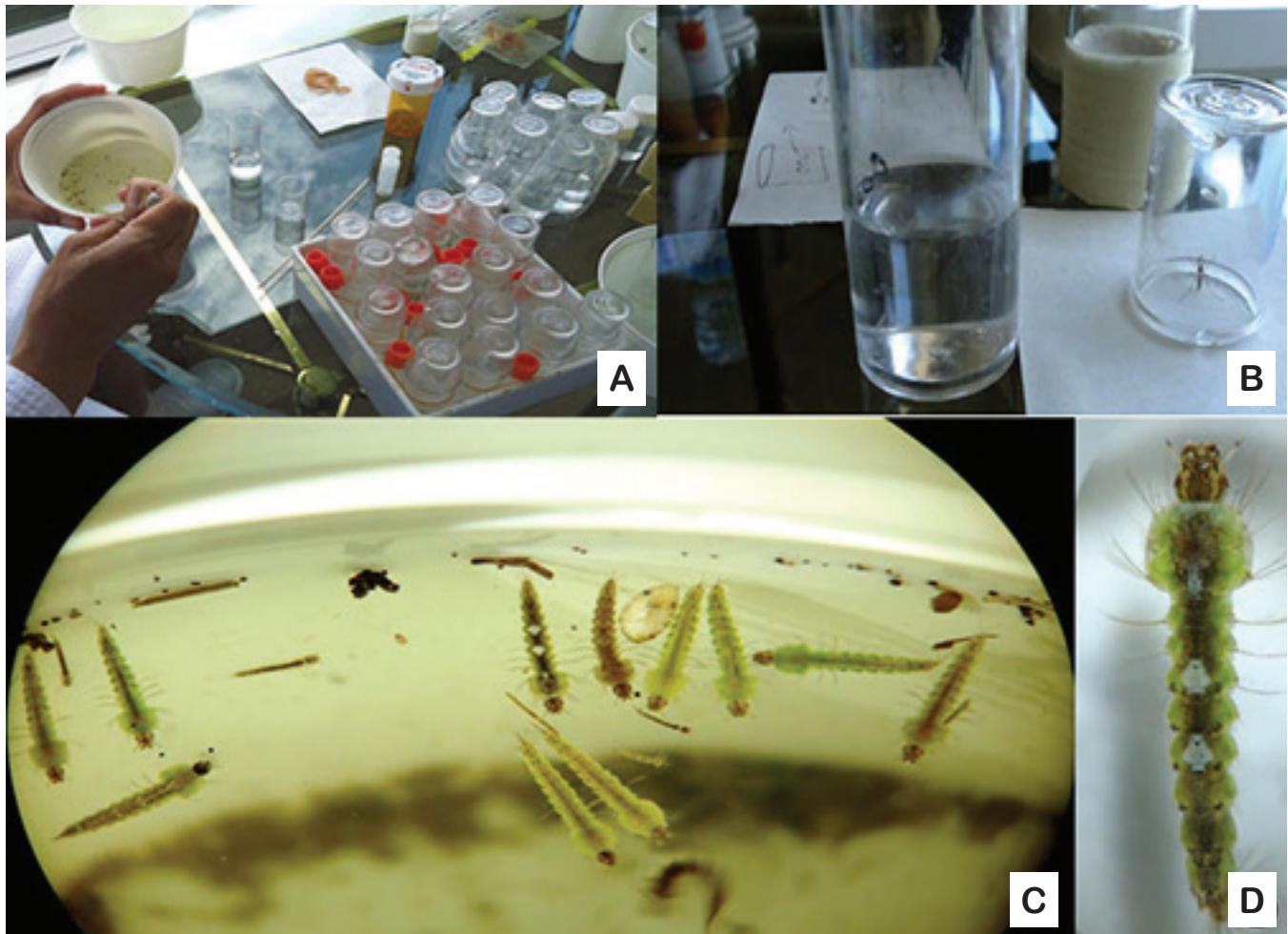


Figure 4. (A) Emergence plastic vials for rearing mosquito larvae and pupae. (B) Newly emerged adult male *Anopheles* mosquito. (C) Collected *Anopheles* Hyrcanus Group larvae showing diverse morphology. (D) *Anopheles* Hyrcanus Group larva, fourth instar, dorsal view.

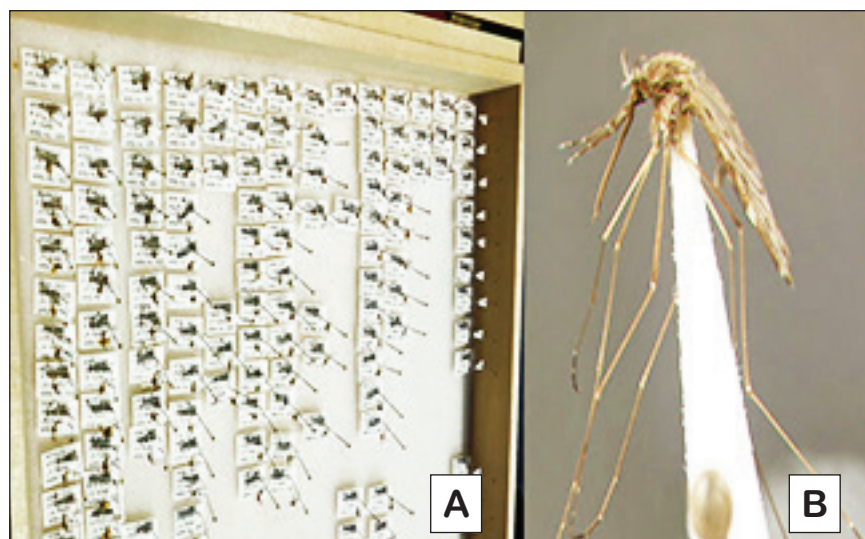


Figure 5. (A) Pinned adult mosquito specimens for deposition in the WRBU, Smithsonian Institution, National Mosquito Collections. (B) Pinned adult female of *Anopheles belenrae*, lateral view.

other Hyrcanus Group larvae (still to be identified using molecular sequences) were also found in association with the following: *Cx. (Cux.) tritaeniorhynchus*, *Cx. (Cux.)* spp.; *Ae. (Finlaya)* spp.; *Ae. (Ochlerotatus)* spp. in rice paddies and irrigation ditches in Nagasaki Prefecture (Isahaya, Moriyama, Obama-Unzen, Onakao).

During the 2013 survey of various localities in Kyushu Island, the rice paddies where we collected the larvae and pupae of *Anopheles* Hyrcanus Group had water pH ranging from 6.68-8.61 (mean, 7.77), millivoltage (175.00-237.00 mV; mean, 215.10) and temperature (30.50°C-32.80°C; mean, 32.10°C). Other water habitats (irrigation ditches, ponds, stream margin, pools, and drainage) that were positive for *Anopheles* larvae and pupae also exhibited variable pH, mV, and temperatures.

Culicine mosquitoes (nonanophelines) collected from Kyushu Island in 2013 included *Ae. (Fin.) japonicus* (Theobald) from Moriyama and Nagasaki (artificial containers, shrine stone bowls); *Ae. (Fin.) togoi* (Theobald) from Isahaya (pond); *Ae. (Ste.) albopictus* (Skuse) from Moriyama and Nagasaki (artificial containers, drainage ditches, shrine stone bowls, tree stumps or holes, temporary seepage); *Cx. (Ocu.) bitaeniorhynchus* Giles from Moriyama (drainage ditches); and *Cx. (Cux.) tritaeniorhynchus* from Moriyama, Obama-Unzen, Hitoyoshi (drainage ditches, irrigation ditches, rice paddies). About 60 mosquito larvae collected from Nagasaki Prefecture could not be identified morphologically, including those in *Ae. (Finlaya)* from Isahaya; *Ae. (Ochlerotatus)* from Nomozaki and Onakao; and *Cx. (Culex)* from Moriyama, Nagasaki, Obama-Unzen, Setoishi, Isahaya, Aikawa, and Onakao. Molecular analysis of those unidentified larval specimens of *Aedes* and *Culex*, together with both larvae and adults of *An. Hyrcanus* Group from 4 prefectures, will be completed in the future.

COMMENT

Among the *Anopheles* Hyrcanus Group species, *An. pullus*, *An. sinensis*, *An. lesteri*, *An. kleini*, and *An. belenrae* are known or potential vectors of *vivax* malaria in the Korean peninsula and other countries. *Anopheles sinensis* is the most common anopheline species in Japan, including the Ryukyu Islands.¹⁴ It has long been suspected as the most important vector of malaria in Japan, including Okinawa and Hokkaido. Even though indigenous malaria has disappeared, this vector remains abundant throughout Japan. It is a known vector of malaria in South Korea and China, and it has a wide distribution in Asia.^{4,5,8-10,14,20} *Anopheles lesteri* (= *anthropophagus*) is a very important vector of malaria in China. To clarify and stabilize the taxon, Rueda and others⁶ designated and described the neotype and alloneotype of *An. lesteri*.

This species was suspected to be an important vector of indigenous malaria in Japan, particularly in Hokkaido where it commonly occurs in great numbers. It is also common in the Ryukyu Islands and has been found more frequently in coastal regions in Honshu and Kyushu.¹⁴ *Anopheles yatsushiroensis* is not known as a vector of indigenous malaria in Japan. *Anopheles belenrae* (Figure 4B), first recorded in Japan in 2013 from Hokkaido,¹⁵ is a potential vector of *vivax* malaria in Korea.²¹ *Plasmodium berghei* Vincke and Lips, a nonhuman specific parasite, was first detected from *An. belenrae* adults in South Korea.²² The morphological details of the head, thorax, abdomen, wings, and legs of *An. belenrae* are shown in the Walter Reed Biosystematics Unit's website.* The other Hyrcanus Group species (ie, *An. sineroides* and *An. engarensis*), as well as several *Anopheles* (*Anopheles*) species (*An. bengalensis* Puri; *An. koreicus* Yamada and Watanabe; *An. lewisi* Ludlow; *An. lindsayi japonicus* Yamada; *An. omorii* Sakakibara; *An. sapersoi* Bohart and Ingram; *An. yaeyamaensis* Somboon and Harbach), are not known vectors of indigenous malaria in Japan.

Most mosquito collections, including *Anopheles* species, noted by Tanaka and others¹⁴ in 1979, are presently deposited at the National Institute of Infectious Diseases (NIID), Tokyo, Japan, where most of the Hyrcanus Group species were examined by author L. M. Rueda during his visit in 2006. In a recent conversation with the authors, Dr Kyoko Sawabe mentioned that there are some possible specimens of *An. yatsushiroensis* collected by Dr M. Otsuru in 1951 and 1964 on Kyushu Island now deposited at the NIID, Tokyo. These specimens should be examined for further morphological and molecular analysis to clarify the existence of this species. In 2003, Dr Motoyoshi Mogi inquired to check the type specimens of *An. yatsushiroensis* from the Department of Parasitology (DP), Faculty of Medicine, Kyushu University, Fukuoka, Kyushu (reported as the depository of *An. yasushiroensis* types by Miyazaki¹² in 1951). However, Professor Isao Tada (former director of the DP) informed Dr Mogi that no type specimens existed at the DP. It may be useful to designate neotypes for *An. yatsushiroensis*, if it is proven as a valid species.

Although previous researchers considered *An. yatsushiroensis* as a synonym of *An. pullus*, they used Korean specimens to obtain their molecular and morphological data.^{23,24} However, because the type locality of *An. yatsushiroensis* is in Japan, it is necessary to do a genetic comparison of *An. pullus* from South Korea with the topotypic specimens from Japan to resolve definitively if the two are synonyms or not. In 1951, Miyazaki,¹² who

*http://www.wrbiu.org/SpeciesPages_ANO/ANO_A-det/ANbIn_A-det.html

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first described *An. yatsushiroensis*, provided elaborate morphological descriptions, ecology, and distributions of this species. We did not collect *An. pullus* during our previous collections from 2002-2008 in Japan, and no report indicates the existence of *An. pullus* in that country. Furthermore, *An. pullus* is considered a major vector of *vivax* malaria in the Korean peninsula.¹⁶ Through biosurveillance, it is also interesting to investigate if another major Korean malaria vector, *An. kleini*, is present in Japan.

In our attempt to recollect specimens of the Hyrcanus Group, particularly *An. yatsushiroensis*, we recently visited numerous localities and conducted extensive larval collections at various habitats in Nagasaki Prefecture and Kumamoto Prefecture (including Yatsushiro City, the type locality of *An. yatsushiroensis* reported by Miyazaki¹²) and neighboring areas from 2006 to 2013. Unfortunately, we were not able to collect samples of *An. yatsushiroensis* from 2006 to 2012.

Although Dr Sawabe mentioned that there are some possible specimens of *An. yatsushiroensis* deposited at the NIID, Tokyo, we have not examined them yet. Furthermore, more than 200 larvae and adults of *An. Hyrcanus* Group collected in 2013 from Kumamoto and Nagasaki Prefectures are still being examined and analyzed by morphological and molecular techniques. Molecular data (PCR, sequences) will be reported later, particularly from the 2013 specimens for possible presence of *An. yatsushiroensis* and other species in *An. Hyrcanus* Group on Kyushu Island.

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**MOSQUITO BIOSURVEILLANCE ON KYUSHU ISLAND, JAPAN, WITH EMPHASIS ON
ANOPHELES HYRCANUS GROUP AND RELATED SPECIES (DIPTERA: CULICIDAE)**

Summary of collection localities and larval habitats for <i>Anopheles</i> (<i>Anopheles</i>) in 4 prefectures of Kyushu Island, Japan (part 1 of 3).								
Prefecture	Location	Grid coordinates	Collection date	Stage	Collector	Habitat type ^b	Collection No.	<i>Anopheles</i> (<i>Anopheles</i>) Species
Fukuoka	Akagawa, Ogori City	33.34975N/130.51352E	19-20 Sep 2008	Adult ^a	L. M. Rueda, Y. Oneda	RC	JP08-9	<i>sinensis</i>
Fukuoka	Takejima, Yasutake-mache, Kurume	33.34975N/130.54597E	19-20 Sep 2008	Adult ^a	L. M. Rueda, Y. Oneda	RC	KP08-10	<i>sinensis</i>
Kumamoto	Amitsu, Uto City	32.69973N/130.60432E	23 Sep 2008	Adult ^a	L. M. Rueda, M. Iwakami, J. Santano	ID, RP	JP08-17, 18	<i>sinensis</i>
Kumamoto	Gyokuto City, Tamana County	32.91638N/130.62565E	22 Sep 2008	Adult ^a	L. M. Rueda, M. Iwakami, J. Santano	PO	JP08-14	<i>sinensis</i>
Kumamoto	Hitoiyoshi	32.22652N/130.77038E	12 Jul 2013	Larva	L. M. Rueda, B. Pagac, M. Iwakami	ID, RH, RP	JP13-19, 21	Hyrceanus Group ^c
Kumamoto	Kato shrine, Yatsushiro	32.47998N/130.57202E	15 Sep 2008	Adult ^a	L. M. Rueda, M. Iwakami, J. Santano	DD	JP08-2	<i>lesteri</i>
Kumamoto	Lake Ezu	32.77755N/130.73855E	24 Sep 2008	Adult	L. M. Rueda, M. Iwakami, J. Santano	LM	JP08-19	<i>sinensis</i>
Kumamoto	Matsubase, Uki City	32.65355N/130.67050E	30 Aug 2006	Adult ^a	M. Iwakami, R. Moore	RP	JP06-2-37A, 40A	<i>lesteri</i>
Kumamoto	Matsubase, Uki City	32.65625N/130.66788E	17 Sep 2008	Adult ^a	L. M. Rueda, M. Iwakami, J. Santano	RP	JP08-7, 8	<i>lesteri</i>
Kumamoto	Matsubase, Uki City	32.65355N/130.67050E	30 Aug 2006	Adult ^a	M. Iwakami, R. Moore	RP	JP06-2-1A, 2A, 3A, 4A, 6A, 25A, JP08-5, 6	<i>sinensis</i>
Kumamoto	Sumiyoshi, Uto City	32.70005N/130.60015E	22 Sep 2008	Adult ^a	L. M. Rueda, M. Iwakami, J. Santano	ID	JP08-17B	<i>sinensis</i>
Kumamoto	Takasima, Yatsushiro	32.52158N/130.57750E	15 Sep 2008	Adult ^a	L. M. Rueda, M. Iwakami, J. Santano	HD, WT	JP08-1, 4	<i>lesteri</i>
Kumamoto	Tamana City, Tamana County	32.91638N/130.54523E	22 Sep 2008	Adult ^a	L. M. Rueda, M. Iwakami, J. Santano	RP	JP08-15, 16	<i>sinensis</i>
Kumamoto	Ueki City	32.88017N/130.68148E	22 Sep 2008	Adult ^a	L. M. Rueda, M. Iwakami, J. Santano	ID, RP	JP08-12, 13	<i>lesteri</i>
Kumamoto	Uto	32.69660N/130.66845E	29 Aug 2006	Adult ^a	M. Iwakami, R. Moore	RP	JP06-1-50A, 51A	<i>lesteri</i>
Kumamoto	Uto	32.69660N/130.66845E	29 Aug 2006	Adult ^a	M. Iwakami, R. Moore	RP	JP06-1-1A, 2A, 3A, 4A, 5A, 7A, 16A	<i>sinensis</i>
Kumamoto	Yatsushiro	32.50033N/130.61932E	11 Jul 2013	Larva, pupa, adult ^a	L. M. Rueda, B. Pagac, M. Iwakami	SP	JP13-18	Hyrceanus Group ^c
Kumamoto	Yatsushiro	32.52158N/130.57750E	16 Sep 2008	Adult ^a	L. M. Rueda, M. Iwakami, J. Santano	RP	JP08-3	<i>sinensis</i>
Nagasaki	Ariake-cho, Nagasaki	32.69414N/130.32505E	20 Jul 1988	Adult ^a		RC	JPM-5	<i>sinensis</i>
Nagasaki	Goto, Fukue Island	32.67867N/128.76802E	17 Jul 2013	Larva, pupa	L. M. Rueda, B. Pagac, M. Iwakami	ID	JP13-31	Hyrceanus Group ^c
Nagasaki	Goto, Fukue Island	32.67867N/128.76802E	17 Jul 2013	Larva	L. M. Rueda, B. Pagac, M. Iwakami	RP	JP13-30	Hyrceanus Group ^c
*Field collected larvae or pupae, reared to emerged adults. ^b DD, drainage ditch; HD, hill or road side ditch; ID, irrigation ditch; LM, lake margin; PO, pond; RC, resting at cowshed or cattle barn; RH, rock hole; pool; RP, rice paddy; SP, stream or river margin or pool; WT, water tank, trough or PVC tube waterer. ^c DNA isolation and sequencing still to be completed.								

^aField collected larvae or pupae, reared to emerged adults.

^bDD, drainage ditch; HD, hill or road side ditch; ID, irrigation ditch; LM, lake margin; PO, pond; RC, resting at cowshed or cattle barn; RH, rock hole, pool; RP, rice paddy; SP, stream or river margin or pool; WT, water tank, trough or PVC tube waterer.

^cDNA isolation and sequencing still to be completed.

Summary of collection localities and larval habitats for <i>Anopheles</i> (<i>Anopheles</i>) in 4 prefectures of Kyushu Island, Japan (part 2 of 3).								
Prefecture	Location	Grid coordinates	Collection date	Stage	Collector ^b	Habitat type ^c	Collection No.	<i>Anopheles</i> (<i>Anopheles</i>) Species
Nagasaki	Goto, Fukue Island	32.67867N/128.76802E	17 Jul 2013	Adult ^a	L. M. Rueda, B. Pagac, M. Iwakami	RP	JP13-30	Hyrcanus Group ^d
Nagasaki	Goto, Fukue Island	32.67867N/128.76802E	17 Jul 2013	Larva	L. M. Rueda, B. Pagac, M. Iwakami	RP	JP13-32	Hyrcanus Group ^d
Nagasaki	Goto, Fukue Island	32.67867N/128.76802E	17 Jul 2013	Adult ^a	L. M. Rueda, B. Pagac, M. Iwakami	RP	JP13-32	Hyrcanus Group ^d
Nagasaki	Isahaya	32.81308N/130.12767E	12 Jul 2013	Adult ^a	NG1	PO	JP13-23	Hyrcanus Group ^d
Nagasaki	Isahaya	32.81308N/130.12767E	12 Jul 2013	Larva	NG1	PO	JP13-23	Hyrcanus Group ^d
Nagasaki	Isahaya	32.81308N/130.12767E	12 Jul 2013	Larva	NG1	RP	JP13-25	Hyrcanus Group ^d
Nagasaki	Isahaya-shi, Kamiimuta, Moriyama-cho	32.80759N/130.10737E	27 May 2006	Adult	T. Yoshio	-	JPM-5	<i>sinensis</i>
Nagasaki	Mikawa-machi	32.78590N/129.88779E	27 May 1962	Adult	NU	-	JPM-5	<i>sinensis</i>
Nagasaki	Moriyama	32.83508N/130.11372E	9 Jul 2013	Adult ^a	L. M. Rueda, B. Pagac, M. Iwakami	RP	JP13-7	Hyrcanus Group ^d
Nagasaki	Moriyama	32.83508N/130.11372E	9 Jul 2013	Larva	L. M. Rueda, B. Pagac, M. Iwakami	RP	JP13-8	Hyrcanus Group ^d
Nagasaki	Nagasaki	32.77217N/129.86950E	20 Jun 1989	Adult	M. Mogi	RP	JPM-5	<i>sinensis</i>
Nagasaki	Nomozaki	32.58570N/129.75660E	15 Jul 2013	Larva	NG2	AC	JP13-26	Hyrcanus Group ^d
Nagasaki	Obama-Unzen	32.71354N/130.20073E	10 Jul 2013	Larva	L. M. Rueda, B. Pagac, M. Iwakami	RP	JP13-14	Hyrcanus Group ^d
Nagasaki	Obama-Unzen	32.71354N/130.20073E	10 Jul 2013	Larva	L. M. Rueda, B. Pagac, M. Iwakami	RP	JP13-15	Hyrcanus Group ^d
Nagasaki	Obama-Unzen	32.71354N/130.20073E	10 Jul 2013	Larva	L. M. Rueda, B. Pagac, M. Iwakami	WC	JP13-16	Hyrcanus Group ^d
Nagasaki	Obama-Unzen	32.71354N/130.20073E	10 Jul 2013	Adult ^a	L. M. Rueda, B. Pagac, M. Iwakami	WC	JP13-16	Hyrcanus Group ^d
Nagasaki	Onako	32.88408N/129.69598E	16 Jul 2013	Larva	NG2	RP	JP13-29	Hyrcanus Group ^d
Nagasaki	Togitsu	32.82683N/129.84866E	7-9 Aug 1956; 22 Jul 1962	Adult	NU	-	JPM-5	<i>sinensis</i>
Nagasaki	Tsushima	34.17745N/129.29039E	27 May 1962	Adult	NU	-	JPM-5	<i>sinensis</i>
Nagasaki	Ukutzugawa	32.79328N/129.92803E	9 Jul 2013	Larva	L. M. Rueda, B. Pagac, M. Iwakami	RP	JP13-13	<i>lindsayi japonicus</i>
Nagasaki	Utzutzugawa	32.79328N/129.92803E	9 Jul 2013	Larva	L. M. Rueda, B. Pagac, M. Iwakami	RP	JP13-13	Hyrcanus Group ^d
Saga	Fukutomi	33.17567N/130.17284E	13, 20, 28 Aug 2005; 11, 13, 24 Sep 2005; 10 Oct 2005;	Adult	M. Mogi	LF	JPM-22-1	<i>sinensis</i>

^aField collected larvae or pupae, reared to emerged adults.^bNG1 indicates L. M. Rueda, B. Pagac, M. Iwakami, Y. Higa, K. Futami. NU indicates Nagasaki University, Entomology Collection. NG2 indicates L. M. Rueda, B. Pagac, M. Iwakami, Y. Higa, K. Futami.^cAC, artificial containers (tires, plastic jugs, kettle, etc); CA, road ditch or small canal; ID, irrigation ditch; LF, lotus field; PO, pond; RP, rice paddy; WC, water well/cistern.^dDNA isolation and sequencing still to be completed.

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Prefecture	Location	Grid Coordinates	Collection date	Stage	Collector	Habitat type ^b	Collection No.	<i>Anopheles</i> (<i>Anopheles</i>) Species
Saga	Kase	33.23807N 130.25824E	17 Sep 2005	Adult	M. Mogi	ID	JPM-21-1, -2, -3	<i>sinensis</i>
Saga	Kinyu	33.24204N 130.29149E	2, 5, 10 Jun 1986	Adult	M. Mogi	RP	JPM-8, 9	<i>lesteri</i>
Saga	Morita	33.09454N 130.10894E	16 May 1995	Adult	M. Mogi	CA	JPM-14	<i>sinensis</i>
Saga	Nabeshima	33.27991N 130.26614E	30 May 1985; 14 Jun 1985; 3, 5, 6, 7, 20 Jun 1986; 9 Jun 1990; 7 Jun 1995; 3 Jun 1996	Adult	M. Mogi	LF	JPM-4, 5, 6, 7	<i>lesteri</i>
Saga	Shiroishi	33.17837N 130.14394E	7 May 2000	Adult	M. Mogi	RP	JPM-19-1	<i>lesteri</i>
Saga	Shiroishi	33.17837N 130.14394E	3 Nov 1997; 7 May 2000	Adult	M. Mogi	NE	JPM-14, 15, 19-2, 19-3, 19-5, 19-5	<i>sinensis</i>
Saga	Yamato-cho	33.14766N 130.14832E	10 Apr 2000	Adult	T. Sunahara	CA	JPM-18	<i>lesteri</i>
Saga	Yamato-cho	33.14766N 130.14832E	5 Jun 1986; 24, 25, 26 Apr 2000; 10, 11, 12, 25 May 2000; 24, 25 Apr 2004	Adult	T. Sunahara, M. Mogi	CA	JPM-8, 15, 16, 17, 18	<i>sinensis</i>
Saga	Tosu City	33.34463N 130.51352E	20 Sep 2008	Adult ^a	L. M. Rueda, Y. Oneda	GT	JP08-11	<i>lesteri</i>

^aField collected larvae or pupae, reared to emerged adults.
^bCA, road ditch or small canal; GT, ground pit or depression; ID, irrigation ditch; LF, lotus field; NE, caught by insect net; RP, rice paddy.



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High-Throughput Vector-Borne Disease Environmental Surveillance By Polymerase Chain Reaction According To International Accreditation Requirements

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ABSTRACT

Although vector-borne diseases are specific to the region of the host, there is a necessity for surveillance or reference laboratories to perform standardized, high-throughput testing capable of meeting the needs of a changing military environment and response efforts. The development of standardized, high-throughput, semiquantitative real-time and reverse transcription real-time polymerase chain reaction (PCR) methods allows for the timely dissemination of data to interested parties while providing a platform in which long-term sample storage is possible for the testing of new pathogens of interest using a historical perspective. PCR testing allows for the analysis of multiple pathogens from the same sample, thus reducing the workload of entomologists in the field and increasing the ability to determine if a pathogen has spread beyond traditionally defined locations. US Army Public Health Command Region-Europe (USAPHCR-Europe) Laboratory Sciences (LS) has standardized tests for 9 pathogens at multiple life stages. All tests are currently under international accreditation standards. Using these PCR methods and laboratory model, which have universal Department of Defense application, the USAPHCR-Europe LS will generate quality data that is scientifically sound and legally defensible to support force health protection for the US military in both deployed and garrison environments.

Vector-borne diseases remain a significant cause of disease for US service members throughout the US European Command, Africa Command, and Central Command, thereby requiring strong surveillance systems and outbreak responses.¹ There is a need for surveillance or reference laboratories to perform standardized, high-throughput testing capable of meeting the needs of a changing military environment and response efforts. An understanding of the significance and location of pathogens is important in the development of prevention programs for human and animals, as well as pest-control activities. Although there are numerous tests to detect arthropod-borne diseases, polymerase chain reaction (PCR) assays offer both high sensitivity and specificity for either DNA or RNA recovered from field-collected arthropod samples.²⁻⁴ The use of real-time PCR assays offers not only the option of high-throughput testing in an otherwise time and labor intensive procedure, but also removes the need for any postamplification processing (ie, agarose gel electrophoresis). This study describes the development, validation, and standardization of real-time PCR and reverse transcription real-time PCR assays to detect *Anaplasma phagocytophilum*,

Ehrlichia spp, *Borrelia* spp (*B burgdorferi*, *B afzelii*, and *B garinii*), Crimean-Congo hemorrhagic fever virus, *Leishmania*, sandfly fever Sicilian virus, dengue virus, *Plasmodium* spp, and chikungunya virus at the US Army Public Health Command Region-Europe.

MATERIALS AND METHODS

At the time of this writing, all methods discussed in the article are accredited by the American Association for Laboratory Accreditation and placed on Laboratory Sciences' ISO/IEC 17025:2005 Biological Scope of Accreditation (certificate number 2138.01). USAPHCR-Europe LS is registered by Bureau Veritas under the DIN EN ISO 9001:2008 Quality Management System standard (certificate number DE002197-1) and the DIN EN ISO 14001:2009 Environmental Management System standard (certificate number DE002198-1).

Homogenization of Arthropods

Negative mosquitoes, sandflies (obtained from the Walter Reed Army Institute of Research, Silver Spring, MD), and larvae, nymph, and adult ticks (Bayer HealthCare AG: Animal Health, Germany) were stored in

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70% ethanol at -80°C. Samples were transferred to 1.5 mL round-bottom tubes (DNA LoBind, Eppendorf AG, Hamburg, Germany) with 400 µL phosphate buffered saline (Sigma-Aldrich, St. Louis, MO). A total of 5 mosquitoes or sandflies were added to tubes and crushed with a micropestle (Kimble Chase, NJ). One tick, regardless of life-stage, was added to each tube and crushed with a micropestle. One 5-mm tungsten carbide bead (Qiagen, Netherlands) was added to each tube. Samples were homogenized using the TissueLyser system (Qiagen, Netherlands) for 10 minutes at 20 Hz. After a short centrifugation step of 20 to 60 seconds at 9,000 rpm, 200 µL of the supernatants were collected and transferred to sample processing cartridges or new 1.5 mL round-bottom tubes.

Automated Nucleic Acid Extraction

Automated nucleic acid extraction was performed using the MagNA Pure96 (Roche Applied Sciences, Germany) and the MagNA Pure LC (Roche Applied Sciences, Germany). A total of 200 µL of arthropod homogenate supernatant was added to 300 µL of external lysis buffer for the MagNA Pure LC using MagNA Pure LC small volume total nucleic acid kit with the External Lysis Protocol (Roche Applied Sciences, Germany) according to manufacturer instructions. A total of 200 µL arthropod homogenate supernatant was extracted using MagNA Pure96 DNA and viral NA small volume kit with the Universal Pathogen Protocol. A total volume of 50 µL nucleic acid was acquired from samples on both automated extraction instruments. Isolated total nucleic acids were stored at -20°C or below until PCR analysis was performed.

DNA and RNA Absorbance Analysis

The 260/280 ratio, 230 nm, and 300 nm results for 2 µL extracted sample were analyzed using a NanoQuant plate (Tecan Group Ltd, Switzerland) on the Mx Pro 200 microplate reader (Tecan Group Ltd, Switzerland).

Real-Time PCR

Real-time PCR reactions were performed using genesig Advanced kit (Primerdesign Ltd, UK) as appropriate for the pathogen being tested and 2X One Step qPCR Master Mix (Primerdesign Ltd, UK). The real-time PCR conditions were: 5 µL of total nucleic acid, 10 µL of 2X OneStep qPCR Master Mix, one µL of target primer, one µL of internal positive control primer, and DNase/RNase free water (Qiagen, Netherlands) to adjust the volume to 15 µL. Amplification was performed in LightCycler 480 96-well PCR plates (Roche Applied Sciences, Germany). Plates were sealed with LightCycler 480 sealing film (Roche Applied Sciences, Germany). The cycling conditions for amplification were performed on

a LightCycler 480 (Roche Applied Sciences, Germany) as follows: initial enzyme activation step at 95°C for 10 minutes, and 40 cycles of 95°C for 10 seconds, 65°C for one minute. Melting curve data was collected immediately after cycle 40; one cycle at 60°C for one minute, and 95°C (0.06°C/second) for 10 minutes.

Real-Time Reverse Transcription PCR

Real-time reverse transcription PCR reactions were performed using genesig Advanced kit and 2X One Step qRT-PCR Master Mix. The real-time reverse transcription PCR conditions were as follows: 5 µL of total nucleic acid, 10 µL of 2X One Step qRT-PCR Master Mix, one µL of target primer, one µL of internal positive control primer, and DNase/RNase free water to adjust the volume to 15 µL. Amplification was performed in LightCycler 480 96-well PCR plates. Plates were sealed with LightCycler 480 sealing film. The cycling conditions for amplification were performed on a LightCycler 480 as follows: reverse transcription at 55°C for 10 minutes, enzyme activation step at 95°C for 8 minutes, and 40 cycles of 95°C for 10 seconds, 65°C for one minute. Melting curve data was collected immediately after cycle 40; one cycle at 60°C for one minute, and 95°C (0.06°C/second) for 10 minutes. It should be noted that new Master Mix formulas (Precision and Precision-PLUS) were recently introduced by PrimerDesign and have not yet been used by the laboratory. The new consumables will be subjected to the same verification and validation procedures presented in this article and in accordance with the LS Quality Management System prior to being incorporated into regular use.

Calculations

Method detection limits, defined as the minimum concentration that can be measured and reported with 99% confidence that the value determined is above zero, were determined as the Student's *t* test value at the 99% confidence level multiplied by the standard deviation of the data set.

RESULTS

It was determined that the method detection limit (MDL) for the pathogen kits using 5 adult female arthropods as the matrix for *Plasmodium* spp, dengue fever virus, chikungunya virus, *Leishmania* spp, and sandfly fever Sicilian virus were 97; 2,500; 25,000; 19,000; and 1,300 copies, respectively. Tick MDLs were determined using one tick per each adult, nymph, and larvae life stage. *Anaplasma phagocytophilum* adult, nymph, and larvae MDLs were determined to be 6,300; 6,900; and 5,400 copies, respectively. *Ehrlichia* spp adult, nymph, and larvae MDLs were determined to be 130,000; 240; and 480 copies, respectively. *Borrelia* spp adult, nymph, and

larvae MDLs were determined to be 28,000; 24,000; and 15,000 copies, respectively. Crimean-Congo hemorrhagic fever virus adult, nymph, and larvae MDLs were determined to be 14,000; 810; and 6,200 copies, respectively. The microplate reader was used to simultaneously verify the success of the extraction procedure and assess the quality of the total nucleic acid extract through absorbency spectroscopy. Results indicating unusual or poor overall nucleic acid purity were based upon the 260/280 ratio and noted on quality control checklists, however, based upon these results, there was no indication of problems processing the samples further.

While only a detect or nondetect result was reported for samples, quantization of target sequences present in a given sample were used to establish decision-making criteria, as well as for in-house quality control purposes. A dilution curve is established using manufacturer-provided positive controls (Primerdesign Ltd, United Kingdom) and a 10-fold dilution range from 10 to 1.0×10^6 copies per sample. Samples containing each of the 6 represented concentrations were analyzed along with a negative sample and appropriate quality assurance controls. Upon run completion, the LightCycler software calculated a best-fit polynomial and second derivative curve for each amplification curve. The maximum of the amplification curve identified the point at which the fluorescence curve underwent the most rapid growth increase or “elbow” (Figure 1).⁵

For samples tested in separate runs, the LightCycler software stored the curves for later use. A new curve was established for each primer kit, and samples tested in subsequent runs were tested along with duplicate positive controls spiked with 1.0×10^4 copies of target. Comparison of these standard concentrations with the stored curve allowed the software to compensate for discrepancies between runs.

To measure the melting temperature (T_m), a temperature program is added to the end of the amplification protocol which briefly cools the samples to 65°C, then slowly increases their temperature to 95°C over the course of approximately 10 minutes while continuously acquiring the fluorescence. The T_m is approximated via software by comparing the resulting melting curve to a best-fit polynomial, then calculating the negative derivative of this curve and identifying its peak. This peak correlates with the point at which the fluorescence decrease was strongest, which subsequently correlates with the T_m value (Figure 2).⁵ Final results were reported as positive or detected if the T_m was within 3 standard deviations of the clean matrix average T_m value, shown in the Table,

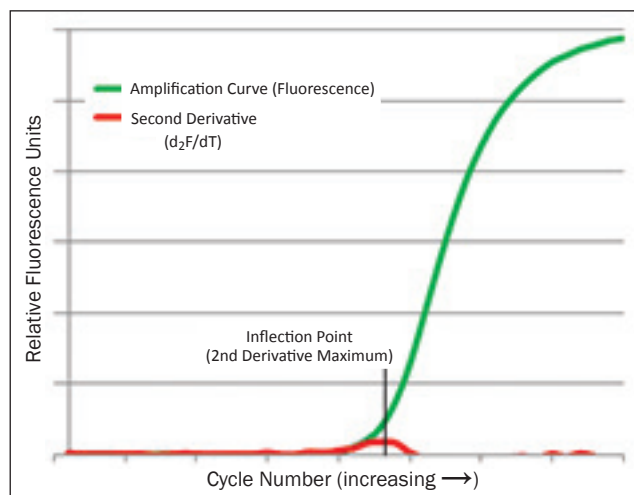


Figure 1. Demonstration of a typical amplification curve and the approximate second derivative. Amplification plots are used to determine the inflection point associated with a detectable rise in nucleic acid product. An inflection point is often referred to as a crossing point (C_p) or a crossing threshold (C_t). Fluorescence is represented on the Y-axis and is provided in relative fluorescence units. The units are directly associated with the strength of signal from a product. A typical product will result in an “S” shaped curve. The X-axis represents the number of cycles. Cycle numbers performed should be optimized to each individual instrument. Generally, the total number of cycles will range from 30 to 50.

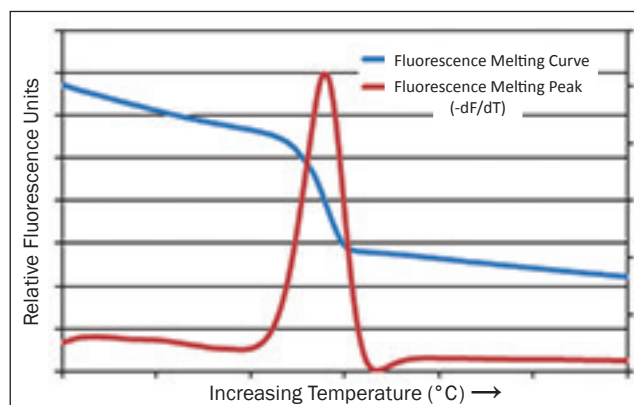


Figure 2. A typical melting temperature (T_m) curve with the negative derivative overlaid. This figure is a representation of a typical fluorescence curve with the negative derivative overlaid. Fluorescence signal is always represented on the Y-axis while the temperature is represented on the X-axis. Melting temperature values are used to ensure that the product is correct based upon the nucleotide base content. As the strands of nucleic acid being to dissociate a change in the melting peak or curve will be visualized.

and the crossing point or inflection point (C_p) was calculated as less than or equal to 35 cycles.

COMMENT

The vector-borne disease laboratory (VBDL) encountered many challenges in becoming a modern Army disease surveillance laboratory. For the purpose of this

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article, these problems will be segregated into the following categories: method accreditation, standardization, traceability, staff turnover and training, proficiency testing, flexibility, throughput, and safety.

Method Accreditation

One challenge the lab faced is the development of accredited testing methods. The PHCR-Europe VBDL decided to use commercially procured, real-time PCR testing kits that contained enumerated positive controls. Using the quantitative positive controls, the VBDL was able to address the accreditation requirements of assessing MDLs. The VBDL assessed these requirements through the spiking of known concentrations of positive controls into clean, vivarium-raised, whole arthropod matrix. The benefit of MDLs is that the lab is able to decrease the possibility of false negative or false positive reporting through proper statistical analysis.

Standardization

Assay standardization was an important consideration in the design of the laboratory. In order to perform the necessary quantitative analysis, 100% of the PCR detection methods were moved to quantitative real-time and quantitative reverse transcription real-time PCR using standardized commercially available kits. All extractions were automated, and were performed on 32-well or 96-well platforms. PCR assays were also moved to a standardized 96-well format, thereby reducing operator error from format changes at each step.

Traceability

Traceability of consumables is another requirement for accreditation. The VBDL designed all methodologies around commercially available consumables that may be procured from ISO registered or accredited manufacturers. Such procurement enables the VBDL to trace the sourcing of materials through a chain of standardized suppliers and thus meet accreditation requirements. Within the lab, the traceability of consumables is maintained through the use of quality control checklists and integrated instrument barcode readers. Both the checklists and the barcode readers generate a traceable audit trail used to meet accreditation requirements, track analysis problems, and provide multiple checkpoints for troubleshooting.

Staff Turnover and Training

Staff turnover in a military laboratory is a paramount concern. As Soldiers move from assignment to assignment, staff turnover can place stress on trained personnel to meet production demands. The VBDL was designed to streamline and simplify training time so that new staff can quickly begin generating quality scientific

Average melting temperature (T_m) values and standard deviation (SD) for individual pathogens determined from a clean matrix.

Target in Clean Matrix	T _m (°C)	± one SD
<i>A. phagocytophilum</i>	78.49	0.80
Crimean Congo hemorrhagic fever virus	80.90	0.69
<i>Ehrlichia</i> ssp	79.72	0.81
<i>Borrelia</i> ssp	79.34	0.12
Chikungunya virus	81.90	3.53
Dengue virus	81.62	2.96
<i>Leishmania</i> ssp	74.72	1.22
<i>Plasmodium</i> ssp	80.00	1.03
Sandfly fever Sicilian virus	77.96	0.54

data. Because all current methods for pathogen detection were developed into a single chemistry type, new employees will only require training on 2 procedures, nucleotide extraction and PCR detection, with minor variation to account for nucleic acid type. Robotic instrumentation and high throughput consumable formats will assist in maintaining production demands while new staff members are trained on laboratory procedures.

Proficiency Testing

A proficiency testing program for the VBDL was another challenge associated with achieving and maintaining laboratory accreditation. Some of the problems initially encountered included shipping and transfer of pathogens in an appropriate matrix, ability to challenge semiquantitative methods, PCR specific rounds, third party management of proficiency testing materials, intellectual property rights, and adaptability of the testing program to other commands. Due to the exacting requirements for proficiency testing, the VBDL used the services of SeraCare Life Sciences (Milford, MA) in the creation of custom proficiency testing panels, the use of which addressed our specific requirements. Because the intellectual property of the testing kits was being used to develop proficiency testing (PT) rounds, SeraCare Life Sciences and Primerdesign Ltd entered into a nondisclosure agreement to ensure the protection of corporate knowledge. SeraCare Life Sciences was then able to develop polycistronic plasmids containing target sequences of interest and produce those plasmids as multitarget positive spikes in order to test the VBDL's methods at multiple concentrations. All PT rounds ship only as either purified plasmids or purified in vitro transcribed RNA. This allows worldwide distribution of the proficiency tests without concern for the shipping of pathogens. Other commands in the world may access the same proficiency tests used at US Army Public Health

Command Region-Europe, provided that they use the same PCR targets.

Flexibility

Adaptability was also built into the PT design to accommodate future pathogens and to provide the utmost flexibility to meet the needs of other regions. SeraCare Life Sciences is able to subclone other targets into the plasmids to meet local or global test requirements. Finally, the PT rounds can be completely managed by SeraCare. They are able to create and issue the proficiency tests, compile all testing data, and issue comparative results for all participating laboratories. This adaptability will enable different commands through the world to use an established proficiency testing scheme for laboratory accreditation that is adaptable to meet localized needs on a flexible timeframe.

Throughput

Due to the ability of the US military to rapidly respond throughout the world, it was necessary to build quick response into the VBDL. For the purpose of this article, rapid response is understood as rapid turnaround time (TAT), or rapid assay development. Rapid results production and fast TATs are achieved through streamlining of detection chemistries, high-throughput consumable platforms, commercially available testing kits, and robotic instrumentation.

The VBDL was also designed to enable quick response to novel pathogen threats encountered by the US military. The VBDL currently uses off-the-shelf testing kits developed by Primerdesign Ltd, an ISO 9001:2008 Quality Management System registered company. Primerdesign Ltd provided consultation and development of new, certified, quantitative testing kits within approximately a 4-week development time. As a result of the expedient delivery, local threats can be addressed in accordance with accreditation requirements without extensive in-house research and development, thus allowing personnel to concentrate on maintaining laboratory operations. After receipt of the new testing kits, the VBDL, in accordance with USAPHCR-Europe Laboratory Sciences' world class quality management system, was required to perform a complete method modification study. The studies were performed to test method accuracy, precision, recovery, and detection limit. Performance of the method validation study ensures that the new assay will meet laboratory accreditation requirements prior to use on customer samples. Any newly developed testing, changes to existing operations, and/or changes in manufacturer consumables for the VBDL will follow the same requirements.

The VBDL wanted to ensure that customers were able to analyze a full range of pathogen genotypes for every sample submitted. For this end the VBDL implemented all methods for whole nucleotide extraction of both DNA and RNA. Whole nucleotide extraction empowers the customer to examine the colocalization of multiple pathogens up to the fidelity of a single arthropod. Current policy of the VBDL requires storage, as space is available, of whole nucleotide extracts for a minimum of one year, allowing the customer access to a limited historical record to query for additional pathogens without additional field work. Whole nucleotide extraction gives the greatest potential to capture the largest data set from every sample submission.

Safety

The VBDL adopted the most prudent safety practices to meet the requirements of *Department of the Army Pamphlet 385-69*,⁶ *Biosafety in Microbiological and Biomedical Laboratories* (Centers for Disease Control and Prevention),⁷ and *Quality Assurance/Quality Control Guidance for Laboratories Performing PCR Analyses on Environmental Samples* (Environmental Protection Agency).⁸ Laboratory layout and equipment was chosen so that safety standards could be maintained during high throughput sample processing with the goal of zero laboratory acquired infections.

In PCR analysis, safety and prevention of cross-contamination work together. The VBDL uses a unidirectional workflow where sample analysis is performed in 3 separate rooms. The first room is for reagent preparation and contains a 6 foot class A2 biosafety cabinet (BSC) where reagents are mixed. No customer samples or controls are permitted in this area, thereby reducing the likelihood of stock reagent contamination. The second room is for sample preparation. All sample homogenization is performed inside of another 6 foot class A2 BSC to provide ample analyst protection from potentially infectious aerosols. Nucleotide purification is completed on a Roche robotic nucleotide extraction instrument to minimize sample handling and to increase safety. After the extraction, all nucleotides are considered noninfectious, but potential problems associated with cross-contamination exist. The sample preparation room also contains 3 PCR workstations to provide increased product protection during PCR setup. Because all sample processing is performed in a BSC that is restricted to one laboratory room, the threat of laboratory acquired infections is minimized. The final room is used for amplification and detection. Any PCR materials, samples, and quality assurance controls that are not prepped and intended for immediate analysis are not permitted in this room. The

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PCR amplification room must be treated with great care. The PCR amplicon can cause a catastrophic contamination of sample, instruments, and consumables. Unidirectional laboratory design therefore serves 2 purposes. First, the potential for cross-contamination is decreased by confining specific PCR procedures to certain areas. Second, safety is increased since all sample processing is performed in a BSC that is restricted to a single laboratory room.

CONCLUSION

Results of MDL studies indicate that vector-borne pathogen detection using real-time PCR and real-time reverse transcription PCR is a high-throughput, semiquantitative method that is capable of meeting and surpassing stringent international accreditation requirements with the possibility to be used military-wide with interlaboratory comparable results.

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Evaluation of a Rapid Immunodiagnostic Rabies Field Surveillance Test on Samples Collected from Military Operations in Africa, Europe, and the Middle East

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ABSTRACT

The Anigen Rapid Rabies Antigen Test Kit (Bionote, Inc, Hwaseong, Korea) was evaluated using 80 clinical samples collected by US military veterinary units. Samples for the study were obtained from brain specimens of domestic and wildlife animals that were submitted to the US Army Public Health Command's Veterinary Laboratory Europe in Landstuhl, Germany, for rabies testing with the direct fluorescent antibody test. The rapid immunodiagnostic test was able to detect rabies virus antigen in clinical samples of brain tissue. The rapid immunodiagnostic test had an overall sensitivity of 96.9% and specificity of 100% when compared to the direct fluorescent antibody test. The rapid immunodiagnostic test for rabies virus antigen detection is a straightforward test that can be run under field conditions and without a microscope or electricity, and yield results in 5 to 10 minutes. This rapid immunodiagnostic test is a quick, inexpensive, and easy to use surveillance tool that can identify rabies positive animals and help focus targeted control measures with the goal of reducing the rabies burden.

Rabies is an acute, progressive, viral encephalomyelitis with the highest case fatality rate of any conventional etiological agent. It is one of the oldest described infectious diseases, having been recognized more than 4,000 years ago. Rabies has a substantial international presence in that it is distributed on all continents but Antarctica. It is the leading viral zoonosis with a significant global burden on veterinary and human public health. Globally, the number of human rabies exposures per year is estimated to be in the tens of millions; the number of human rabies deaths per year was estimated to be over 55,000 in 2005.¹ The rabies virus is a negative strand RNA-virus belonging to the genus *Lyssavirus*, family *Rhabdoviridae* of the order *Mononegavirales*.^{2,3}

Different animal species are involved in the maintenance and transmission of rabies around the world. While the predominance of any one reservoir species varies by geographical region, the domestic dog remains the most significant reservoir for human rabies in overall case numbers and with regard to transmission, accounting for more than 90% of rabies exposures worldwide and more than 99% of human rabies deaths. Although rabies control and elimination is possible in dogs, stray and free-roaming, infected dogs present barriers to success.^{1,4,5}

In the Eastern Mediterranean region as defined by the World Health Organization (WHO), which includes Afghanistan and Iraq,⁶ rabies continues to be a public health problem, predominantly affecting vulnerable,

impoverished populations living in remote, rural locations. In 2002, 5,000 human rabies deaths were recorded in the region, mostly from Afghanistan, the Islamic Republic of Iran, and Pakistan, whereas most other countries reported fewer than 10 cases per country.⁷ Unlike in developed countries, vaccination coverage of domestic animals in Afghanistan, Iraq, and similar countries is low. Absence of adequate vaccination within these countries makes them high risk for rabies in terrestrial animals and has resulted in a high prevalence of rabies within the dog population.^{7,8}

Unfortunately, current reported numbers of animals infected with rabies in Iraq and Afghanistan are variable. Infrastructure is not in place to support testing for rabies in these regions, so reporting of cases is often based on clinical signs and is therefore limited and inconclusive.⁹ These countries lack a much needed, effective surveillance network to assess the magnitude of disease and to focus vaccination and control efforts. These countries also lack proper diagnostic facilities. Reliable national, systematic surveillance of rabies-related human deaths and animal rabies prevalence is urgently needed to garner support for effective prevention strategies.^{4,10,11}

For animal rabies diagnosis, the direct fluorescent antibody test (DFAT) is the most frequently used and is the gold-standard test approved by the Centers for Disease Control and Prevention (CDC), WHO, and the World Organisation for Animal Health. This test is performed

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on brain tissue from animals suspected of being rabid and can only be performed postmortem.¹²⁻¹⁵ The DFAT is one of the quickest and most reliable testing methods, providing an accurate diagnosis in 98% to 100% of rabies suspect cases.^{13,16,17}

In remote locations, the use of DFAT is often not feasible because of transportation issues and lack of adequate cold chain. Laboratories are not able to comply with the strict requirements to perform DFAT accurately. The lack of infrastructure and logistical support hinders DFAT as a realistic expectation. Currently cases go undetected, and surveillance is not actively pursued. The lack of diagnostic and surveillance capability results in a low level of awareness of the actual incidences of rabies in these regions, and the virus remains hidden and endemic with a potential to increase.¹⁸ The US Army did evaluate the use of another test, the direct rapid immunohistochemical test, for field surveillance. While this is an inexpensive test with excellent sensitivity and specificity comparable to DFAT, the need for CDC-certified training, refrigeration, multiple chemicals, and proper microscopic training made this unrealistic as a suitable surveillance test in military environments.

There are many challenges in the implementation of effective rabies diagnosis and surveillance programs in developing countries. Development and international acceptance of a validated test that can be used worldwide are essential to overcome these challenges. Financial and logistical barriers are additional obstacles that prevent use of such a test in developing countries with the greatest need. A rapid immunodiagnostic test (RIDT) for rabies virus has been developed, and this test shows potential in meeting these criteria. This lateral flow test uses gold conjugated detector antibodies, including a monoclonal antibody directed against the lyssavirus nucleoprotein.¹⁸ Although this method has only been used for qualitative analysis, it provides rapid detection of rabies antigen. Advantages over conventional immunoassays include lower cost, inexpensive equipment, simplicity of procedure, rapid operation, and long-term stability over a range of environmental conditions. The test is suited for on-site testing by personnel with limited technical expertise.^{18,19}

The objective of this study was to evaluate the use of the Anigen Rapid Immunodiagnostic Test Kit for detection of rabies virus in clinical samples for application as a surveillance test among animal populations in areas with deployed military units. Clinical samples had previously been submitted to the US Army Public Health Command Region Europe Veterinary Laboratory Europe (VLE), in Landstuhl, Germany, for rabies testing with the DFAT.

MATERIALS AND METHODS

Clinical Samples, Field Isolates, and Diagnosis

A total of 79 clinical samples collected between 2004 and 2011 were examined for rabies using the Anigen RIDT. An additional clinical sample from 1996 was also tested. Total samples numbered 80. As shown in Table 1, all specimens were brain tissue collected from the following animals: canine (n=46), bovine (n=5), feline (n=18), macaque (n=3), porcine (n=1), mongoose (n=1), equine (n=1), jackal (n=1), rat (n=1), and bat (n=3). The majority of samples tested with RIDT originated from Iraq (n=26) or Afghanistan (n=45). Samples also originated from Turkey (n=1), Bosnia (n=1), Germany (n=3), Kuwait (n=3), and Qatar (n=1). Detailed information about the animals was not available. All samples were collected by US military personnel and submitted to VLE. When testing with the RIDT was first initiated in 2010, all specimens were from banked samples stored at VLE and previously tested with DFAT and, in some cases, with rabies murine neuroblastoma cell culture (MN). Thus, at that time, all results were previously known positives or negatives, and the investigators were not blinded to the results. Since that initial batch run of 39 tests, the RIDT was used concurrently on samples at the time of testing with DFA and MN. The sensitivity and specificity of the RIDT were determined using DFAT as the reference method.

Rapid Immunodiagnostic Test Kit

Test Principles

The Anigen Rapid Rabies Antigen Test Kit (Bionote, Inc, Hwaseong, Korea) is an immunochromatographic assay designed for the qualitative detection of rabies virus antigen in canine, bovine, and raccoon dog salivary secretions and brain homogenates. The test uses gold conjugated detector antibodies to detect rabies virus antigen.²⁰

Application of the RIDT

The rapid immunodiagnostic test was performed according to the instructions supplied by the manufacturer.²⁰ In the study, final results were read 5 to 10 minutes after application of the sample as per the guidelines. In 2 cases, final results were read at 30 minutes after application of the sample to the test well. Examples of positive and negative results are shown in the Figure.

RESULTS

Sensitivity and Specificity of the RIDT Kit

Of the 80 samples used in the study, 45 were negative on DFAT, 32 were positive on DFAT, and 3 had an indeterminate result on DFAT. When the RIDT was run on these samples, there were 49 negative results and 31 positive results. Although the intensity of the test lines

was found to vary among the different samples, all tests were clearly readable. Seventy-eight samples reacted within the 10-minute cut-off time for interpreting the test, but 2 samples were negative at 10 minutes and had faint positive results at 30 minutes. The 3 tests that were indeterminate on DFAT were negative on the RIDT.

Thirty-six of the 41 samples tested with both DFAT and RIDT in 2011 had also been tested with rabies murine neuroblastoma cell culture (MN). Of the 36 samples, 31 were negative on all tests, 3 were positive on all tests, and 2 were indeterminate on DFAT and MN but negative on RIDT.

One of the samples that was indeterminate on DFAT and MN but negative on RIDT was from a bat from Afghanistan. The other sample that was indeterminate on DFAT and MN but negative on RIDT was from a canine from Afghanistan. The third sample that was indeterminate on DFAT and negative on RIDT was from a canine from Kuwait. This sample was not subjected to the MN test.

Using DFAT as the reference method for the results of the samples tested, the RIDT kit was 96.9% sensitive and 100% specific. The 3 tests that were indeterminate on DFAT and MN were not used in the calculations.

Results by Species and Geographic Region

Results obtained from using the RIDT were evaluated by species (Table 2) and geographic region (Table 3). Given the concern regarding interactions between military personnel and canines, the results for this species in Afghanistan and Iraq, 2 regions with significant military presence, are further highlighted here.

Canine—Forty-six canine samples were tested. Excluding the samples with indeterminate results, sensitivity and specificity were both 100% for canine samples in the study.

Afghanistan—Excluding the indeterminate results, the RIDT was 100% sensitive and specific for Afghanistan samples.

Table 1. Species and number of brain tissue samples tested with RIDT in this study from 1996 to 2011

Year	Species	Number of Samples Tested
1996	Bovine	1
2004	Canine	1
2005	Canine	2
2005	Porcine	1
2006	Canine	3
2007	Canine	3
2007	Mongoose	1
2008	Canine	5
2008	Bovine	4
2008	Jackal	1
2009	Canine	11
2009	Feline	2
2009	Macaque	2
2009	Equine	1
2010	Canine	1
2011	Canine	20
2011	Feline	16
2011	Rat	1
2011	Bat	3
2011	Monkey	1

NOTE: Bovine – *Bos primigenius*
 Canine – *Canis familiaris*
 Porcine – *Sus domesticus*
 Mongoose – *Herpestidae*
 Jackal – *Canis sp.*
 Feline – *Felis catus*
 Macaque – *Macaca sp.*
 Equine – *Equus ferus*
 Rat – *Rattus sp.*
 Bat – *Chiroptera sp.*

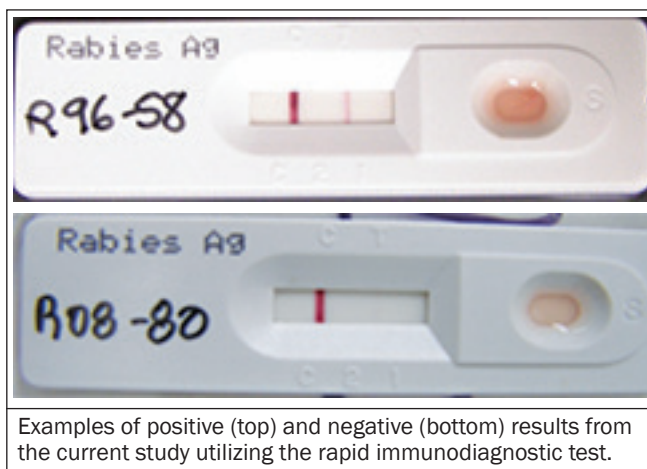
Iraq—Based on interpretation of the delayed test results as positive, the RIDT was 95% sensitive and 100% specific for Iraq samples. Using the 10-minute recommended cutoff time for RIDT interpretation, the sensitivity was 85%.

COMMENT

In the present study, we describe a simple and rapid surveillance test for rabies virus infection based on the principle of immunochromatography. This lateral flow immunoassay system is widely used and accepted for the diagnosis of many human and animal diseases.

Rabies surveillance is lacking for many areas where troops are deployed, and no rigorous epidemiological data exist largely because of the lack of operational rabies diagnostic capabilities. The RIDT is a practical tool for field application to gather surveillance data of rabies-suspect animals, especially in resource poor regions where fluorescent antibody testing is impractical.¹⁸

In this study, the RIDT was highly sensitive (96.9%) and highly specific (100%) compared to the DFAT. The sensitivity and specificity of the RIDT, both 100%, compared to DFAT for the canine samples tested demonstrate the utility of the RIDT as a surveillance tool among canines, the rabies reservoir of significant concern for transmission to military troops. The significance of data in species other than



Examples of positive (top) and negative (bottom) results from the current study utilizing the rapid immunodiagnostic test.

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canines is limited for this study by the small sample sizes. Sensitivity and specificity were also calculated separately for Afghanistan and Iraq, the 2 regions that had enough samples for meaningful interpretation. Afghanistan samples were 100% sensitive and 100% specific with the RIDT. Iraq samples were 95% sensitive and 100% specific with the RIDT. The data are presumably not reflective of the true extent of rabies in the region since samples were collected only by Army personnel in selected locations and not by local veterinarians throughout the regions. In addition, sensitivity and specificity may be affected by the ability of the RIDT to detect regional rabies virus variants.

The RIDT can fulfill the CDC surveillance objectives for “uniformity, simplicity, and brevity.”²¹ It is a straightforward test that is simple and quick to perform. There are no critical points to field use such as cold storage since the test kit is self contained and stable when stored at room temperatures or refrigerated. Kang et al¹⁴ demonstrated that the test is capable of detecting low amounts of virus at an excellent sensitivity level that is slightly less than that of a well-executed FAT. The study by Markotter et al¹⁸ found excellent correlation of results when testing samples with both FAT and the RIDT.

As with any new surveillance or diagnostic tool, strict quality control and test validation are essential before the test can be relied upon for meaningful results. Preliminary validation studies performed by Kang et al¹⁴ showed the RIDT to have significant potential as a rabies diagnostic method. In the present study, the sensitivity of samples from Iraq must be considered in light of the 2 DFAT-confirmed positive tests that were initially negative on the RIDT after 10 minutes, but turned positive after 30 minutes. The delayed positive results could have been a result of the samples having a viral

Table 2. Comparison of the rapid immunodiagnostic test (RIDT) to the direct fluorescent antibody test (DFAT, reference method) and murine neuroblastoma cell culture (MN) by species tested.

Species	Results	Number of Samples		
		RIDT	DFAT	MN
Canine	Positive	23	23	3
	Negative	23	21	14
	Indeterminate	2	1	
Feline	Positive			
	Negative	18	18	15
	Indeterminate			
Bovine	Positive	4	5	
	Negative	1		
	Indeterminate			
Jackal	Positive	1	1	
	Negative			
	Indeterminate			
Macaque	Positive			
	Negative	3	3	1
	Indeterminate			
Bat	Positive			
	Negative	3	2	
	Indeterminate	1	1	
Rat	Positive			
	Negative	1	1	1
	Indeterminate			
Mongoose	Positive	1	1	
	Negative			
	Indeterminate			
Porcine	Positive	1	1	
	Negative			
	Indeterminate			
Equine	Positive	1	1	
	Negative			
	Indeterminate			
Total	Positive	31	32	3
	Negative	49	45	31
	Indeterminate	3	2	

NOTE: Canine – *Canis familiaris*
Feline – *Felis catus*
Bovine – *Bos primigenius*
Jackal – *Canis sp.*
Macaque – *Macaca sp.*
Bat – *Chiroptera sp.*
Rat – *Rattus sp.*
Mongoose – *Herpestidae*
Porcine – *Sus domesticus*
Equine – *Equus ferus*

load close to the limit of detection, thus delaying the result. However, accurate interpretation is not possible outside of the manufacturer’s recommend time frame, 10 minutes for the RIDT. These 2 samples highlight the need for additional test validation.

While further laboratory and field evaluations are needed, these results are promising for the benefit of the RIDT as a surveillance tool in those regions without other immediate capability. Capacity for effective rabies surveillance programs is crucial to determine those geographical areas of operations where soldiers may be at risk for encountering a rabid animal, especially among free-roaming dogs and dog packs, which are a significant burden on military installations.

Even though the RIDT was not evaluated on specimens other than dog, cattle, and raccoon dog in the initial study by Kang et al,¹⁴ the results from the present study suggest that the RIDT may have application as a surveillance tool for multiple species. Further research with greater case numbers in multiple species is necessary to determine if the RIDT is capable of detecting multiple rabies virus variants.

Surveillance is an essential component of infectious disease risk assessment of military members during deployments.^{22,23} As a surveillance tool, the RIDT can help guide the most appropriate and cost effective use of animal control procedures and resources where they are most needed and will be beneficial to long-term rabies control.

Continued on-site surveillance using the RIDT can also serve as a validation of vaccination control efforts. Military use of the RIDT has the potential to lead to country-wide acceptance and approval of this test with implementation among local veterinary organizations. Because it does not require specialized equipment or training, RIDT kits would be an excellent

addition to military veterinary field supplies. This will further allow easy and accessible rabies surveillance capabilities throughout the regions. According to the manufacturer (BioNote, November 6, 2013), a single test costs approximately \$9.60 USD, which is significantly less than the costs associated with establishing a laboratory equipped with fluorescent microscopy.

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Table 3. Comparison of the rapid immunodiagnostic test (RIDT) to the direct fluorescent antibody test (DFAT, reference method) and murine neuroblastoma cell culture (MN) by geographic region.

Region	Results	Number of Samples		
		RIDT	DFAT	MN
Afghanistan	Positive	11	11	3
	Negative	34	32	25
	Indeterminate		2	2
Iraq	Positive	19*	20†	
	Negative	7†	6	2
	Indeterminate			
Bosnia	Positive	1	1	
	Negative			
	Indeterminate			
Turkey	Positive			
	Negative	1	1	
	Indeterminate			
Germany	Positive			
	Negative	3	3	1
	Indeterminate			
Kuwait	Positive			
	Negative	3	2	2
	Indeterminate		1	
Qatar	Positive			
	Negative	1	1	1
	Indeterminate			
Total	Positive	31	32	3
	Negative	49	45	31
	Indeterminate	3	2	

*Includes the 2 samples that did not show a positive result for 30 minutes

†One sample that was positive for DFAT and negative on RIDT was also positive on the DRIT.

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Trends in Rates of Chronic Obstructive Respiratory Conditions Among US Military Personnel, 2001-2013

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ABSTRACT

Background: The US military has been continuously engaged in combat operations since 2001. Assessing trends in respiratory health diagnoses during this time of prolonged military conflict can provide insight into associated changes in the burden of pulmonary conditions in the US military population.

Purpose: To estimate and evaluate trends in rates of chronic obstructive pulmonary diseases in the active duty US military population from 2001 through 2013.

Methods: A retrospective analysis of ambulatory medical encounter diagnosis data corresponding to a study base of over 18 million personnel-years was performed to estimate average rates and evaluate temporal trends in rates of chronic obstructive lung conditions. Differences in rates and the time trends of those rates were evaluated by branch of military service, military occupation, and military rank.

Results: During the 13-year period, we observed 482,670 encounters for chronic obstructive pulmonary disease and allied conditions (ICD-9 490-496) among active duty military personnel. Over half (57%) of the medical encounters in this category were for a diagnosis of bronchitis, not specified as acute or chronic. There was a statistically significant 17.2% average increase in the annual rates of this nonspecific bronchitis diagnosis from 2001-2009 (95% CI: 13.5% to 21.1%), followed by a 23.6% annual decline in the rates from 2009 through 2013 (95% CI: 8.6% to 36.2%). Statistically significant declines were observed in the rates of chronic bronchitis over time (annual percentage decline: 3.1%; 95% CI: 0.5% to 6.6%) and asthma (annual percentage decline: 5.9%; 95% CI: 2.5% to 9.2%). A 1.6% annual increase in the rate of emphysema and a 0.1% increase in the rate of chronic airways obstruction (not elsewhere classified) over the study period were not statistically significant ($P > .05$). The magnitude of the estimated rates of these chronic obstructive lung conditions, and, to a lesser extent, the temporal trends in these rates, were sensitive to the requirement that there be persistence of the diagnosis evidenced in the medical record in order to qualify as an incident case.

Conclusions: We observed decreases in the rates of asthma and chronic bronchitis over the 13-year study period. The increase, and then decrease, over time in rates of bronchitis that has not been specified as acute or chronic drives the overall trends in chronic respiratory disease trends.

Chronic obstructive pulmonary diseases are a group of respiratory conditions characterized by difficulty breathing, airflow limitation, and symptoms that include cough, wheeze, and sputum production. This category of conditions includes bronchitis, not specified as acute or chronic, chronic bronchitis, emphysema, asthma, bronchiectasis, extrinsic allergic alveolitis, and chronic airways obstruction, not elsewhere classified. Asthma is a chronic inflammatory condition of the lungs characterized by intermittent, reversible airway obstruction. The prevalence of asthma is 8.2% in the general adult population of the United States.¹ Emphysema and chronic

bronchitis are often associated with a history of cigarette smoking, and characterized by fixed, irreversible airway obstruction. In 2011, the prevalence of chronic obstructive pulmonary disease (COPD) (emphysema and chronic bronchitis combined) was approximately 6% in the US adult population.² The prevalence of COPD increases with age, rising from 3.2% among those aged 18 to 44 years to more than 11.6% among those 65 years old and older. Together, chronic lower respiratory diseases constituted the third leading cause of death in the United States in 2008, although deaths from chronic lung disease occur primarily after age 65.³

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In 2011, respiratory diseases were responsible for over 250,000 medical encounters among active duty US military personnel, excluding respiratory infections.⁴ Although the burden of respiratory disease among the military is dwarfed by those imposed by injuries, mental disorders, and musculoskeletal diseases, respiratory conditions can be debilitating and sufferers' lives can be severely affected. Trends in respiratory health have implications for force readiness, allocation of military healthcare resources, and Veterans' care.

In October 2001, the US military initiated combat operations in Southwest Asia. More than a decade later, many of the impacts of prolonged military engagement on injuries, mental health, and behavioral disorders among military personnel have been well documented.⁵⁻¹¹ The potential effect of deployment-associated environmental exposures on lung health is also of concern,¹² but associations between military deployment and incidence of chronic obstructive lung conditions are not as well characterized. Some studies have reported associations between pulmonary health status and deployment,¹³⁻¹⁷ while others have not.^{18,19}

Changes in the respiratory health of the US military population over time may result from variation in the demographic profile of the population, trends in accession standards, deployment-associated and other environmental exposures, and trends in smoking behaviors.

The purpose of this surveillance effort was to estimate and evaluate longitudinal trends in rates of chronic respiratory conditions in the active duty US military population from 2001 through 2013, and answer the following questions:

1. What are the rates of these conditions in the military population?
2. Have the rates changed over the past 13 years?
3. Do the rates, and particularly the trends in these rates, vary by branch of military service, job category, or rank?

METHODS

Study Population

The study population consists of active duty personnel serving in the Army, Air Force, Navy, Marine Corps, or Coast Guard, and served by Tricare* at any point during the period January 2001 through December 2013.

*Tricare is the Department of Defense health care program for members of the uniformed services, their families, and their survivors. Information available at <http://www.tricare.mil>.

Ascertainment of Respiratory Diagnoses

Incidence rates (2001-2013) of chronic obstructive pulmonary diseases among US military personnel during the period 2001 through 2003 were estimated using diagnostic records for ambulatory medical encounters maintained in the Defense Medical Surveillance System (DMSS). Records for medical encounters within the military health system and doctor visits in the private sector that were paid for by Tricare are included in DMSS. Annual rates for the conditions of interest were calculated by dividing the total number of cases by the total person-years at risk during the year.

Definition of Respiratory Diagnoses

Trends in annual incidence rates were assessed for each subclassification in the broad International Classification of Diseases, Clinical Modification (ICD-9) category of COPD and allied conditions (ICD-9 codes 490-496). Case status was defined using 3 increasingly specific rules: The primary definition required there to be at least 2 ambulatory medical encounters recorded in DMSS with identical ICD-9 codes within 2 years (730 days). For example, to qualify as an asthma case using this definition, personnel were required to have a minimum of 2 outpatient encounters coded with ICD-9 493 within 730 days. The second, more sensitive case definition required the appearance of only a single ambulatory medical encounter with a given ICD-9 code. The third, more specific case definition required there to be at least 3 ambulatory medical encounters with identical ICD-9 codes within 2 years. In all cases, the date of the first medical encounter with the corresponding qualifying ICD-9 code was defined as the date of incidence for the purpose of person-time calculation. Individuals with a given diagnosis prior to 2001 were excluded from the analysis. Cases identified in a given year were excluded from the person-time and rate calculations for subsequent years.

Statistical Analysis

We analyzed anonymized ambulatory encounter diagnoses data that had been aggregated by year. The data were received for the entire population and stratified by rank (junior enlisted (E1-E3), senior enlisted (E4-E6), junior officer (O1-O3), senior officer (O4-O6)) and branch of military service (Army, Air Force, Navy, Marine Corps, Coast Guard). Trends in rates and natural log-transformed annual rates over time were assessed using linear regression analyses. Assessment of curvilinear relationships between medical encounter rates and year were assessed by including a quadratic term for year (year²) in the models.

Differences in annual rates and the time trends of those rates were evaluated by branch of military service, military job category (combat, healthcare, other), and category of military rank.

To assess whether time trends differed by branch of military service, models were constructed to include main effects for year of diagnosis and indicator variables for each branch of service, as well as interaction terms defined as the product of year of diagnosis and each indicator variable. The Army was used as the reference group for analyses of service-specific trends. Noncombat roles were the reference group for military occupation, and junior enlisted personnel served as the reference group for categories of military rank.

All statistical analyses were conducted using SAS 9.2 (SAS Institute Inc, Cary, NC). The trends over time are presented using the primary case definition. Differences in the estimated average rates for each respiratory diagnosis using the more strict case definitions are also presented.

The Public Health Review Board of the US Army Public Health Command reviewed and approved this evaluation.

RESULTS

Demographic Summary

A summary of demographic and military characteristics of the study population is presented in Table 1. The military population at risk of respiratory health conditions in this study included 3,800,676 individuals and over 18.1 million person-years of observation. The majority of the study population were male (84%) and of white, non-Hispanic race/ethnicity (64%). Army personnel comprised 38% of the study population. Almost half of the population (47%) was aged between 20 and 24 years.

We obtained diagnosis codes for the broad category of COPD and allied conditions (ICD-9 490-496) corresponding to 482,670 ambulatory medical encounters

Table 1. Demographic and military characteristics, active component service members, 2001-2013.*

	n	%
Gender		
Male	3,189,666	83.9
Female	611,010	16.1
Service		
Army	1,454,958	38.3
Navy	890,350	23.4
Air Force	784,278	20.6
Marine Corps	587,395	15.5
Coast Guard	83,695	2.2
Rank		
Junior Enlisted (E1-E3)	2,506,273	65.9
Senior Enlisted (E4-E6)	873,722	23.0
Junior Officer (O1-O3)	329,815	8.7
Senior Officer (O4-O6)	90,866	2.4
Military occupation		
Combat	818,644	21.5
Healthcare	277,607	7.3
Other	2,704,425	71.2
Age group (years)		
<20	475,754	12.5
20-24	1,801,244	47.4
25-29	793,778	20.9
30-34	451,184	11.9
35-39	191,551	5.0
40-44	64,255	1.7
45-49	17,327	0.5
50-54	3,971	0.1
≥55	168	0.0
Race, ethnicity		
White, nonhispanic	2,419,033	63.6
Black, nonhispanic	610,109	16.1
Other/unknown	771,534	20.3

*This is a dynamic population. To characterize time-varying characteristics (age and occupation), we identified all individuals in service for at least one day during the surveillance period (the population at risk), then identified the demographic record closest to the midpoint of their period of service and used that record to identify age and military occupation.

Data Source: Defense Medical Surveillance System.

occurring during the 13-year time period from January, 2001 through September, 2013. Of these, more than half (57%) were encounters for bronchitis, not specified as acute or chronic (ICD-9 490) and more than a third (37%) were for asthma (ICD-9 493) (Table 2). Requiring 2 ambulatory visits with the same diagnosis within 2 years to qualify as an incident case results in a total of 156,516 personnel with a chronic obstructive lung condition. Requiring 3 ambulatory visits with the same diagnosis within 2 years further reduces the total number to 81,843 incident cases. Seventy-eight percent of the cases for this last, most restrictive case definition were for asthma, and almost 18% were for bronchitis, not specified as acute or chronic.

Rates of Bronchitis, Not Specified as Acute or Chronic (ICD-9 490)

Over the 13-year study, 276,878 ambulatory medical encounters for “bronchitis, not specified as acute or chronic” (ICD-9 490) occurred among active duty US military personnel, yielding an average rate for this nonspecific diagnosis of 27.7 cases per 10,000 person-years (95% CI: 21.4-35.9) over the study period using the primary case definition requiring at least 2 visits in 2 years (Table 3). Relaxing the requirement for there to be at least 2 ambulatory encounters coded with ICD-9 490 within 2 years results in a dramatic increase in the estimated average rate (144.3 cases per 10,000 person-years; 95% CI: 122.9-169.5). Requiring at least 3 encounters within 2 years to define case status resulted in a correspondingly dramatic lowering of the estimated rate of bronchitis not specified as acute or chronic to 7.0 cases per 10,000 person-years (95% CI: 5.1-9.5).

Branch of military service was a statistically significant predictor of the rate of bronchitis not specified as acute or chronic, independent of the year of diagnosis. Army personnel had significantly higher rates relative to all other branches of military service except for Marine Corps personnel, although the differences were

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only statistically significant in comparison to Navy ($P=.0017$) and Air Force ($P=.0425$) personnel. Marines had a higher average rate of bronchitis, not specified as acute or chronic, relative to Army personnel ($P=.0425$). Rates were lower among those with military occupation classified as combat, relative to those in noncombat occupations ($P<.0001$). Rates of bronchitis, not specified as acute or chronic, were also lowest among junior enlisted personnel relative to senior enlisted personnel and officers ($P<.0001$).

The temporal trend in rates for this nonspecific bronchitis diagnosis followed a \cap -shaped curve ($P_{\text{quadratic year term}}=.0003$) (Table 4). Rates increased by an average of 17 cases per 10,000 person-years per year from 2001-2009 ($P<.0001$), then decreased by almost 24 cases per 10,000 person-years per year from 2009-2013 ($P=.0175$) (Figure 1). By 2013, the rate (15 cases per 10,000 person-years) returned to levels similar to those observed in 2001 (17 cases per 10,000 person-years). Notably, both the increase prior to 2010 and the subsequent decrease in the rates of this diagnosis were much more pronounced for Marines than personnel in any other branch of military service.

Although the magnitudes of the rates differed, the \cap -shaped pattern of the trend in rates were consistent, albeit more pronounced when using the more sensitive case definition ($P_{\text{quadratic year term}}=.0002$), and almost identical when using the more specific definition requiring 3 or more ambulatory encounters within 2 years ($P_{\text{quadratic year term}}=.0020$) with diagnoses of bronchitis, not specified as acute or chronic.

Significant statistical interactions were not observed between year and branch of service ($P_{\text{interactions}}\geq .0697$),

military occupation ($P_{\text{interactions}}\geq .8055$), or military rank ($P_{\text{interactions}}\geq .3072$).

Rates of COPD: Chronic Bronchitis, Emphysema, and Chronic Airways Obstruction, Not Elsewhere Classified

Over the 13-year study period, we observed 13,195 ambulatory medical encounters for chronic bronchitis (ICD-9 491), 2,467 encounters for emphysema (ICD-9 492), and 11,020 encounters for chronic airways obstruction, not elsewhere classified (ICD-9 496). The average of the annual rates for these outcomes were very low, ranging from less than one case per 10,000 person-years (emphysema) to less than 2 cases per 10,000 person-years (chronic bronchitis and CAO) when estimated using the primary case definition (Table 3). Requiring at least 2 encounters within 2 years lowered the rates of these 3 conditions to less than 1 case per 10,000 person-years.

Rates for chronic bronchitis varied by branch of service, with Coast Guard personnel having an average rate that was significantly higher than all other service branches by between 1 and 2 cases per 10,000 person-years ($P<.0001$). Rates of emphysema were highest, on average, among Army personnel. Both Air Force and Marine Corps personnel had emphysema rates that were significantly lower than those in the Army ($P<.0255$). The average rates of CAO were highest among Army personnel and Air Force personnel, and significantly lower among Marine Corps ($P<.0001$), Navy ($P=.0021$), and Coast Guard ($P<.0477$) personnel, relative to Army personnel.

Personnel in combat occupations had lower rates of chronic bronchitis ($P<.0051$), emphysema ($P=.1147$), and CAO ($P<.0002$) relative to those in other military occupation categories. Senior personnel had higher rates of chronic bronchitis ($P<.0001$), emphysema ($P\leq .0788$), and CAO ($P<.0001$), relative to junior personnel.

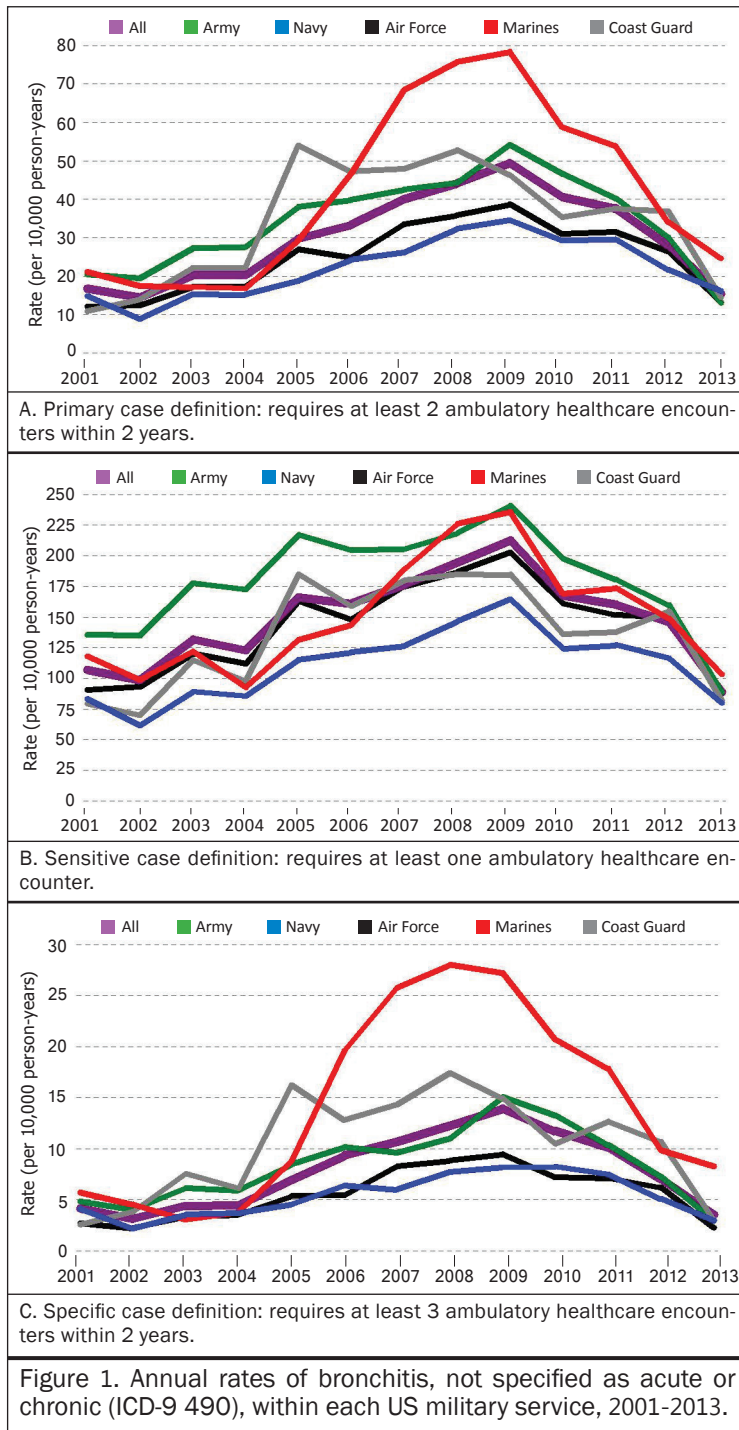
Overall, there was a statistically significant downward trend in the rate of chronic bronchitis ($P_{\text{trend}}<.0264$) over the 13-year period, a small increase over time in emphysema rates that was borderline statistically significant ($P_{\text{trend}}=.0785$), and almost no change in the rates of CAO ($P_{\text{trend}}=.9547$) over the study period (Table 4). For each of these outcomes, the average annual change was less than one case per 10,000 person-years. Although rates

Table 2. Number and percentage of cases of selected chronic respiratory conditions in the US military from 2001-2013, by ICD-9-coded condition.

Respiratory Condition	ICD-9 Code	Primary Case Definition*		Sensitive Case Definition*		Specific Case Definition*	
		n	%	n	%	n	%
Bronchitis, not specified as acute or chronic	490	55,853	35.5	276,878	57.4	14,575	17.8
Chronic bronchitis	491	2,085	1.3	13,195	2.7	761	0.9
Emphysema	492	826	0.5	2,467	0.5	427	0.5
Asthma	493	94,858	60.2	177,234	36.7	64,026	78.2
Bronchiectasis	494	488	0.3	1,196	0.2	316	0.4
Extrinsic allergic alveolitis	495	104	0.1	680	0.1	55	0.1
Chronic airways obstruction, not elsewhere classified	496	3,302	2.1	11,020	2.3	1,683	2.1

*The primary case definition required at least 2 ambulatory medical encounters recorded in DMSS with identical ICD-9 codes within 2 years (730 days). The more sensitive case definition required only a single ambulatory medical encounter with a given ICD-9 code. The more specific case definition required at least 3 ambulatory medical encounters recorded in the DMSS with identical ICD-9 codes within 2 years.

Data Source: Defense Medical Surveillance System .



were lower, the decreasing trend in rates of chronic bronchitis over time was similar when using the case definition requiring at least 3 encounters for chronic bronchitis within 2 years ($P_{\text{trend}}=.0241$). No linear trend over time was observed using the case definition requiring at least 3 encounters for chronic bronchitis in a 2-year period ($P_{\text{trend}}=.434$) (Figure 2). Increasing linear trends in emphysema rates over time were observed using the second case definition ($P_{\text{trend}}=.0555$) and third case definitions

($P_{\text{trend}}=.0385$) (Figure 3). Using the more specific case definitions of CAO resulted in a reversal in the downward trend observed for the primary case definition, although the linear trends were not statistically significant ($P \geq .3494$) (Figure 5).

Statistically significant interactions between year of diagnosis and branch of service were not observed for chronic bronchitis rates ($P_{\text{interactions}} \geq .06$) but were observed by rank, with the downward trend in rates being attenuated for senior enlisted personnel ($P_{\text{interactions}}=.0260$) and junior officers ($P_{\text{interactions}}=.0028$), relative to junior enlisted personnel. Statistical interactions were observed between year and branch of service for emphysema and CAO rates, specifically for Navy ($P_{\text{interactions}} \leq .0021$) and Air Force ($P_{\text{interactions}} \leq .0323$) personnel.

A statistically significant interaction between year of diagnosis and military occupation was observed for CAO, with the slope of the downward trend in the rate over time attenuated among personnel in combat occupations, relative to those with noncombat military occupations ($P_{\text{interactions}}=.0302$). A similar interaction was not observed between military rank and both CAO rates over time ($P_{\text{interactions}} > .2012$) and rates of emphysema over time ($P_{\text{interactions}} > .3627$).

Rates of Asthma

We observed 177,234 ambulatory medical encounters for asthma (ICD-9 493) over the 13-year period, yielding an average annual rate of 49.1 cases per 10,000 person-years (95% CI: 40.5-59.4) using the primary definition (Table 3). Requiring only one ambulatory encounter to qualify as an asthma case resulted in a considerably higher rate (91.9 cases per 10,000 person-years (95% CI: 76.9-109.9)), while requiring at least 3 encounters within 2 years decreased the rate to 32.8 cases per 10,000 person-years (95% CI: 26.2-41.0). Among the conditions assessed, asthma diagnoses were the most persistent (Table 2).

Independent of the year of diagnosis, rates of asthma varied by branch of service. Asthma rates were highest among Army personnel and at least 28 cases per 10,000 person-years lower in all other branches ($P < .0001$). Asthma rates were 27.1 cases per 10,000 person-years higher, on average, among those with noncombat military occupations, compared to those with combat occupations ($P < .0001$). Asthma rates were highest among junior enlisted personnel, and significantly lower among

TRENDS IN RATES OF CHRONIC OBSTRUCTIVE CONDITIONS AMONG US MILITARY PERSONNEL, 2001-2013

Table 3. Average rates with 95% confidence intervals of chronic respiratory conditions in the U.S. military for the 2001-2013 study period.*

Chronic Respiratory Condition†	Average Rate per 10,000 Person-years	95% Confidence Interval Lower Limit Upper Limit
Bronchitis, not specified as acute or chronic (ICD-9 490)		
Primary case definition	27.73	21.43 - 35.88
Sensitive case definition	144.30	122.89 - 169.45
Specific case definition	7.00	5.1 - 9.5
Chronic bronchitis (ICD-9 491)		
Primary case definition	1.10	0.95 - 1.26
Sensitive case definition	6.45	4.82 - 8.63
Specific case definition	0.40	0.34 - 0.47
Emphysema (ICD-9 492)		
Primary case definition	0.43	0.37 - 0.50
Sensitive case definition	1.31	1.20 - 1.44
Specific case definition	0.21	0.17 - 0.27
Asthma (ICD-9 493)		
Primary case definition	49.05	40.49 - 59.42
Sensitive case definition	91.89	76.86 - 109.86
Specific case definition	32.78	26.18 - 41.03
Bronchiectasis (ICD-9 494)		
Primary case definition	0.24	0.18 - 0.32
Sensitive case definition	0.63	0.56 - 0.71
Specific case definition	0.15	0.10 - 0.21
Extrinsic allergic alveolitis (ICD-9 495)		
Primary case definition	0.05	0.05 - 0.06
Sensitive case definition	0.31	0.22 - 0.45
Specific case definition	0.03	0.02 - 0.04
Chronic airways obstruction, not elsewhere classified (ICD-9 496)		
Primary case definition	1.73	1.47 - 2.02
Sensitive case definition	5.81	5.10 - 6.62
Specific case definition	0.86	0.70 - 1.06

*Averages were calculated by exponentiating the average of natural log-transformed annual encounter rates.

†The primary case definition required at least 2 ambulatory medical encounters recorded in DMSS with identical ICD-9 codes within 2 years (730 days). The more sensitive case definition required only a single ambulatory medical encounter with a given ICD-9 code. The more specific case definition required at least 3 ambulatory medical encounters recorded in the DMSS with identical ICD-9 codes within 2 years.

Data Source: Defense Medical Surveillance System.

definitions, similar statistically significant downward trends in asthma rates over time were observed when using case definitions requiring only one asthma-coded encounter ($P_{\text{trend}} < .0001$) and at least 3 encounters ($P_{\text{trend}} = .0106$) with asthma (Figure 4).

Rates of Bronchiectasis and Extrinsic Allergic Alveolitis

We observed 1,196 ambulatory medical encounters for bronchiectasis (ICD-9 494) and 680 for extrinsic allergic alveolitis (ICD-9 495) over the 13-year period (Table 2). Requiring at least 2 encounters within 2 years for our primary case definition resulted in estimated incidence rates that were less than 3 cases per 100,000 person-years. Although we analyzed the trends in rates of these conditions, we present only minimal results, because the rates for these conditions were so low. There was no statistically significant evidence that time trends in the rates of either bronchiectasis or extrinsic allergic alveolitis varied over time ($P_{\text{trend}} > .2066$), nor that trends were modified by branch of military service ($P_{\text{interactions}} \geq .3408$), military occupation ($P_{\text{interactions}} \geq .0827$), or military rank ($P_{\text{interactions}} \geq .1386$).

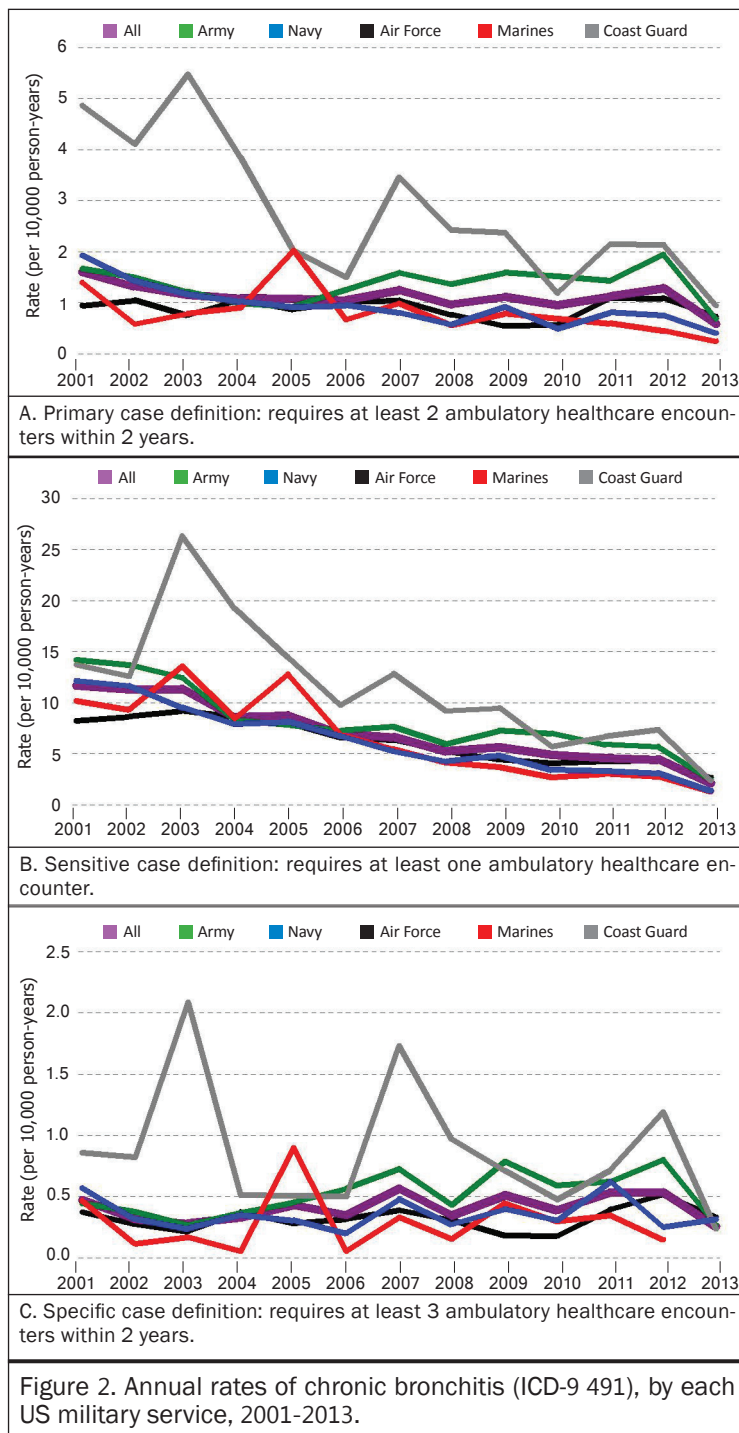
COMMENT

The purpose of this study was to estimate and evaluate longitudinal trends in rates of chronic respiratory conditions in the active duty US military population from 2001 through 2013. We observed downward trends in the rates of chronic bronchitis and asthma over the study period, almost no change in the annual rates of chronic airways obstruction, and a nonstatistically significant increase in the rates of emphysema. Our findings are not consistent with a hypothesis that there have been persistent increases in the rates of respiratory illnesses in the US armed forces over the past decade.²⁰

senior enlisted ($P < .0001$), junior officer ($P < .0001$), and senior officer ($P < .0001$) personnel.

Overall, there was a statistically significant linear trend over time in the rate of asthma, with the rate decreasing annually by an average of 6.3 cases per 10,000 person-years ($P_{\text{trend}} = .0019$) (Table 4). The slope of the time trend in asthma rates varied by branch of military service ($P_{\text{interactions}} < .0001$). Time trends in asthma rates between 2001 and 2013 did not differ significantly by military rank ($P_{\text{interactions}} \geq .4931$) or category of military occupation ($P_{\text{interactions}} \geq .3150$). Although the magnitude of asthma rates differed when using alternative case

The majority of ambulatory encounters in the large group of chronic obstructive respiratory conditions were given a diagnosis of bronchitis, not specified as acute or chronic (ICD-9 490). Across the entire time period, the average rate of this nonspecific bronchitis diagnosis was more than double that for any of the other diagnoses assessed in this investigation. Rates for bronchitis, not specified as acute or chronic, increased from 2001 to 2009, and then decreased from 2009 through the end of the study period in 2013. Although we have



not identified a definitive explanation for the increase in these rates between 2001 and 2009, nor for the subsequent decrease in the rates, this diagnostic category likely includes a large proportion of patients who have acute bronchitis or a similar condition. Requiring evidence of persistence of the diagnosis in the medical record by stipulating that cases have at least 2 ambulatory encounters within 2 years, for example, resulted in a

dramatic drop in the estimated rate of this diagnosis, more so than for any other of the conditions we assessed. Similar \cap -shaped patterns were observed among all military branches and across all categories of military rank and occupation. The slope of the trends in the conditions over time frequently varied by the service branch of the US armed forces, although not in a manner that was consistent across diagnoses.

In a study with up to 4 years of postdeployment follow-up, Abraham et al observed a 25% increase in the rate of medical encounters for respiratory symptoms (RR=1.25; 95% CI: 1.20-1.30) and a greater than 50% increase in the rate of asthma (RR=1.54; 95% CI: 1.33-1.78) among personnel formerly deployed in support of Operation Iraqi Freedom (OIF), relative to a nondeployed reference group of personnel stationed in the United States.¹³ This same study found elevated rates of medical encounters for COPD and allied conditions, although the increased rates were generally not statistically significant.

Szema et al reported an elevated risk of asthma (OR=1.88; 95% CI: 1.38-2.56) among patients who had visited OIF/Operation Enduring Freedom (OEF) clinics at a Veterans Administration Medical Center (VAMC) in Long Island, NY, relative to patients at the same VAMC who had not visited the OIF/OEF clinics.¹⁴ Szema et al also reported a statistically significant increase in the proportion of patients with respiratory symptoms and a greater proportion with referrals for spirometry (OR=1.88; 95% CI: 1.38-2.56) among Veterans attending the OIF/OEF clinics, relative to a reference group of Veterans who were patients at the VAMC, but who did not visit the OIF/OEF clinics.¹⁵ Among those referred for spirometry in this later study, both groups had similar forced expired volume in one second/forced vital capacity (FEV₁/FVC) ratios.

Smith et al found deployment to be associated with newly reported respiratory symptoms among military personnel and Veterans participating in the Millennium Cohort Study.¹⁹ This association was modified by branch of military service, being lowest among Navy/Coast Guard personnel (OR=1.06; 95% CI: 0.86-1.32), and highest among Army personnel (OR=1.73; 95% CI: 1.57-1.91). Chronic bronchitis or emphysema and asthma rates were not significantly elevated among those who had deployed relative to those who had never deployed. Although not explicitly stated by the authors,

TRENDS IN RATES OF CHRONIC OBSTRUCTIVE CONDITIONS AMONG US MILITARY PERSONNEL, 2001-2013

Table 4. Trends in rates of encounters with chronic obstructive pulmonary diseases and allied conditions (ICD-9 490-496) in the US military, 2001-2013, by diagnosis.*

Chronic Obstructive Pulmonary Disease or Allied Condition	ICD-9 Code	Percentage Increase in Trend [†]	95% Confidence Interval		P value
			Lower Limit	Upper Limit	
Bronchitis, not specified as acute or chronic [‡]	490	-2.54%	-3.56	-1.51	0.0003
Chronic bronchitis	491	-3.61%	-6.60	-0.52	0.0264
Emphysema	492	3.47%	-0.46	7.55	0.0785
Asthma	493	-5.91%	-9.23	-2.47	0.0033
Bronchiectasis	494	4.69%	-2.89	12.85	0.2066
Extrinsic allergic alveolitis	495	2.35%	-2.40	7.33	0.3057
Chronic airways obstruction, not elsewhere classified	496	0.12%	-4.24	4.67	0.9547

* Rates were estimated using a case definition that required evidence of persistence of the diagnosis in the medical record, i.e., at least 2 encounters with the same diagnosis code within 2 years.

[†] The percent increase in the linear slope is derived from the slope estimate from a regression model of year as a continuous independent predictor of natural log-transformed rates.

[‡] A statistically significant curvilinear trend was observed for the bronchitis, not specified as acute or chronic outcome. As such, we present only the percent change in the quadratic, derived from the quadratic term from a regression model of year² as a continuous independent predictor of natural log-transformed rates in a model that also contains the main effect of year as a continuous independent predictor.

Data Source: Defense Medical Surveillance System.

the maximum follow-up time for the Millennium Cohort analysis was approximately 4 years (OEF began in the Fall of 2001, and the study used data from questionnaires returned between June 2004 and February 2006).

Using outpatient medical encounter diagnosis data to estimate rates of chronic obstructive lung conditions allowed for efficient and large-scale assessment of trends over a long period of time. There is a time-lag between true incidence of a condition and clinical diagnosis for that condition that is not accounted for in this investigation. However, on average, it is unlikely that the magnitude of this lag changed over the study period.

False-positive and false-negative misclassification of health outcomes is also likely to have occurred. To address this limitation, we used 2 additional case definitions: a more sensitive definition that did not require evidence of persistence of the diagnosis and a more specific case definition that required cases to have at least 3 ambulatory encounters with the same ICD-9 coded diagnosis within 2 years.

Using case definitions requiring evidence of persistence of the diagnosis over time resulted in much lower estimated rates for the conditions we assessed. This is consistent with a hypothesis that many ambulatory encounters are assigned specific diagnostic codes corresponding to chronic obstructive respiratory conditions but do not meet diagnostic criteria for those conditions.²¹ These transient findings may reflect working diagnoses

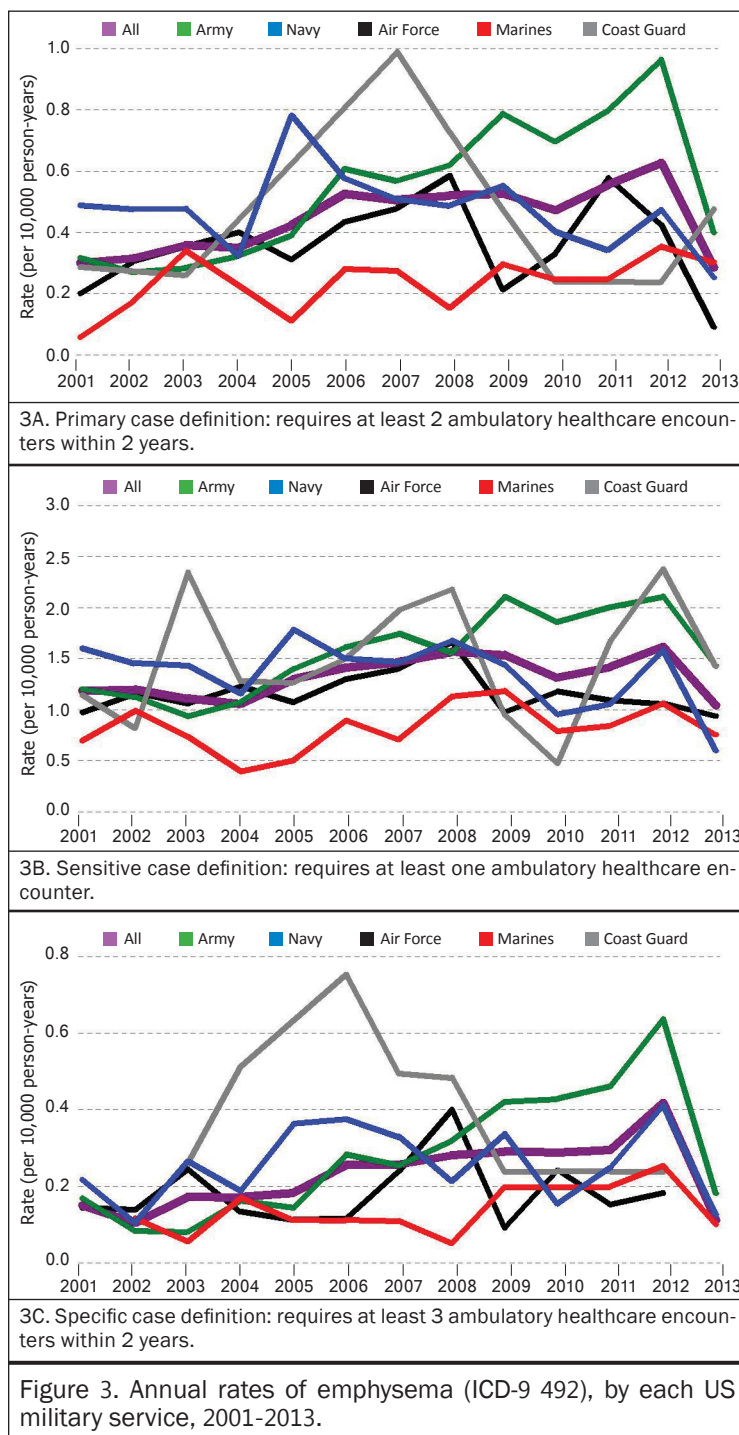
which change over time, imprecise coding, or misdiagnoses. Although the rates were lower, the overall temporal pattern observed in the rates of unspecified bronchitis, chronic bronchitis, and asthma were similar when using less sensitive, but more specific, case definitions. However, we did note qualitative differences in temporal trends for emphysema and CAO. The rising temporal trend in emphysema became borderline statistically significant when requiring at least 2 encounters within a 2 year period, and was statistically significant when requiring at least 3 encounters within 2 years. The downward temporal trend observed using our primary case definition of CAO reversed direction when using the more specific case definitions, although the rising temporal trends we observed were not statistically significant.

Regardless of the specificity of the case definition, false-positive cases would have resulted from ambulatory care encounters that are assigned an incorrect or inappropriate ICD-9 code. Additionally, an unknown number of incident chronic obstructive lung conditions likely remain undiagnosed and therefore not enumerated in our study (false-negatives). If the degree of misclassification remained constant over the study period, the estimated rates would be biased, but the trends in rates would remain unbiased. Changes in the frequency of outcome misclassification over time, due to changes in coding practices, for example, would result in biased time trends as well.

Potential explanations for the observed relationships between time and health condition rates include confounding by time-varying predictors of obstructive pulmonary condition diagnoses, such as an external factor that changes from year to year, similar to rates of flu. Subsequent work will attempt to parse out these possible co-relationships so that trends independent of these confounders can be evaluated.

Rates of chronic obstructive conditions during this time period were generally low, and similar to, or lower than, corresponding rates in the general population.²

Branch of military service, military rank, and job category were associated with rates of chronic obstructive pulmonary conditions defined using ambulatory medical encounter data. A decreasing temporal trend in asthma rates was consistently observed. Trends in bronchitis



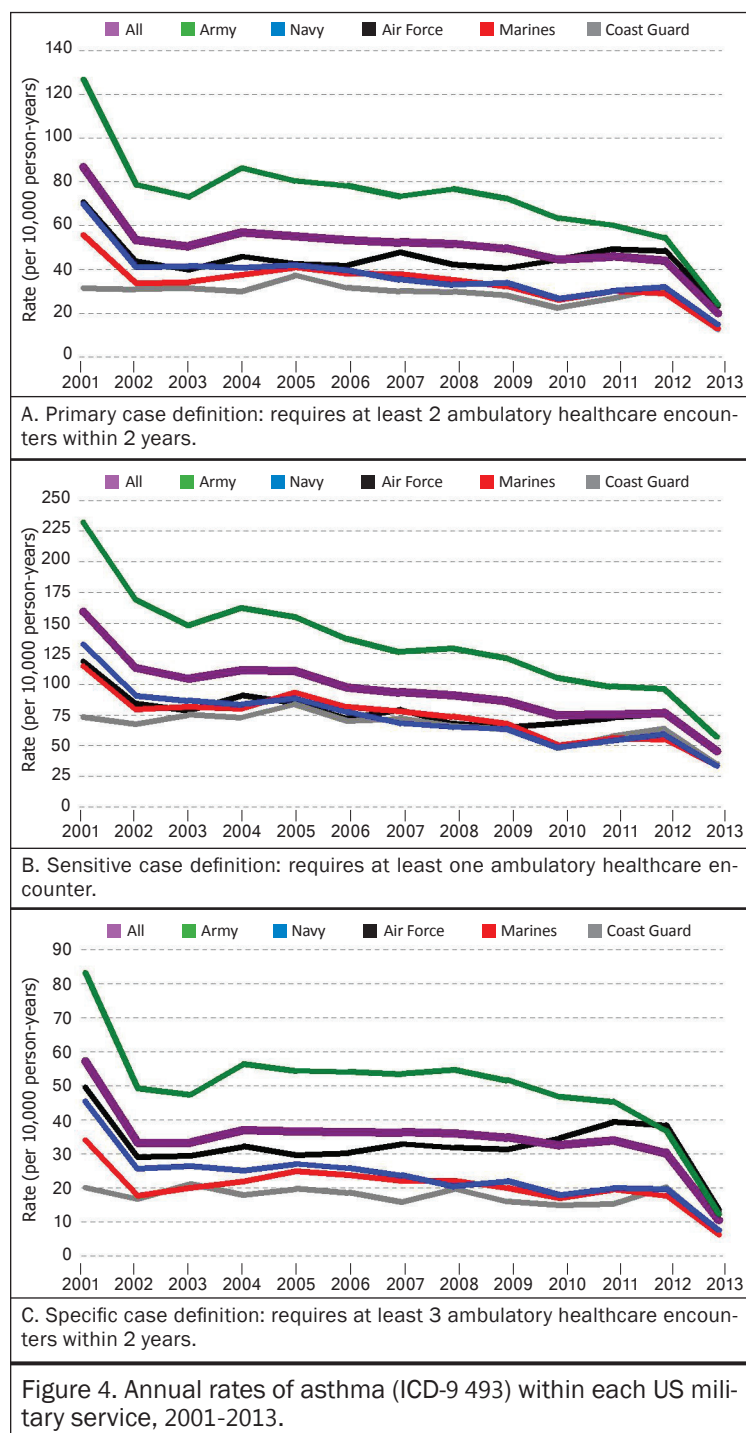
rates, too, generally decreased over time, with the notable exception of the those for bronchitis, not specified as acute or chronic, which increased significantly between 2001 and 2009. This assessment did not discriminate between military personnel with and without a history of deployment to Southwest Asia. Future work should focus on assessing rates of these conditions among

personnel with prior history of deployment in support of OEF, OIF, and Operation New Dawn.

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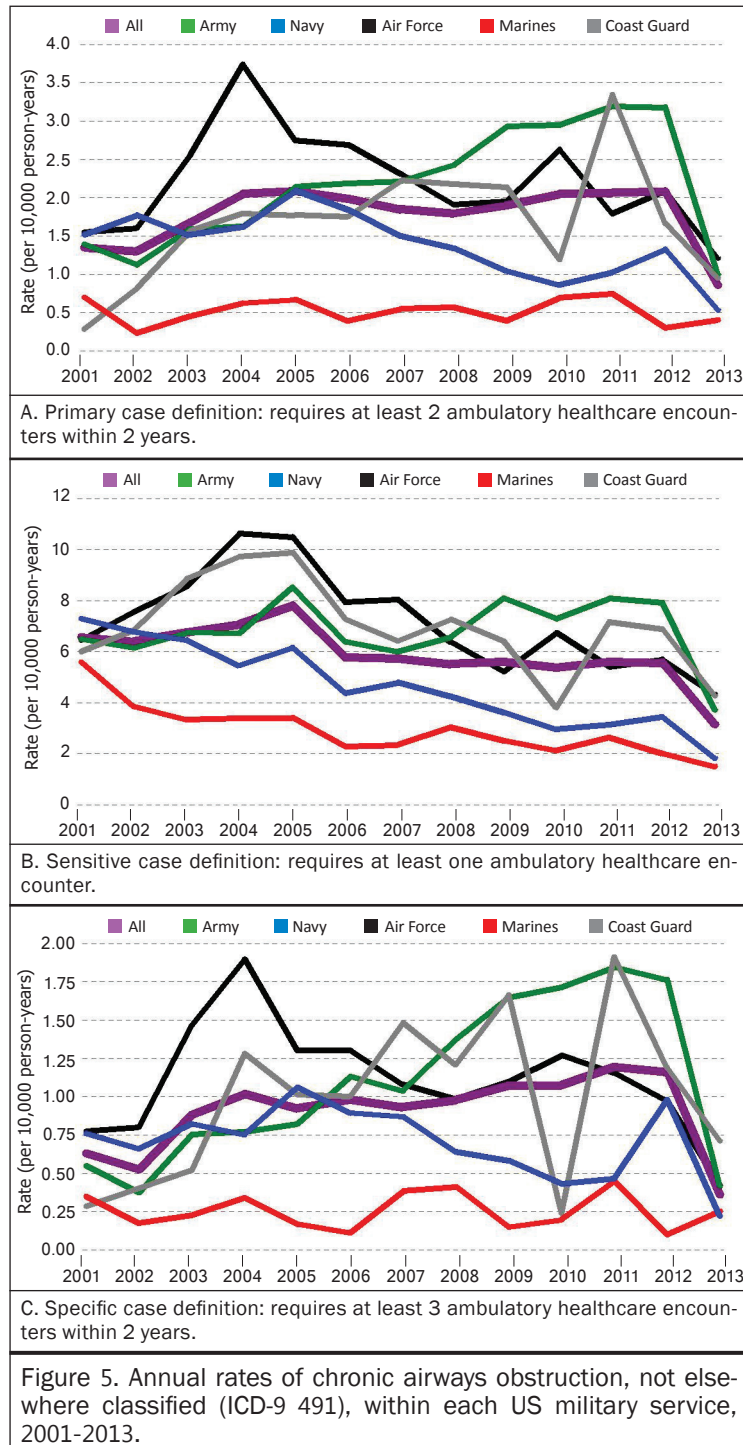
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Department of Defense Participation in the Department of Veterans Affairs Airborne Hazards and Open Burn Pit Registry: Process, Guidance to Providers, and Communication

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BACKGROUND

Concerns related to potential service-related exposures arose following the first Gulf War (1991). Similarly, exposures occurring in theater while supporting Operations Enduring Freedom (OEF), Iraqi Freedom (OIF), and New Dawn have also caused concern among service members.¹ During deployment, personnel may have been exposed to environmental hazards that could affect their respiratory health, such as ambient particulate matter (PM) indigenous to the desert environment, local industry-related pollutants, exhaust from the engines of vehicles, machinery, and generators used by both military and civilians, and smoke emitted as a result of oil-well fires and during the combustion of waste burned in open air burn pits.²⁻⁵ With more than 2.3 million US military personnel deployed to Southwest Asia since 2001,^{6,7} concern over myriad possible exposures can be far-reaching.

Burn pits were widely used as a method of solid waste disposal prior to 2010 at many OEF and OIF locations. A burn pit is defined by the US Department of Defense (DoD) as:

An area, not containing a commercially manufactured incinerator or other equipment specifically designed and manufactured for burning of solid waste, designated for the purpose of disposing of solid waste by burning in the outdoor air at a location with more than 100 attached or assigned personnel and that is in place longer than 90 days.⁸

Burn pit emissions, which may include PM, volatile organic compounds, and polycyclic aromatic hydrocarbons, likely vary due to heterogeneity in the trash stream and use of accelerants.⁹ Personnel activity patterns, distance from the burn pit site, and meteorological conditions additionally influence burn pit emissions exposures.

Although no studies have identified as yet an association between burn pit emissions exposure and postdeployment chronic lung conditions, exposures to burn pit emissions have been implicated as a cause of chronic respiratory illnesses.^{10,11} Current and future research efforts will continue to investigate potential associations between chronic health effects of deployment-related airborne hazards and burn pit exposures. Notably, a 2011 Institute of Medicine report, *Long-Term Health Consequences of Exposure to Burn Pits in Iraq and Afghanistan*, found that:

...service in Iraq or Afghanistan—that is, a broader consideration of air pollution than exposure only to burn pit emissions—might be associated with long-term health effects, particularly in highly exposed or susceptible populations, mainly because of the high ambient concentrations of PM from both natural and anthropogenic, including military, sources.¹²

Subsequently, as part of the Dignified Burial and Other Veterans Benefits Improvement Act of 2012,¹³ Congress mandated that the Department of Veterans Affairs (VA) establish an “Open Burn Pit Registry.” The VA later expanded the scope of the registry, renaming it the “Airborne Hazards and Open Burn Pit Registry,” to capture information regarding all potential exposures experienced by our service members during deployment that may have possible impacts on future respiratory health. The Airborne Hazards and Open Burn Pit Registry will collect data concerning potential exposures related to emissions from both burn pits and other sources as mentioned above. As such, any veteran or service member with a history of deployment to any Southwest Asia contingency operation on or after August 2, 1990, (as defined in 38 CFR §3.317)¹⁴ or in Afghanistan or Djibouti on or after September 11, 2001, is eligible to participate.

These regions include the following countries and bodies of water, and the airspace above these locations:

Iraq	Djibouti
Afghanistan	Oman
Kuwait	Qatar
Saudi Arabia	United Arab Emirates
Bahrain	
Gulfs of Aden and Oman	
Waters of the Persian Gulf, Arabian Sea, Red Sea	

The VA will use deployment data provided by the DoD to validate eligibility status.

With the creation of the Airborne Hazards and Open Burn Pit Registry, both service members and veterans are now able to voluntarily document their exposure experiences and health concerns collected by way of a web-based, self-reported questionnaire. The questionnaire requests information on various topics such as deployment history and exposures, military occupational exposures, environmental exposures, air pollution, places lived, work history, home environment and hobbies, medical history, health concerns, and healthcare utilization. As such, the data collected from the registry questionnaire may be the most comprehensive exposure profile available for most service members and veterans. Potential health effects of interest include, among others, breathing problems which may or may not have resolved following deployment, although the questionnaire also addresses other conditions. Veterans and service members who had more exposure or underlying medical conditions may be more likely to experience or develop reduced lung function or cardiopulmonary disease, which can also be captured on questionnaire response.

Individual level benefits of participation in the registry include creating a snapshot from which to identify future changes in health status for service members and veterans. The completed questionnaire can also be used to more easily discuss any concerns with a healthcare provider. The registry will allow DoD and VA public health officials to monitor health concerns and conditions affecting eligible veterans and service members who participate. From a population-level perspective, data from the registry will also be used to generate hypotheses for future efforts regarding the health status of all service members and veterans who have deployed to the above mentioned locations. The data will also be used to improve public health programs and initiatives geared towards assisting veterans and service members with deployment exposure concerns.

Under the leadership of the Director, VA Office of Public Health Post 9/11 Era Environmental Health Program, public health professionals from various disciplines within the US Army Public Health Command (US-APHC), along with stakeholders from the Air Force, Navy, and Marine Corps as well as subject matter experts in web development, collaborated and assisted in the creation of the registry. Senior leadership at the Office of the Assistant Secretary of Defense for Health Affairs has also supported efforts related to the overall development of Airborne Hazards and Open Burn Pit Registry. Currently, the registry is slated to launch in 2014.

VETERANS

Any veteran meeting the previously discussed eligibility criteria is welcome to participate in the Airborne Hazards and Open Burn Pit Registry. Although the registry does not require medical evaluation for participation purposes, veteran registry participants will have the opportunity to request a no-cost medical assessment for deployment-related health concerns. If requested, medical follow-up will be provided to authorized veterans through the VA healthcare system. Subsequently, VA healthcare providers will be able to access registry questionnaire responses electronically through the specially-developed “VA Provider Portal” data system which is accessible by VA physicians during medical evaluations. However, it is important to note that the registry is not intended to be used for disability and compensation purposes for veterans, and participation does not affect access to healthcare or benefits. Any combat veteran not yet enrolled in VA healthcare can receive free medical care for any condition possibly related to service for 5 years after discharge. Application for VA health benefits may be submitted online at <https://www.1010ez.med.va.gov/sec/vha/1010ez/>.

ACTIVE DUTY, RESERVE, AND NATIONAL GUARD PERSONNEL

Active duty military personnel, including activated and inactive National Guard, Reserve, and US Coast Guard, who meet the eligibility criteria are also eligible to participate and register. Participation in the registry is entirely voluntary. To ensure the DoD efforts are congruent with those of the VA, upon request, DoD will provide medical assessments to active duty service members. The VA will provide, upon request, medical assessments to members of the National Guard and Reserve forces who are not presently on active duty. The extent of the assessments should be dictated by an individual’s medical and occupational health history, and the healthcare provider’s clinical assessment and concerns.

DEPARTMENT OF DEFENSE PARTICIPATION IN THE DEPARTMENT OF VETERANS AFFAIRS AIRBORNE HAZARDS AND OPEN BURN PIT REGISTRY: PROCESS, GUIDANCE TO PROVIDERS, AND COMMUNICATION

The USAPHC is the lead activity pursuant to a November 6, 2013, tasking by the Assistant Secretary of Defense for Health Affairs to develop a DoD medical follow-up program consistent with the VA's approach. A schematic guidance of the medical follow-up process and a summary of the VA's registry and its purpose have been developed and are intended for use by healthcare providers who will manage patients with deployment-related concerns. The USAPHC and the VA have jointly developed a "DoD Fact Sheet" for service members, with a brief summary of the registry and instructions about where to receive the voluntary medical assessment, which can be printed from the registry web site, along with the general joint VA/DoD "participation letter."

REGISTRATION PROCESS AND SPECIFICS

When an active duty service member logs in to the registry website, then registers and completes the questionnaire, the website will generate the joint VA/DoD individualized participation letter and the DoD Fact Sheet. The DoD Fact Sheet instructs the participant that he or she should immediately go to the nearest emergency room, call 911, or contact their primary care manager for instructions if they are currently experiencing any urgent symptoms, such as difficulty breathing or chest pains. In addition, the letter and Fact Sheet informs service members of the availability of voluntary, no-cost follow-up medical evaluation for health concerns related to deployment, although it specifically states that it is not required for the participant to be considered "in" the registry. Upon completion of the questionnaire, the participant may save and print the questionnaire containing the individual's responses, and is encouraged to keep a copy for their records and to bring a copy of their completed health questionnaire to their healthcare provider if a clinical medical evaluation is desired. The completed questionnaire may also be saved on and printed from the registry website, as well as saved electronically to the participant's own computer or other device. When requesting a medical appointment, the service member is instructed to indicate that the appointment is for "health concerns related to the Airborne Hazards and Open Burn Pit Registry exposures."

The location and scheduling of the voluntary medical evaluation differs for those service members currently on active duty and those who are not presently on active duty. The DoD Fact Sheet includes the following specific instructions:

1. For the location and scheduling of the voluntary medical evaluation, active duty service members, including the National Guard and Reserve forces on active duty orders for greater than 30 days,

are instructed to obtain the medical evaluation through the DoD either at their designated military medical treatment facility, or through their DoD primary care manager.

2. For the location and scheduling of the voluntary medical evaluation, members of the National Guard and Reserve forces not presently on an active duty tour, are specifically instructed to contact the VA for the medical evaluation. National Guard and Reserve forces, whether discharged or still serving, will be managed by the VA in the same manner as other veterans. The VA will provide a voluntary medical evaluation upon request. If the participant is a Veteran or inactive/separated National Guard or Reservist, and is enrolled in the VA healthcare system, they are instructed to contact their primary care physician or Patient Aligned Care Team (PACT) to schedule an appointment for a medical evaluation. If the participant is a Veteran or inactive/separated National Guard or Reservist, and is not enrolled in the VA healthcare system and would like to schedule an initial no-cost medical evaluation, please contact a VA Environmental Health Coordinator (EHC) in your area by visiting this link: <http://www.publiehealth.va.gov/exposures/coordinators.asp>

WHAT MILITARY HEALTHCARE PROVIDERS SHOULD KNOW

Each service's medical departments have been directed to provide appropriate medical follow-up actions in response to requests by registry participants. Again, guidance on the registry web site recommends that service members calling for an appointment for the voluntary medical assessment state the purpose is to "address health concerns related to the Airborne Hazards and Open Burn Pit Registry exposures," so providers will be made aware in advance that a participant requires these type of assessments and can prepare. The registry also allows the participant to print a paper copy of the completed questionnaire to bring to their medical assessment. The questionnaire is lengthy, about 25 pages depending on responses. Presently, DoD providers cannot access service member registry questionnaires electronically, however, DoD is working to provide this access. Currently the service member will have to provide a printed copy to the provider. The printed questionnaire may be scanned into the medical record.

Healthcare providers are reminded that the extent of these medical assessments should be dictated by an individual's medical and occupational health history, and the healthcare provider's professional judgment and

skills, clinical assessment, and concerns. To be clear, there is no “required registry medical examination,” and no “required checklist.” There are no required medical tests, and there is no reporting of any results or clinical findings back to the registry. Neither “active” follow-up (ie, “call backs”) nor “case management” are required by either the VA or DoD as a result of responses on the questionnaire.

Though the DoD does not require a specific format for the clinical assessment, patients with health concerns should have their registry questionnaire reviewed and discussed by the provider, and receive appropriate reassurance, clinical evaluations, and, when indicated, diagnostic studies and/or specialty consultation. The scope of a voluntary medical assessment should depend on the individual’s history and clinical findings. While some service members may have health concerns that can be addressed through a minimal assessment consisting of a brief history and review of pertinent positives on the questionnaire, others having significant respiratory symptoms (such as dyspnea, cough, increased sputum production, chest tightness or discomfort, wheezing, or decreased exercise tolerance) may require a more comprehensive approach, including diagnostic testing and specialty consultation in some circumstances. In the latter case, a thorough occupational and environmental exposure history, especially to airborne hazards and tobacco smoke, and a physical examination focusing on the cardiopulmonary exam may be indicated. The provider may also consider requesting pulse oximetry, spirometry, radiography, and/or a complete blood count. Specialty consultation may be indicated for further evaluation. If providers have questions regarding an individual’s responses on the questionnaire, including reported exposures, which cannot be resolved locally, they may consider consultation with their respective service’s center for occupational and environmental medicine, or consultant in occupational medicine:

Navy and Marine Corps Public Health Center:
(757) 953-0700

USAPHC Consult Service: (410) 436-2714,
usarmy.apg.medcom-phc.mbx.emp@mail.mil

US Air Force managers in Public Health: DSN 761-6992,
commercial (703) 681-6992; or Bioenvironmental Engineering: DSN: 761-7688, commercial (703) 681-7688

Each service’s medical department has also been directed to use procedures and communication products to inform healthcare providers and service members about the registry, its purpose, and the availability of the voluntary clinical medical assessment for health concerns

related to deployment. The DoD is developing a communications plan, including press releases and the use of social media, to supplement the internal activities of the military services. Information for providers and frequently asked questions will be made available through the military services. The USAPHC will post communication products, which may be used by the other services, on its e-catalog website: <https://usaphcapps.amedd.army.mil/HIOShoppingCart/default.aspx>.

In addition, USAPHC is developing provider education and training for physicians, physician-assistants, and nurse practitioners who may be seeing these DoD participants for the voluntary medical assessment. The brief training will offer continuing medical education units, and familiarize military providers with the registry and its purpose, coding and recording guidance, and provide additional optional clinical tools for assessment which have been developed by the VA and DoD, such as an algorithm for primary care providers which details a clinical approach to the participant/patient requesting a voluntary medical assessment. Further details about this provider education and training will be distributed by the military services.

RISK COMMUNICATION

Perception of risk is reality for most people, regardless of the risk itself. From a medical perspective, the layperson’s perception about perceived health risks or exposures can be equally or more important than the scientific or medical data. Accepting the patient’s perceptions and understanding of health risks and spending time addressing those concerns is absolutely critical to communicating health risks effectively. Ignoring or downplaying stakeholder perceptions or concerns because the provider does not consider them valid can have detrimental effects. These effects can include a loss of credibility, seeming callous or uncaring, and having patients become noncompliant in actions necessary to negate potential health risks. Understanding the patient’s perceptions is one of the first steps in a good risk communication effort.

A loss of trust and credibility is likely if the patient perceives the care provider to imply or somehow demonstrate a lack of value to the Airborne Hazards and Open Burn Pit Registry questionnaire. It is absolutely essential that the provider instill in the patient a sense of value of not only the questionnaire but the entire registry process. Use the following guidelines to ensure successful risk communication practices are used during the medical evaluation portion of the Airborne Hazards and Open Burn Pit Registry process.

DEPARTMENT OF DEFENSE PARTICIPATION IN THE DEPARTMENT OF VETERANS AFFAIRS AIRBORNE HAZARDS AND OPEN BURN PIT REGISTRY: PROCESS, GUIDANCE TO PROVIDERS, AND COMMUNICATION

Important considerations when communicating with service member patients who have deployed:

- ♦ Accept that scientific and medical knowledge may be limited and take advantage of “teachable moments.” Although situational assessments may be difficult to explain and understand, use appropriate terminology when necessary, followed immediately by a brief, understandable explanation.
- ♦ Know when facts or data should be secondary to a more empathetic response. Trivializing or discounting concerns and emotions will only serve to escalate them (eg, “there’s no reason to worry about that...”). Verbally acknowledge and validate risk perceptions and emotions related to a health risk, regardless of assessment or findings.
- ♦ Limit technical data and statistics until perceptions and emotions related to the health risk have been identified or addressed, to the extent possible.
- ♦ Provide information in manageable “layers.” Offer concrete examples or actions. Doing so can help prioritize important information and provide the layperson with some level of control regarding the level of information detail.
- ♦ Reference third party credible sources, when possible. For instance, stating that the Centers for Disease Control and Prevention, the Environmental Protection Agency, the Occupational Safety and Health Administration, the National Research Council, etc, follow similar assessment guidelines can help demonstrate transparency and increase familiarity.
- ♦ Be sensitive that your own perceptions of service members can make risk communication efforts more difficult. Assuming that a service member will not understand the information, would not be interested in it, or is just trying to be difficult will only make risk communication efforts harder for you.
- ♦ Anticipate the most difficult questions and develop key points to reference in all potential responses. For example:
 - Will breathing high levels of dust for a year cause lung problems?
 - Why do they keep using burn pits when they know they’re bad for us?
 - To what was I exposed, and how much?
- ♦ Improve your nonverbal skills and strive to match words and actions.
- ♦ Be willing to say “I don’t know,” combined with specific actions and timeframes about how you will find the answer if possible.

Communication of health risk information requires very specialized skills gained by practice and refinement over time. Awareness of how risks are determined and

perceived and how to identify and develop appropriate messages and 2-way dialogue opportunities is critical to successful risk communication efforts.^{15,16}

ENVIRONMENTAL MEDICINE CLINICAL CONSULT SERVICE

To supplement the questionnaire responses, site-specific deployment exposure summary reports or the Periodic Occupational and Environmental Monitoring Summary (POEMS) are available for many deployment locations. The POEMS is unclassified and intended for service members and their healthcare providers, though POEMS is population-based and not an individual’s exposure summary. While they are not intended to go in a medical record, they serve as a good starting point for an exposure history and evaluation, so we encourage providers and service members (and veterans) to request the POEMS for their deployment locations. The provider may review it to aid in determining whether deployment-related exposures may apply to the participant. A POEMS is quite long, but has brief summaries at the beginning for doctors and service members.

More specifically, POEMS documents are official DoD location-specific summaries developed by the USAPHC to assist healthcare providers and service members. Archived occupational and environmental health (OEH) information, monitoring data, reports, and documents are used to develop POEMS.¹⁷ The POEMS standardizes the documentation of all the acute (during deployment) and chronic (long-term, postdeployment) OEH health risks and their potential medical implications at major deployment sites. The information is based on ambient monitoring data collected from multiple media (air, soil, water) over an extended period (eg, a year or more). It includes the rationale for health risk estimates and recommendations for any medical action/follow-up/surveillance. While this assessment may reflect similar exposures and risks pertaining to historic or future conditions at this site, the underlying data is limited to the time period(s) and area(s) sampled and thus may not reflect fluctuations or unique occurrences. It also may not be fully representative of all the fluctuations during the period. To the extent data allow, this summary describes the general ambient conditions at the site and characterizes the risks at the population level. While useful to inform providers and others of potential health effects and associated medical implications, it does not represent an individual exposure profile, and is therefore inappropriate for inclusion in a medical record. Actual individual exposures and specific resulting health effects depend on many variables and should be addressed in individual medical records by providers as appropriate at the time of an evaluation. In addition, POEMS are not medical

disability documents since disability is not automatically granted based upon environmental surveillance data, exposures, or assessed risks from that data. There may not be POEMS documents for some deployment locations, or they may still be in development.

The POEMS documents are available by contacting the applicable Service Surveillance Center for most pertinent documentation:

USAPHC, (800) 222-9698

Navy and Marine Corps Public Health Center,
(757) 953-0700

US Air Force School of Aerospace Medicine,
(888) 232-3764

Requests for POEMS can be submitted at <https://usaphcapps.amedd.army.mil/msrv/ServiceRequest.aspx> (select POEMS). Completed POEMS documents can be accessed via request and password at <https://mesl.apgea.army.mil/mesl/> and are also available by email request to usarmy.apg.medcom-phc.mbx.emp@mail.mil or by phone to 410-436-2714.

The USAPHC's Environmental Medicine Program offers an Environmental Medicine Clinical Consult Service, the only official environmental medicine level V support offered through the Army Medical Command which provides documents and presents recommendations regarding diagnostics and/or medical documentation to address individual concerns associated with environmental exposures:

USAPHC Environmental Medicine Consult Service
5158 Blackhawk Road; Building E1570
Aberdeen Proving Ground-Edgewood Area, Maryland
21010-5403

Telephone: (410) 463-2714

Email: usarmy.apg.medcom-phc.mbx.emp@mail.mil

If providers in the other services have questions regarding an individual's responses on the questionnaire, including reported exposures, which cannot be resolved locally, they may consider consultation with their respective service's center for occupational and environmental medicine or consultant in occupational medicine:

Navy and Marine Corps Public Health Center
(757) 953-0700

US Air Force Occupational Medicine Consultant
(703) 681-6868

Providers for US Coast Guard personnel may contact the USAPHC Environmental Medicine Consult Service with any questions. These services facilitate more comprehensive evaluation, documentation, and recording of

various environmental exposure incidents occurring in theater, and improve the ability of DoD to address post-deployment health concerns related to such exposures.

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DEPARTMENT OF DEFENSE PARTICIPATION IN THE DEPARTMENT OF VETERANS AFFAIRS AIRBORNE HAZARDS AND OPEN BURN PIT REGISTRY: PROCESS, GUIDANCE TO PROVIDERS, AND COMMUNICATION

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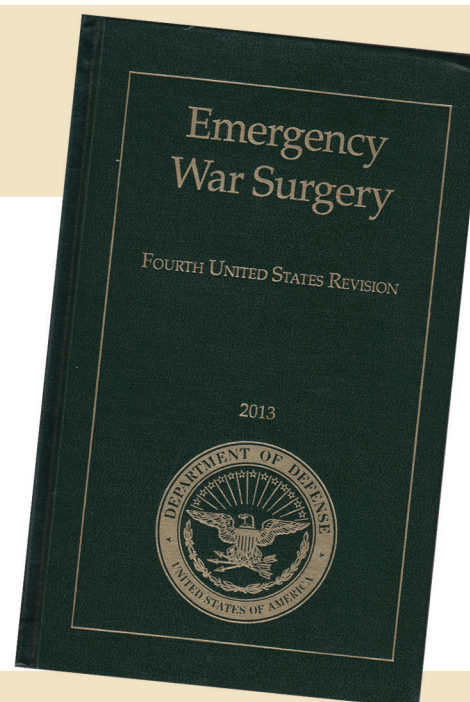
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EMERGENCY WAR SURGERY 4TH US REVISION

As an update to the much-referenced 2004 version, information in this edition reflects lessons learned from American involvement in Iraq and Afghanistan, and represents state-of-the-art principles and practices of forward trauma surgery. This publication expertly addresses the appropriate medical management of blast wounds, burns, multiple penetrating injuries, as well as other battle and nonbattle injuries. Topics include triage, hemorrhage control, airway/breathing, shock and resuscitation, anesthesia, infections, critical care, damage control surgery, face and neck injuries, soft-tissue injuries, ocular injuries, head injuries, extremity fractures, thoracic injuries, amputations, abdominal injuries, pediatric care, and more.



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Coinfection of *Mycoplasma Pneumonia* with Chronic Q Fever in a Nurse Deployed to Operation Iraqi Freedom: A Case Study

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Jason R. Pickett, MD

Q fever is considered a worldwide zoonosis due to the intracellular rickettsia, *Coxiella burnetti*. In the United States, data has shown a 3.1% seroprevalence.¹ However, prevalence rates vary widely among countries based on their ability to conduct proper surveillance. For example, rates are noted to be 18.3% in Morocco, 32.3% in Turkey, and 10% to 37% in northeast Africa.²⁻⁴ Cautiously, these estimates may underestimate the true incidence of disease due to its polymorphic clinical presentation.⁵

Typically, Q fever is considered an occupational hazard affecting persons in greatest contact with farm or laboratory animals. The reservoir includes a variety of wild and domestic mammals, birds, and arthropods.⁵ Urine, feces, milk, and birth products of infected animals are the main sources for transmission. Human infections primarily originate from either inhalation of contaminated aerosols or ingestion of raw milk products. The route of inhalation may occur directly from parturient fluids of infected animals during the birthing process.⁵ Additionally, it is highly resistant to harsh environments up to several weeks, and prevailing wind patterns have been known to transport this organism great distances from its source.⁵ As a result, Q fever may occur in patients without history of animal contact. Furthermore, the long incubation period (14-21 days) of this disease contributes to its elusive presentation in both acute and chronic progression.⁶

In acute cases, the most common clinical presentation is usually a self-limited febrile illness of unknown origin; however, there are degrees of its severity. Complications include but are not limited to granulomatous hepatitis, atypical pneumonia, and meningoencephalitis.⁷ Although not reported in the United States, progressive chronic fatigue has also been described in England and Australia; however, this syndrome is not considered diagnostic of an ongoing infection.⁸⁻¹⁰

Rarely does chronic Q fever develop (1% of acute cases). It may occur, however, more often (39%) in patients with preexisting cardiac valvulopathy.¹¹ This may be defined by a clinical evolution more than 6 months duration

with the presence of phase 1 immunoglobulin (Ig) G *C. burnetti* antibodies.⁵ The most common clinical manifestation of chronic infection is endocarditis involving the aortic and mitral valves.⁵ Interestingly, the majority of patients who develop chronic Q fever are older men (aged over 40 years) even though both genders may have similar exposures.⁷ Risk factors include immunosuppressed or immunocompromised persons, pregnancy, and vascular abnormalities. Nonetheless, preexisting valvulopathy, specifically prosthetic heart valves, remain the most predominant risk factor.^{5,11,12} Without treatment, phase 1 IgG titers remain persistently high along with further clinical deterioration.^{11,13}

Diagnosis is primarily made by serologic testing. The method of choice is immunofluorescence assay.^{5,14} In the acute phase, phase 2 IgG and IgM antibodies are usually elevated around 1-2 weeks after the onset of symptoms, and around 90% of all cases seroconvert by the third week.¹⁵ A phase 2 IgG antibody titer of 1:200 or more and a phase 2 IgM antibody titer of 1:50 or more are highly suggestive of an acute infection.¹⁵ In contrast, the phase 1 IgG antibodies are predominant during chronic infections. In this stage, titers of 1:800 or more are considered to be significant.¹⁵ Antibodies generally peak around 1-2 months after the onset of symptoms.¹⁵ Gradually, the titers usually decrease in the following year; but IgG antibodies may persist while IgM antibodies disappear.¹⁵ When high levels of phase 1 antibodies remain positive, chronic Q fever is highly suggestive.¹⁵

CASE

On March 31, 2011, a 39-year-old white female complained of generalized myalgias, nausea, headache, night sweats, subjective fevers, and chills for the past day followed by fatigue. Vitals were remarkable for slightly elevated heart rate (107) and temperature (101.9°F). Her occupation was described as an Army Reserve nurse deployed to Mosul, Iraq, in a combat support hospital. She had no significant past medical or recent surgical history. She denied any sick contacts to either humans or animals. She also denied any contact to unusual food or water sources. Intravenous fluids improved her condition

COINFECTION OF *MYCOPLASMA PNEUMONIA* WITH CHRONIC Q FEVER IN A NURSE DEPLOYED TO OPERATION IRAQI FREEDOM: A CASE STUDY

with no significant physical exam findings. Urine pregnancy test, blood counts, chemistries, rapid influenza, monospot test, and chest x-ray were all within normal limits. Despite the negative influenza swab, symptoms were consistent with a flu-like diagnosis. Consequently, the patient was prescribed a 5-day course of oseltamivir.

Two days later, her symptoms progressed to nausea, vomiting, and physical exam findings of cool, clammy skin. Although her blood cultures were negative, she was noted to have elevated liver enzymes: alanine aminotransferase (ALT 443), aspartate aminotransferase (AST 288) and alkaline phosphatase (AP 364). Yet, her right upper quadrant ultrasound was interpreted as normal. Zofran and intravenous fluids were given along with outpatient management.

On April 12, 2011, the patient had reoccurring myalgias; however, she now developed rhinitis, headache, anorexia and night sweats. She was afebrile on the visit but demonstrated sinus tachycardia (heart rate 125) that improved with an intravenous fluid bolus. She reported a history of persistent fevers as high as 102°F. Her physical exam was unremarkable. Although her urinalysis was normal, her blood counts were significant for decreased hemoglobin (Hgb 11) levels, hyperglycemia (glucose 200), elevated erythrocyte sedimentation rate (ESR 49) and c-reactive protein (CRP 24), but a resolving transaminitis (ALT 90, AST 36, AP 184).

During the second week of illness, the patient developed worsening erythematous, nonpruritic, but tender to palpation nodules on her bilateral legs (Figure 1). Initially, the primary diagnosis was presumed insect bites although no specific arthropod or species were identified. Follow-up 4 days later revealed nighttime 10/10 joint pains with nonresolving bilateral leg nodules and

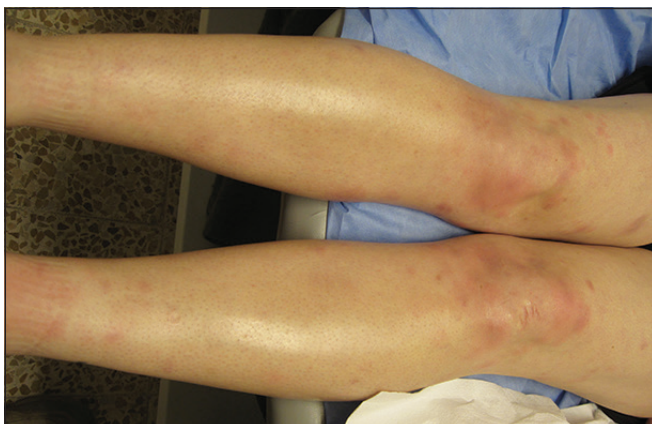


Figure 1. Worsening erythematous, nonpruritic, but tender to palpation nodules on the patient's bilateral legs that developed during the second week of illness.

a progressive rash to both arms. The nodules now appeared confluent including a rash to both palms of the hands (Figure 2). A diagnosis of erythema nodosum was made. Additionally, she complained of wakening night sweats and "hot flashes" during daytime hours. Vitals were unremarkable as additional labs continued to reveal anemia (Hgb 9.6 with schistocytes) along with persistent elevation of inflammatory markers (ESR >140 and CRP 19.2). Other pertinent labs such as human immunodeficiency virus (HIV), hepatitis B and C, rapid plasma reagin, leishmaniasis cultures, liver function tests, and thyroid panel were all concluded as negative. Her pelvic exam was normal, and antigens for gonorrhea and chlamydia were also negative.



Figure 2. Rash nodules on palms and legs.

As a result, she was diagnosed with fever of unknown origin and evacuated to Landstuhl Regional Medical Center for further evaluation. Additional consultations revealed a negative tuberculin skin test, antistreptolysin O, hepatitis panel, nuclear antibody panel, ferritin, rheumatoid factor, *histoplasma* and *coccidioides* antibody titers. The TORCH panel* revealed positive IgG antibodies for cytomegalovirus, herpes simplex virus, and rubella with no active lesions identified. Otherwise, her inflammatory markers were on a declining trend (CRP 3.16, ESR 65). Notably, her *mycoplasma* antibody was positive and she was treated for *mycoplasma pneumoniae*.

On day 41, *C. burnetti* results, shown in the Table, returned with a concern for Q fever. As a result, further cardiac testing was completed. An electrocardiogram revealed a sinus arrhythmia while an echocardiogram diagnosed a mild left atrial enlargement, insignificant pulmonary insufficiency, moderate eccentric mitral regurgitation, as well as mild to moderate tricuspid regurgitation.

*A group of tests for toxoplasmosis, rubella, cytomegalovirus, herpes simplex, and HIV, but it can also include other infections.

Detailed questioning failed to reveal any occupational or casual exposure to common Q fever vectors. The patient did not have any contact with livestock or likely animals. She had been quartered in an enclosed containerized housing unit (CHU) and denies any field exposure outside the combat support hospital housing area. Her CHU was located adjacent to a MEDEVAC helicopter landing zone where rotor downwash may have aerosolized soil particles that led to infection, although no other case reports were identified in her area of operations.

Based on the diagnosis of Q fever, the patient was treated with doxycycline for a 3-week course and returned to the combat theater to complete her tour. Initially, her phase 2 IgM titers were elevated consistent with an acute infection on day 41. Increasing phase 2 IgG titers followed on day 218 even after treatment. Later, her constitutional symptoms of fever, rash, and night sweats eventually resolved. However, follow-up serologies revealed persistent phase 1 IgG titers, consistent with a chronic infection.

Two years after diagnosis, the patient complained only of persistent arthralgias varying from 2 to 5 out of 10 on a visual analog pain scale, a common complication of chronic disease. Follow-up titers indicated decreasing IgM titers consistent with convalescence, shown in the Table. Additionally, her serologic inflammatory markers returned to normal levels. Repeat echocardiogram on January 24, 2013, showed mild thickening of the anterior leaflet of the mitral valve, but otherwise there were no significant changes in her condition or cardiac function.

Date	Phase 1 IgG	Phase 2 IgG	Phase 1 IgM	Phase 2 IgM	ESR	CRP
04/27/11	<1:16	<1:16	1:1024	1:2048	65	3.16
05/23/11	1:256	1:4096	1:4096	1:2048	–	–
11/03/11	1:1024	1:16384	1:256	1:16	–	–
08/22/12 ^a	≥1:256	≥1:256	Negative	Negative	–	–
10/17/12 ^a	1:4096	1:8192	Negative ^b	Negative	16	0.63
04/11/13 ^a	1:128	1:128	Not Performed	Not Performed	11	0.40

^aAll subsequent lab results from 08/22/2012 to 04/11/2013 were processed by ARUP Laboratories (University of Utah, Salt Lake City).
^bAlthough the test was deemed negative by the laboratory's screening lab, titers were processed by the Director of Laboratory Operations and read as 1:16.

COMMENT

Since Operation Iraqi Freedom began, there have been reports of over 100 cases of Q fever among deployed US military personnel ascertained through a Department of Defense medical database.^{6,15-21} The most frequent presentation includes fever, pneumonia, or hepatitis.^{8,22} Despite these typical nonspecific signs and symptoms of the disease, Q fever is also known to possess a wide spectrum of manifestations including 7 distinct presentations

described by Raoult: fever, pneumonia, hepatitis, meningitis, meningoencephalitis, pericarditis, and myocarditis.⁸ Although cases of acute cholecystitis have been associated with this disease in some medical literature,²³⁻²⁶ it is not well described as part of the Q fever diagnosis. Consequently, this broad variation in clinical presentation can delay diagnosis and further treatment.

Our patient denied having typical risk factors including exposure to livestock or consumption of local meat or dairy products. However, it is known that direct exposure to the source is not necessary for an infection to occur.^{8,21,22} Further, coinfection with *Mycoplasma pneumoniae* is not well described in the literature. However, atypical pneumonia have been discussed in limited regions of the world²⁷ and more recently with investigations among HIV-infected patients.²⁸

Additionally, chronic Q fever is infrequently reported among females. Her valvulopathy discovered on echocardiogram was considered mild to moderate without serious untoward symptoms or signs of endocarditis. There were no indications of a preexisting cardiac condition in her medical history. Once identified as an infection of *C. burnetii*, prompt treatment was initiated with direct follow-up. Subsequent laboratory studies confirmed resolution of her Q fever with an uncomplicated clinical course.

More importantly, Q fever is considered a category B biologic agent and is a potential threat to deployed Soldiers.²⁹ In this case, direct contact with infected animals is not required for military personnel to be considered exposed. Transmission factors within military populations include sleeping in barns, tick bites, and living near helicopter landing zones where environmental aerosols are generated.¹⁶

In conclusion, this case report is an important reminder to medical providers of the existence of a myriad of unique infectious sources among deployed Soldiers or those returning from abroad. A heightened awareness of this insidious disease will ensure prompt diagnosis and treatment ultimately preventing future complications. Lastly, the occupational and environmental history is a key determinant of success for any clinical practice.

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Over the Ear Tactical Communication and Protection System Use by a Light Infantry (Airborne) Brigade in Afghanistan

MAJ Leanne Cleveland, MS, USA

HISTORY

The acronym TCAPS, for Tactical Communication and Protection Systems, was introduced in the Army Hearing Program Special Text 4-02.501, released in 2008,¹ and is quickly becoming a known and understood acronym in the vernacular of many American Soldiers' Army line units. Broadly categorized as in-the-ear, over-the-ear, wired, or wireless, TCAPS is the generic term for the growing selection of amplified hearing protection systems available for purchase.

A number of manufacturers have employed modern hearing aid technology to create these systems for the military population using a variety of modern digital signal processing algorithms, including digital compression and/or active noise reduction. In 1993, the Bose Corporation (Framingham, MA) became the first company to supply an active noise reduction (ANR) system to the US Army's armored vehicle personnel with the combat vehicle crewman headset.² The more current TriPort Tactical Headset Series 2 ANR headset was used in many wheeled armored vehicles throughout Operation Iraqi Freedom and continues to be used today in noise hazardous military vehicles such as the M-1114 High-Mobility, Multipurpose Wheeled Vehicle and the Stryker. In 2007, the US Marine Corps contracted with Honeywell Safety Products (Smithfield, RI) to provide Marines with in-the-ear, wired TCAPS under the trade name of Integrated Intra Squad Radio Hearing Protection Headsets.³ In 2012, the US Army Rapid Equipping Force acquired a source of supply code for the Peltor over-the-ear ComTac III headsets (3M Personal Safety Division, St Paul, MN) TCAPS for regular Army purchase through the Defense Logistics Agency. Previously, the source of supply code had been maintained and used only by Special Operations Forces.⁴ The TEA INVISIO X50 (TEA Inc, Brewster, NY) is one of the most current TCAPS receiving attention from the US Army Hearing Program. In October 2013, the US Army's Program Executive Office Soldier awarded a \$7.5 million contract to TEA Inc for INVISIO X50 systems to address the TCAPS requirement.⁵ The X50 will be fielded to 3 brigade combat teams during 2014 at Ft Campbell, Ft Drum, and Ft Bragg.⁶ Even amidst these large scale contracts

and research endeavors, we still see small groups of Soldiers who spend precious, limited unit funds or even their personal funds on one or more TCAPS devices and accessories.

DATA COLLECTION

This quality assurance data report concerns a US Army Alaska light infantry brigade (airborne) which redeployed to their home duty station, the Fort Richardson side of Joint Base Elmendorf-Richardson, after a year-long combat tour in Afghanistan. The infantryman's job description includes 3 tasks: shoot, move, and communicate. Good hearing is a force multiplier. A sudden temporary or permanent hearing loss from acoustic trauma in combat has the potential to render the individual Soldier, or even the entire unit, ineffective, which could result in mission failure. Experience has shown that Soldiers completely understand the importance of both having robust, clear, communication abilities on the battlefield and the protection of the precious sense for that capability—hearing.

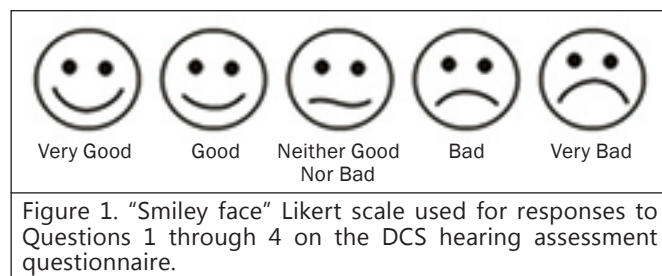
All Soldiers who deploy or redeploy from combat are required to undergo a series of health assessments through a process known as Soldier Readiness Processing. US Army Alaska refers to this process as deployment cycle support (DCS). At the Fort Richardson Soldier Centered Medical Home, the DCS health assessment process includes, among other things, a check of each Soldier's current hearing ability to determine and document each individual's Hearing Readiness status in the US Army Medical Protection System per *Army Regulation 40-501*.⁷ The Soldier is fitted with a new pair of hearing protection, typically filtered (nonlinear) or nonfiltered (linear) hearing protection in conjunction with the DCS hearing check. The entire process is fairly intense, with long lines of jetlagged, homesick Soldiers who want to finish quickly so that they can go home and decompress with their family and friends. It was during the postdeployment DCS hearing check and earplug fitting that each Soldier was asked: "what type of hearing protection did you wear in Afghanistan?" After asking this question to the first few hundred troops, we noticed that several indicated they had used an identical brand of over-the-ear

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(OTE) TCAPS during dismounted operations. Recognizing this to be a good opportunity for data collection and quality assurance reporting, I prepared a questionnaire that evening and began handing it out through the rest of the DCS process to any Soldier who reported that he had used this particular OTE TCAPS. In addition to analyzing the subjective data from the surveys, objective data (the pre- and postdeployment hearing tests) of the 56 OTE TCAPS users was compared to the non-TCAPS users. Both subjective and objective outcomes are presented.

Subjective Responses: Questionnaire Results

Fifty-six surveys were collected from October 13 to October 21, 2012. All respondents were male. The average age was 29 years. More than 50% were infantry or mortar team Soldiers (43% and 11% respectively). The survey used a Likert scale of 5 simple “smiley faces” ranging from a big smile to a big frown, shown in Figure 1, for Questions 1 to 4. The smiley face Likert scale was selected over a numeric scale because the goal was to keep the survey as simple and user-friendly as possible, especially given that the respondents were, for the most part, very sleepy and experiencing jetlag, and were not enthusiastic about the DCS process.



The subjective data collected from Questions 1 through 5 of the surveys are as follows:

1. How do you rate the comfort of the OTE TCAPS?

Very Good	Good	Neither Good Nor Bad	Bad	Very Bad
41%	36%	21%	2%	0

2. How do you rate the clarity of radio communications with the OTE TCAPS?

Very Good	Good	Neither Good Nor Bad	Bad	Very Bad
75%	25%	0	0	0

3. How clear was spoken language from other Soldiers around you using the external microphone in dismounted operations (not radio communications)?

Very Good	Good	Neither Good Nor Bad	Bad	Very Bad
54%	39%	5%	2%	0

4. Overall, how much do you think the OTE TCAPS helped to improve your warfighter lethality and survivability on the battlefield?

Very Good	Good	Neither Good Nor Bad	Bad	Very Bad
63%	33%	4%	0	0

5. Did the OTE TCAPS improve your situational awareness?

Yes	No	No Response
84%	14%	2%

Many responses to Questions 6 and 7 included additional information and/or explanations which are synthesized as follows:

6. What OTE TCAPS feature did you LIKE the most?

Radio communications	40%
Dismounted operations	19%
Localization of sound	14%
Other	27%

The 27% of respondents who indicated “Other” for Question 6 typically included some explanation of how impressed and satisfied they were with a system that amplifies quiet speech sounds while dampening unexpected impulse noises, which is encouraging for Army audiologists who are searching for incentives to convince Soldiers to wear hearing protection in hazardous noise environments. The statistic that 14% of Soldiers indicated that they liked the ability to localize sound is surprising. Situational awareness is key for survivability on the battlefield. The human brain uses subtle differences in intensity, spectral, and timing cues in an open, uncovered ear to determine the location of a sound source. One of the concerns with OTE TCAPS is that covering the ear adversely affects the ability of the wearer to use interaural time delays between the ears and the head shadow effect, which could compromise their ability to localize the origin of dangerous sounds. This is especially true given the microphone placement on the front of the OTE TCAPS, which would give the wearer the impression that all sounds originate directly from the front. However, consider the infantry patrol for a moment. Every dismounted patrol is set up with a point, rear, and flank guard. Each individual is responsible for their assigned sector in front of them, which may explain why amplifying sounds from directly in front helped this group of Soldiers, primarily infantrymen, and gave them the impression of improved localization ability.

In response to Question 7, 60% specifically wrote that the OTE TCAPS became too hot and/or too tight after a while, typically after 8 to 12 hours of continuous use. Several surveys described pouring out their “sweat

7. What did you DISLIKE the most about the OTE TCAPS?

Too hot and/or too tight after extended wearing, typically 8 to 12 hours	60%
Wires	7%
Other	33%

pools” that collected in the ear cups after extended periods of use. At first this appears contradictory to the responses in Question 1, in which 77% described the comfort as Good or Very Good. But it is also possible that the comfort issues that arise after 8 to 12 hours of continuous use may be a reflection of their environment. The vast majority of Afghanistan is undeveloped, usually only dirt and sand, where Soldiers can go for days without a shower. Sweat will always attract dirt and sand. The combination of sweat and dirt may have made the OTE TCAPS feel like sandpaper being worn on their ears, and yet the 56 survey respondents continued to wear them. The comfort issues described may have more to do with the basic challenges a Soldier faces living in a war zone than issues with the fit or design of the OTE TCAPS.

8. Would you recommend that OTE TCAPS become a unit issue for Soldiers?	Yes	No
In your military occupational specialty (MOS)	98%	2%
In another MOS	75%	25%
In every MOS	49%	51%

The responses to Question 8 speak to the frugality of experienced Soldiers. Perhaps not all Soldiers need TCAPS. If everybody had one, it could get very costly which should be considered during this time of fiscal constraint. Then again, every Soldier is exposed to noise just by being in the Army, especially in field training and deployed environments. Priority should initially be given to those who need them the most, but a universal Army-wide or even Department of Defense-wide TCAPS issue is something that almost half of this survey group would like to see.

OBJECTIVE DATA: COMPARISON OF PRE- AND POSTDEPLOYMENT HEARING LEVELS

Every US Army Soldier’s hearing test data is stored in the Defense Occupational and Environmental Readiness System–Hearing Conservation (DOEH-RS-HC) data repository. Queries to that repository for data of the 2,801 Soldiers who underwent postdeployment hearing tests at Fort Richardson from October 13 to October 21, 2012, indicated that 1,068 were non-OTE TCAPS users assigned to the same units as the 56 OTE TCAPS users who responded to the questionnaire. Further, comparison

of pre- and postdeployment hearing test data showed a positive, significant threshold shift (STS) in 85 of those 1,068 non-OTE TCAPS users, as shown in the Table. The Department of Defense uses the Occupational Safety and Health Administration’s definition of an STS⁸: a change in hearing threshold relative to the baseline audiogram of an average of 10 dB or more at 2000 Hz, 3000 Hz, and 4000 Hz in either ear. Only one of the 56 OTE TCAPS users showed a STS, which is equivalent to a 1.78% STS rate. Figure 2 presents the average pre- and postdeployment audiograms for the 56 OTE TCAPS users. In contrast, the non-OTE TCAPS group from the same units had a 7.95% STS rate.

Questionnaire Data Used for χ^2 Analysis.

	TCAPS Users Surveyed Oct 13-21 1.78% STS Rate	No TCAPS Use Surveyed Oct 13-21 7.59% STS Rate	Rest of Brigade No TCAPS Use 10% STS Rate	Total
STS	1	85	168	254
No STS	55	983	1,509	2,547
Total	56	1,068	1,677	2,801

A χ^2 analysis compared the STS rate in the group of 56 OTE TCAPS users to the STS rate in the group of 1,068 non-OTE TCAPS users, with the assumption that, given that they were assigned to the same units, a portion of the 2 groups of Soldiers must have gone together on the same missions, and therefore were exposed to a similar level (if not the exact same) of hazardous noise. Results showed a significant difference between the 2 groups’ STS rates ($P=.022642$), demonstrating that OTE TCAPS users had significantly less hearing loss than those who did not wear OTE TCAPS.

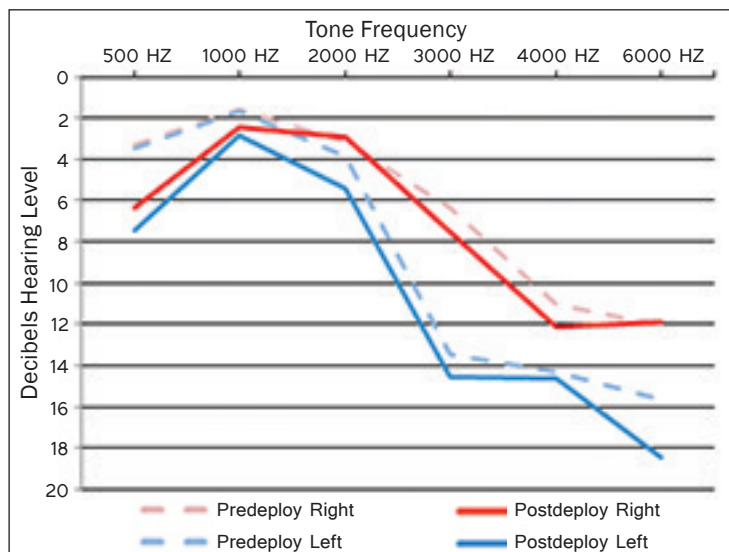


Figure 2. Average pre- and postdeployment audiogram results for the 56 questionnaire respondents who indicated that they had consistently worn OTE TCAPS throughout the deployment.

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SUMMARY AND CONCLUSION

The value of this quality assurance data report is that it was initiated at the individual Soldier level, using one of the oldest and most basic OTE TCAPS technologies available. The device that was used by the Soldiers in this report meets ruggedization standards per *MIL-STD 810*⁹ and electromagnetic compatibility per *MIL-STD-461*.¹⁰ Also of interest considering the repeated exposure to often considerable perspiration, these OTE TCAPS meet the standard for salt water submersion (3 feet for 30 minutes).¹¹ Over-the-ear devices do not require special fitting, as opposed to in-the-ear devices which must be fitted by medically trained personnel.¹² Although the system is technically complex and sophisticated, it is very user-friendly. There are only 2 control buttons on this OTE TCAPS: press and hold one button to turn on or off; press each button in short duration to adjust the volume level to louder or softer. Batteries (AA) are easy to find, inexpensive, and last approximately 270 hours. Analog compression technology uses a peak clipping strategy to block any hazardous impulse noise. There is no active noise reduction for protection from steady state noise, but the tight fitting and well-sealed gel ear cups provide maximum passive attenuation. There are optional push-to-talk (PTT) devices for radio connectivity. Soldiers who carry 2 radios can use 2 PTTs, or a single PTT with a toggle switch. Given the current and future TCAPS innovations using smaller, smarter digital, custom, and wireless technology, there is considerable potential for advancement in active noise reduction for protection from steady-state noise, as well as digital compression for protection from hazardous impulse noise. As the Army continues to endorse a more preventive approach and emphasis in all aspects of healthcare, the provision of hearing aids for service-related hearing loss may some day become only a minor component of the Army Hearing Program.

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Health Hazard Assessment and the Toxicity Clearance Process

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In 1981, The Army Surgeon General established the Health Hazard Assessment (HHA) Program to evaluate the potential adverse health effects on Soldier users and maintainers of operating military weapon systems.¹ In 1983, *Department of Defense Directive 5000.1* (re-designated as *DoDD 5000.01*² in 2003) directed all uniformed services to consider health hazards as an integral part of their materiel acquisition process. Also in 1983, *Army Regulation 40-10*³ formally established the US Army Center for Health Promotion and Preventive Medicine (USACHPPM) HHA Program. The Army Surgeon General designated the USACHPPM (now the US Army Public Health Command) as the lead agent of the HHA process in 1985, with the primary goal of identifying health hazards, assigning risk, and providing recommendations to eliminate or control those health hazards associated with the life cycle management of weapons, equipment, clothing, training devices, and other materiel systems.

HEALTH HAZARD ASSESSMENT PROGRAM AND TOXICOLOGY PORTFOLIO

When health hazards are identified, estimates of health risk severity and probability are established using risk assessment codes. The risk assessment code procedure, adopted from *Military Standard 882E*,⁴ is used to quantify health risks to military personnel who will be operating or maintaining Army systems during testing, training, or combat. The following health hazards categories are assessed by the HHA program and defined in *Army Regulation 40-10*³:

acoustic energy	shock
biological substances	temperature extremes
chemical substances	trauma
oxygen deficiency	ultrasound
radiation energy	vibration

This article focuses exclusively on toxicity clearances (TC) and the HHA process that deals with chemical substances. When a new chemical substance not previously approved for Army use is proposed for use in an item under assessment by the HHA Program, the HHA Program will normally ask the AIPH Toxicology Portfolio

(TOX) to conduct a toxicity evaluation of the chemical. The toxicity evaluation leads to the development of a TC for inclusion or reference in the HHA report. When a new chemical is proposed for use not associated with a particular weapon or piece of equipment but generically throughout the Army, approval must be obtained via a TC. The Army Surgeon General's TOX Portfolio at AIPH is described in *Army Regulation 40-5*.⁵

A toxicity evaluation and clearance for a specific chemical or material prior to its use helps to ensure the safety of Army personnel. A TC involves a toxicity evaluation of chemicals and materials prior to the introduction into the Army supply system. In some cases, a TC given for one item with a given use scenario may not be accepted for an item with the same compound for another use scenario. The materiel developer is responsible for identifying technically feasible materials and requesting appropriate consultation from AIPH TOX Portfolio.

In order to initiate the TC, the materiel developer must provide background information concerning the product material along with the request for the TC. The information should include the scope and length of use on the commercial market, human and/or animal toxicity data, a safety data sheet,* reports of any known adverse health effects, and manufacturing use information that will help ascertain the means and magnitude of exposure to military personnel. The requirement for additional toxicity testing will vary with the intended use of the candidate item and its chemical attributes. Examples of items requiring a TC are:

solvents	energetics
fire extinguishing agents	propellants
repellents	pyrotechnics
fabric finishes	hydraulic fluids
refrigerants	metals/alloys
explosives	pest control agents

Toxicity clearances are granted for specific applications. In many cases, approval for one situation may not apply for a different use if the exposure scenario has changed.

*Occupational Safety and Health Administration Form 20

HEALTH HAZARD ASSESSMENT AND THE TOXICITY CLEARANCE PROCESS

Following the TOX Portfolio review of the pertinent information, guidance is issued in the form of a TC memorandum regarding the safe use of the proposed material. It is possible that a TC may not be granted because of insufficient toxicological data. In that case, additional toxicological testing is recommended. It is also possible that additional safety and health procedures, equipment, and/or controls are recommended for the safe use of a particular material in a specific application.

The HHA Program then reviews the TC developed by the TOX Portfolio and incorporates the applicable findings into the HHA report. A risk assessment code and a mitigation strategy may be developed with a residual risk assessment code assigned by the subject matter expert assuming the mitigation strategy is applied.

A TC is an extremely valuable tool for the materiel developer to make a more-informed decision on the possible use of a chemical or material. It is important to remember that a TC is application and exposure scenario specific.

The TOX Portfolio does recommend substitute material(s) based on efficacy of a product (for example: is chemical X a better solvent than chemical Y?) during the research, development, test and evaluation phase of acquisitions. The decision-maker at the requesting organization, with appropriate medical health and safety guidance from the AIPH, is responsible for those decisions and recommendations for a candidate substitute.

Formerly, chemicals and materials used in the development and sustainment of Army systems were addressed in military specifications and standards. As a result of the implementation of acquisition reform/streamlining throughout the Department of Defense, performance specifications, commercial item descriptions, and consensus standards are replacing military specifications and standards. Military specifications and standards that may have received an initial toxicity review upon development, and those still in effect, are reviewed periodically to evaluate newly developed toxicity information. Because numerous products and chemicals without appropriate medical and toxicological evaluation are being proposed as alternatives, the TC is an even more valuable tool for Army leadership responsible for procurement or acquisition-related decisions.

The materiel developer must contact the AIPH TOX Portfolio to request a TC on a chemical or material early

in the acquisition process to avoid delays. Direct contact with TOX Portfolio to determine if a TC has been completed on a chemical/material is recommended.

CONCLUSION

Since 1981, the Army HHA Program has provided an invaluable service to capability and materiel developers by providing recommendations designed to eliminate or control health hazards associated with weapon systems and other materiel. The HHA Program has consistently strived to improve its services by providing more meaningful and efficient assistance to the acquisition community, such as incorporation of the TC process. In the uncertain fiscal times ahead, the Army HHA Program and TOX Portfolio will continue to provide valuable and cost-effective solutions to mitigate health risks associated with the use of new and improved materiel systems.

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Chemical and Biological Warfare: Teaching the Forbidden at a State University

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Interest in the subject of chemical and biological warfare has resurged recently. In the United States, the interest had waned substantially due in part to the 1969 decision by President Richard Nixon to ban research on the development or use of these weapons for offensive purposes.¹ Although chemical and biological weapons have always been perceived as potential hazards in the world of asymmetric warfare, the general focus of those concerned with weapons of mass destruction (WMD) tended to be on nuclear weapons. Several events led policy makers, medical planners and others to reconsider this narrow focus. Among the first of these events was the realization that the Soviet Union had continued to develop a broad range of biological and chemical weapons despite being a signatory of treaties that banned such research and development. The defection of Ken Alibek, a high-ranking Soviet scientist involved in development of biological weapons, revealed a sizeable infrastructure in the Soviet Union for development of biological WMD.² The dissolution of the Soviet Union raised concerns among scientists in the west that the substantial stocks of biological agents in the Soviet laboratories could make their way into the hands of terrorists or rogue nations.³ An earlier event in which a weaponized chemical was used in the subways of Tokyo by a religious cult seemed to justify this concern,⁴ as did the stated interest by other terrorist groups, including Al Qaida, in obtaining and using these weapons. The heavy use of chemical weapons in the Iran-Iraq war of the 1980s also brought attention to these agents, especially with the increased involvement of the United States in the Middle East beginning with Operations Desert Shield and Desert Storm. The suspected presence of chemical and biological weapons in Iraq eventually played an important role in the decision to invade that country in 2003. Although weaponized chemicals may not have played a significant role in the decision to invade Afghanistan, subsequent suspected use of toxic agricultural chemicals against the students in girls' schools of that country⁵ in 2010 suggested a willingness by groups hostile to the United States to use such chemicals. More recently, the chemical weapons of the Syrian regime and the suspected use of those weapons in that country's civil war have ensured that WMDs have continued to be in the public eye. The United States and other countries

are currently working to obtain and destroy the Syrian chemical weapons.

Since 2012, the graduate Missouri State University (MSU) Department of Defense and Strategic Studies (DDSS) has taught an online graduate course in chemical and biological warfare to students in the university's Master of Science degree in Defense and Strategic Studies. More recently, the course has become a requirement in the Master of Science Degree in Weapons of Mass Destruction Studies, a collaborative program of Missouri State University and the National Defense University. The course has evolved over a short time to address the needs of an increasingly diverse group of students. This article describes the development, content, and current status of that course. The purpose is to demonstrate how collaboration between the military, the government, and academia can address the nation's need for persons trained in the study of chemical and biological warfare.

COURSE HISTORY AND DEVELOPMENT

The need for an online graduate course in chemical and biological warfare is a reflection of the unique mission of the MSU DDSS. The graduate DDSS was established at the University of Southern California in 1972 and flourished under the directorship of the late Professor William R. Van Cleave. Based on his experience as a member of the original US delegation to the US-Soviet Strategic Arms Reductions Talks, Professor Van Cleave was concerned that the academic approach to the study of international security issues was overly theoretical, and did not prepare students well for professional careers in the field, either in government or industry. Consequently, Professor Van Cleave designed the Defense and Strategic Studies (DSS) graduate curriculum to include the practice of international relations as a main focus of the curriculum. Every course included an understanding of the actual practice of international relations and the practical application of concepts and theory as a student learning goal. While some graduates of the DSS program moved into academic positions, most pursued careers in government, the military, defense industry, and the "think tank" community. Many of the early graduates now hold senior positions in government, industry, or think tanks. For example, the recent

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Secretary of the Air Force, Michael Donley, is a graduate of the Defense and Strategic Studies program, as is J. D. Crouch, who served as the Deputy National Security Advisor to President George W. Bush.

Professor Van Cleave moved the DSS program to MSU in Springfield, Missouri, in 1987 and continued to emphasize professional education for public service. Upon his retirement in 2005, MSU relocated the entire department to Fairfax, Virginia, to enable students to take advantage of the many resources available only in the Washington, DC, area for students in this field. Such resources include unparalleled access to professors with deep and pertinent professional experience in government, and readily available internships in government and industry offices. The program's focus continued to follow the guidelines established by Professor Van Cleave, that is, professional training for students interested in careers in national security.

In 2012, DDSS participated in an open competition among universities in the Washington, DC, metropolitan area to work in cooperation with the National Defense University on a 2-year MS degree program in Countering Weapons of Mass Destruction (CWMD). The degree would be for personnel from the Department of Defense. The DDSS of MSU won the competition and was awarded the effort. Following a rigorous application and selection process from among Department of Defense personnel, the first cohort of National Defense University CWMD Fellows entered the new DSS CWMD degree program in August 2012. This initial class included 17 CWMD fellows. These Fellows were sponsored by the Department of Defense, but had to attend classes and complete assignments on their own time. Consequently, the CWMD degree program will be completed while the Fellows maintain a fulltime work-load for the Department of Defense. Obviously, CWMD Fellows are highly-motivated, serious students. The initial 2012 cohort is a highly-diverse class by all measures, and consists largely of mid-career civil servants engaged professionally in a broad range of the Department of Defense's counter WMD efforts. Almost all members of this initial 2012 class already hold graduate degrees, including doctoral degrees in chemistry, biology, microbiology, and medicine. In addition, many Fellows have extensive operational experience. For example, one CWMD Fellow in the initial 2012 class had just completed a tour in Afghanistan as an emergency room physician, and another is playing a pivotal role in current operations associated with chemical weapons in Syria.

Few members of the entering class had any previous academic background in the areas of the CWMD

curriculum, which focuses on international relations theory and practice, nuclear deterrence policy, proliferation, arms control, public health issues associated with chemical and biological weapons, counterterrorism, and regional area security studies. The goal of the CWMD Fellows Program is to provide a cadre of professionals within the Department of Defense who have a broad base of expertise in countering WMD. The program is jointly operated by the National Defense University (NDU) and the MSU DDSS.

At this writing, it appears that the graduation rate for the initial 2012 NDU cohort (commencement set for July, 2014) will be approximately 80% of the entering class. This is an extremely high graduate degree completion rate compared to national averages. The NDU Fellows who entered the CWMD degree program in the 2013 cohort are progressing with comparable success.

The NDU and the DDSS worked collaboratively on developing the curriculum for the master's degree and agreed that a course on chemical and biological warfare was essential to the completeness of the curriculum. A MSU faculty member on the university's main campus in Springfield, Missouri, was first approached about developing an introductory course to chemical and biological warfare in the fall of 2011, and the first iteration was offered in the spring semester of 2012. As of April, 2014, the course had been taught 5 times, including once during a summer term (the summer term is 8 weeks long as opposed to the 16-week fall and spring semesters.) Initially, the course was offered exclusively to students in MSU's regular master's degree in defense and strategic studies. The course has evolved significantly with each iteration, but the most important changes were made when the course became a requirement for the CWMD Fellowship. At that time, the course reading list was expanded to allow a greater focus on policy aspects of the subject. Nevertheless, the very nature of the biological and chemical agents requires a solid foundation in the epidemiological and toxicological aspects of these weapons. The instructor considered this foundation essential because policy that is based on an erroneous understanding of the weapons or agents can itself be flawed.

However, the CWMD degree program is not intended to be limited to biologists or medical professionals. As noted earlier, the original degree program in the DDSS was essentially an international security affairs program in which the students were primarily focused on policy and operational aspects of defense studies. With the advent of the CWMD Fellowship, a broader spectrum of highly experienced students entered the course with the result

that the typical class included political scientists, intelligence analysts, military officers, medical personnel and others. This more diverse and experienced student body created a need to improve the definition of course objectives. More specifically, the course needed a balance of the medical or technical aspects of the course with the policy focus of the program. Therefore, new, more specific objectives, listed below, were written to guide further development of the class.

After completion of this course, the student will be able to:

1. Identify and describe the most important agents that have been developed for use in chemical warfare and categorize the agents by class.
2. Identify and describe the most important agents that have been developed or used in biological warfare.
3. Discuss the advantages and disadvantages of using weapons of mass destruction in the form of chemical and biological warfare from the perspective of the user.
4. Discuss the environmental and logistical problems associated with attempts to deploy chemical and biological weapons.
5. Describe how response efforts and preparedness can reduce the effects of chemical and biological agents.
6. Identify barriers to the implementation of effective response initiatives.
7. Identify important events in the history of chemical and biological weapons and rank them in order of importance with regard to impact on the outcome of war, health of the public and military populations, and changes in public policy.
8. Compare and contrast the strategies for the use of chemical weapons as demonstrated during wars of the 20th century.
9. Contrast the potential use of chemical and biological agents by terrorists with the historical use of these agents during war, discussing the motivations for use of these weapons by state as opposed to nonstate actors.
10. Describe current events that involve the potential or realized use of chemical and biological warfare or terrorism and discuss efforts to eliminate or reduce the use of the weapons.

11. Discuss the role that technology and globalization may have on the development, dissemination, disarmament, and use of chemical and biological agents.

The objectives require extensive background reading to address issues ranging from the epidemiology of relevant diseases to the history of treaties and official policy regarding the use of weapons of mass destruction. Initially, the course did not use a textbook and the course reading list was gathered from a variety of online sources. The Homeland Security Digital Library proved very useful in obtaining relevant readings. The Borden Institute's Textbooks of Military Medicine (<http://www.cs.amedd.army.mil/borden/>) were also very useful, especially the sections on the history of development and use of biological and chemical weapons. The Borden Institute's textbooks also provide extensive sections on technical, biological, and medical subjects. However, some chapters were too medically oriented for some students, so only select parts of many chapters were required. The most recent reading list is provided in Table 1.

A textbook was identified and used during two of the later iterations of the class, *The Soviet Biological Weapons Program: A History*.⁶ A large book of over 900 pages, it provides an exhaustive treatment of the subject, but some students thought that its use resulted in an over-emphasis on the biological weapons at the expense of the chemicals. The book is inexpensive when bought in electronic form, so portions of it are still used in the course, though only about a quarter of the book will be assigned in future classes. All of the other readings are available online for free either through the Borden Institute (online) or the university library.

TEACHING WITH AN ONLINE MODALITY

For a variety of reasons (including the fact that the instructor is on the main campus in Springfield, Missouri, and the university's graduate DDSS is located in Fairfax, Virginia), the decision was made to offer the chemical and biological warfare course exclusively online. Although this modality expands access to the course for many students, it also presents some limitations, particularly the potential of reduced interaction between the instructor and students. The university uses the Blackboard teaching software to offer online courses in many departments, so the course was built on this platform. One major advantage of this platform is that it can store very large files such as PowerPoint lectures with a recorded voice track. Such lectures would be difficult to send through most e-mail services. The instructor wrote the lectures and recorded them using Microsoft PowerPoint software, then posted them on the

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Table 1. Required reading list for graduate course in chemical and biological warfare taught as part of the Countering Weapons of Mass Destruction fellowship and degree program for the National Defense University.

History and Policy
Weapons of Mass Destruction: A Primer. Bernstein PI. 2006. Prepared by SAIC, Inc, for the Advanced Systems and Concepts Office of the Defense Threat Reduction Agency.
History of Chemical Warfare. Hilmas CJ, Smart JK, Hill BA Jr. Chapter 2; <i>Medical Aspects of Chemical Warfare</i> . 2008. Borden Institute.
History of Biological Weapons: From Poisoned Darts to Intentional Epidemics. Martin JW, Christopher GW, Eitzen EM Jr. Chapter 1; <i>Medical Aspects of Biological Warfare</i> . 2007. Borden Institute.
Historical trends related to bioterrorism: An empirical analysis. Tucker JB. <i>Emerging Infectious Diseases</i> . 1999, vol 5, no 4, pp 498-504.
A farewell to germs: the US renunciation of biological and toxin warfare, 1969-70. Tucker JB. <i>International Security</i> . 2002, vol 27, no 1, pp 107-148.
The development of the norm against the use of poison: what literature tells us. van Courtland Moon JE. <i>Politics and the Life Sciences</i> . 2008, vol 27, no 1, pp 55-77.
Chemical Agent Classes
Decontamination of Chemical Casualties. Braue EH Jr, Boardman CH, Hurst CG. Chapter 16; <i>Medical Aspects of Chemical Warfare</i> . 2008. Borden Institute.
Vesicants. Hurst CG, Petrali JP, Barillo DJ, Graham JS, Smith WJ, Urbanetti JS, Sidell FR. Chapter 8; <i>Medical Aspects of Chemical Warfare</i> . 2008. Borden Institute.
Nerve Agents. Sidell FR, Newmark J, McDounough JH. Chapter 5; <i>Medical Aspects of Chemical Warfare</i> . 2008. Borden Institute.
Toxic Inhalational Injury and Toxic Industrial Chemicals. Tuorinsky SD, Sciuto AM. Chapter 10; <i>Medical Aspects of Chemical Warfare</i> . 2008. Borden Institute.
Specific Biological Agents
Anthrax. Purcell BK, Worsham PL, Friedlander AM. Chapter 4; <i>Medical Aspects of Biological Warfare</i> . 2007. Borden Institute.
Plague. Worsham PL, McGovern TW, Vietri NJ, Friedlander AM. Chapter 5; <i>Medical Aspects of Biological Warfare</i> . 2007. Borden Institute.
Glanders. Gregory BC, Waag DM. Chapter 6; <i>Medical Aspects of Biological Warfare</i> . 2007. Borden Institute.
Melioidosis. Vietri NJ, Deshazer D. Chapter 7; <i>Medical Aspects of Biological Warfare</i> . 2007. Borden Institute.
Tularemia. Hepburn MJ, Friedlander AM, Dembek ZF. 2007. Chapter 8; <i>Medical Aspects of Biological Warfare</i> . 2007. Borden Institute.
Brucellosis. Purcell BK, Hoover DL, Friedlander AM. Chapter 9; <i>Medical Aspects of Biological Warfare</i> . 2007. Borden Institute.
Q Fever. Waag DM. Chapter 10; <i>Medical Aspects of Biological Warfare</i> . 2007. Borden Institute.
Smallpox and Related Orthopoxviruses. Jahrling PB, Huggins JW, Ibrahim MS, Lawler JV, Martin JW. Chapter 11; <i>Medical Aspects of Biological Warfare</i> . 2007. Borden Institute.
Alphavirus Encephalitides. Steele KE, Reed DS, Glass PJ, Hart MK, Ludwig GV, Pratt WD, Parker MD, Smith JF. Chapter 12; <i>Medical Aspects of Biological Warfare</i> . 2007. Borden Institute.
Viral Hemorrhagic Fevers. Jahrling PB, Marty AM, Geisbert TW. Chapter 13; <i>Medical Aspects of Biological Warfare</i> . 2007. Borden Institute.
Agricultural Terrorism or Warfare
State Agro-BW Programs. Millett PD, Whitby SM. <i>Agro-Terrorism: What is the Threat?</i> Proceedings of a Workshop Held at Cornell University, Ithaca, NY, November 12-13, 2000. Available at https://www.hsdl.org/?view&did=3513 .
Covert Biological Weapons Attacks Against Agricultural Targets: Assessing the Impact Against US Agriculture. Pate J, Cameron G. <i>Agro-Terrorism: What is the Threat?</i> Proceedings of a Workshop Held at Cornell University, Ithaca, NY. November 12-13, 2000. Available at https://www.hsdl.org/?view&did=3513 .
NOTE: Only portions of some readings are required as they may be too medically oriented for some students whose focus is more on policy and international affairs.

Blackboard (Blackboard, Inc, Washington, DC) course website. This technology worked well for disseminating the lectures which were as large as 86,463 kb, including the voice track. Table 2 lists the titles of lectures that were used in the course as presented in the fall semester of 2013. Lectures varied in length, some were as long as 70 minutes. Subsequent student evaluations of the course called for the use of multiple, shorter lectures that are easier to download, so future iterations of the class will use more but shorter lectures not to exceed 30 minutes in length.

As mentioned earlier, the online modality can sometimes result in limited student participation in distance courses. Students may have minimal involvement especially if there is a long period of time between due dates for assignments or tests. For this reason, it is important to encourage multiple interactions between the student and the instructor via the course website. For the chemical and biological warfare course, the student is required to log onto the course website for a specific task at least 4 times each week. The tasks are divided into 3 categories: essays, comments/questions, and answers. Each

week, an essay is assigned based on the lecture of the week and part of the reading list. The essays are at least 500 words in length and must answer a specific question posed by the instructor. Example assignments or questions include:

- Propose a list of the top 10 most important events in the history of chemical warfare and terrorism in descending order. Justify your choice and the ranking of each event.
- Describe how the strategies for the use of chemical warfare agents by a nation-state might differ from those of a terrorist organization, using examples from World War I, the Italian-Ethiopian War, and the Iran-Iraq War. Address purpose, means of dispersal, and limitations as appropriate
- From the assigned readings, construct a table of 8 important characteristics and variables for 7 biological agents. Based on the table that you have constructed, identify the 2 agents in your table that have the most potential in biological warfare. Justify your choices.
- Explain the concept of the offense-defense balance and describe why it affects the decision to use biological weapons.

The essays that answer the questions are posted on Thursday of each week. Every student must then select 2 essays written by classmates on which to make a thoughtful comment of at least 50 words. At the end of that comment, the student must pose a question to the author of the essay. The comments with questions are

Table 2. Online lectures used in class on chemical and biological warfare taught by Missouri State University for the National Defense University's Countering WMD Fellows program.

Course Introduction, Procedures and Expectations
Basic Biology for the Non-biologist Interested in Chemical and Biological Warfare Agents: Toxicology
Basic Biology for the Non-biologist Interested in Chemical and Biological Warfare Agents: Epidemiology
History of Chemical and Biological Warfare
Introduction of Chemical Warfare Agents: Chemical Classes
Toxicology of Neurotoxins and Applications in War
The Vesicants
Strategies for Use of Chemical Agents in WWI, the Italy-Ethiopia War, and the Iran-Iraq War
Toxic Industrial Chemicals and Materials: Potential in War and Terrorism
Decontamination of Chemical and Biological Warfare Agents
Concepts of Biological Warfare
Agricultural Terrorism and Warfare

NOTE: All lectures are PowerPoint presentations delivered through the Blackboard online education platform. Each lecture has a voice track and length varies from 15 to 70 minutes.

due by Monday at midnight. Students must then answer the questions on their own essays that were posed by their classmates; those answers are due by Wednesday night. Thus, students must log onto the site at least 4 times each week: first, to download the assignment and supplemental readings; second, to post an essay on the discussion board; third, to read the essays of 2 classmates and to post comments with questions; and fourth, to answer the 2 questions from classmates on their own essays. Even though some of these tasks may take only a few minutes, the multiple interactions between the student and the web site ensure consistent student involvement throughout the course. Essays are graded by the instructor each week and sent to the students privately. The instructor also reviews the discussion board and comments on students' discussions that are based on the comments, questions, and answers. This process is very time-consuming for the instructor but the routine of the class encourages maximum, sustained student participation. New assignments are posted weekly.

INDIVIDUAL PROJECTS

As with most graduate level courses, the faculty saw a need for an individual project that would provide the students with the ability to explore topics of particular interest to them. The project encourages students to become familiar with the scholarly and technical literature of chemical and biological warfare and to become more familiar with current events in the field. The students were thus given a choice between doing an annotated bibliography on an instructor-approved subject, or a news journal in which the student summarized the content of 50 news articles on chemical and biological warfare that had been published in the last 25 years. Although the student could write the annotated bibliography on any approved subject, several were suggested by the instructor and most students chose to write the bibliographies on the suggested topics. The instructor-suggested topics are listed in Table 3. The suggested topics were provided to reflect the great diversity of interest of the students and to encourage a degree of self-direction. The bibliography had to have a minimum of 20 annotations from reliable sources of literature. Some students, however, wanted to become more familiar with current events as reported in the news media. Those students opted for the 50-article news journal. In fact, in the latest iteration of the class, the majority of the students chose the news journal option.

EVALUATION OF STUDENTS

The students were evaluated primarily on the essays that were submitted weekly, though some credit was also given for participation in the class discussion board. Essays were worth 50% of the score, and discussion 10%.

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Table 3. Suggested topics for the annotated bibliography required as part of the course Chemical and Biological Warfare in the Department of Defense and Strategic Studies, Missouri State University.

Agroterrorism
Domestic Terrorism and the Chem-Bio Threat
The Role of Chembio in the Decision to go to War in Iraq
Tularemia as a Bioagent
Bhopal as a Model of Chemical Agent Terrorism
Decontamination of Equipment and Sites
Potential Chemical Weapons Use in the Middle East
Detection of Chemical and Biological Agents
Toxicology of Blood Agents
Dispersal Techniques For Chem/Bio Agents
Allegations of Chem/Bio Warfare in WWII
Treaties and Chem/Bio Weapons
Business and Organizational Continuity
History of the Soviet BW/Chem Program
Anthrax as a Bioagent
Smallpox as a Bioagent
Decontamination of Personnel
Emerging Diseases as Potential Bioagents
Medical Preparedness For a Chemical Event
Toxicology of Vesicating Agents
Biotoxins as Chemical/Biological Agents
History of Incapacitating Agents
The Role of Immunization in Biodefense
Disarmament and Chem/Bio Weapons

The individual project (annotated bibliography or news journal) was worth 16%. A proctored final exam composed primarily of objective questions accounted for the rest of the grade. The instructor added a final exam to the course when it became part of the CWMD fellows program to ensure a more thorough knowledge of the assigned readings on the part of the students. The final exam questions came primarily from the readings and from weekly comments on the assignments provided by the instructor.

STUDENT EVALUATIONS OF THE COURSE

Initial student evaluations of the course were generally, though not universally, favorable. The most recent student evaluations have been quite positive. Earlier, some students saw the material as too difficult, others as too easy, but most were satisfied with the content, pace, and presentation of the course. One consistent concern has been the online format which some students do not like, finding the subject matter difficult to address in that modality. Another consistent trend is that the students find the online discussion board using comments and questions from the students themselves to be the least advantageous part of the course. On a scale of 1 to 5 with 5 being excellent, the discussion board has been the only

component to receive a score of less than 4. The news journal that many of the students complete as a project is routinely very popular. Students report that it provides them with a systematic opportunity to become familiar with current events.

LESSONS LEARNED

After 5 iterations of the course, several improvements have been made based on student evaluations and other observations. Some of the lessons learned are discussed below:

- ◆ Student understanding and participation is improved when the student must log onto the course web page multiple times each week. Otherwise, the student may lose track of class subject matter and discussion material.
- ◆ The online modality is generally suitable for the chemical and biological warfare subject, but some students require additional instruction on the use of online technology such as the instructional software. This is difficult to do when the instructor is in a different geographical area. Also, the online modality is potentially susceptible to plagiarism and other forms of academic dishonesty. Instructors must be well-versed in ways to prevent and detect violations.
- ◆ Some review and instruction in the biology and toxicology of chemical and biological agents is essential, especially for those who do not have academic backgrounds in science. The amount of review varies with each iteration of the class. One way to address this issue is to have a series of short online review lectures that are available to those students in need of the review. Students are held responsible for the information in the lectures but students with backgrounds in biology, chemistry, or medicine usually need only a cursory examination of the material.
- ◆ The academic and professional backgrounds of students in this course vary greatly, probably more so than in many other classes. Some exhibit a very complete knowledge of various aspects of the field, but may have little knowledge of others. Other students may initially have almost no understanding of the material. The use of student biographies in the first week of the class provides the instructor with the opportunity to gauge the range of knowledge and experience within the class. The biographies can also help direct student discussions. Students with particular expertise may be asked to address a subject in a special online discussion board. The student biographies can also allow the instructor to make last-minute modifications that allow the course to address areas of particular interest to a

particular cohort of students or to provide additional leveling material prior to introducing an unfamiliar subject.

CONCLUSION

The graduate course on biological and chemical warfare taught by the Missouri State University Department of Defense and Strategic Studies in conjunction with the National Defense University Countering Weapons of Mass Destruction Fellows program offers a unique combination of perspectives, from the academic to the military to the political and diplomatic. Teaching with such a broad range of perspectives to a group of students with an even broader range of education and professional experience can be challenging. The ability to effectively address the nation's needs in the field requires

people with cross-disciplinary education and the ability to operate in diverse environments. Recent events have demonstrated the need for people with field experience, technical training, and significant academic education in the field of weapons of mass destruction. The course described herein is a part of a larger degree program that includes courses in nuclear strategy, arms control, counter-proliferation, intelligence-counterintelligence, terrorism, ethics, defense policy, and other subjects. The content of the course will, of necessity, evolve to address the changing issues of terrorism, insurgency, diplomacy, globalization, and war, but it will hopefully contribute to a cadre of professionals with the backgrounds, critical thinking skills, and education to protect the nation from the threat of chemical and biological agents and other weapons of mass destruction.

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UPCOMING RELEASES FROM THE BORDEN INSTITUTE

*Medical Management
of Chemical Casualties
Handbook*

*Psychiatry
in the Vietnam War*



*Traumatic Brain Injury
Toolkit*

*Airborne Hazards
Related to Deployment*



<http://www.cs.amedd.army.mil/borden>

An Introduction to Public Health Law for Leaders and Clinicians

Joseph Baar Topinka, JD, MHA, MBA, LLM

Military preventive medicine is, in fact, the product of military thought and activities and of the intellectual, scientific, economic, and political movements and forces in the civilian world. Therefore, the evolution of preventive medicine in the United States Army cannot be considered as an isolated affair. Rather, it is to be regarded and understood as the result of the interaction between civilian and military knowledge and opinion as to what should be done, and how to do it, to preserve the health of soldiers.

BG Stanhope Bayne-Jones¹

The words of BG Bayne-Jones stand the test of time, providing a wonderful perspective on the subject of public health law. This area of law is truly about the interaction between the military and civilian world, but so often, leaders and clinicians do not understand its breadth. They often think of public health law in terms of public health emergency law, but that is just a very small part within this area of law. Public health law covers so many areas which have made headlines in recent years, such as childhood obesity and its effect on chronic disease, the controversial reduction in drink sizes for carbonated beverages in New York City, municipal bans on foods in restaurants in Chicago, nosocomial infections and their effect both inside and outside the hospital setting, along with national pharmaceutical shortages to name a few. While I certainly do not expect leaders and clinicians to be experts in this broad practice field, I do believe some heightened sensitivity to this area of the law is critical.

THE FUNDAMENTALS

In his text, *Public Health Law: Power, Duty, and Restraint*,² Professor Lawrence Gostin notes that the legal powers and duties of the state are to assure conditions for people to be healthy, and the limitations on the power of the state to constrain autonomy, privacy, liberty, property, or other legally protected interests of individuals for the protection or promotion of the community health. "State" is a general term of government which does not specifically refer to a particular level of government. As such, state can refer to the federal, state, county, borough, parish, township, and/or municipal governments. Because each refers to a different level of government, it is important to be clear whether the reference is to the federal government, especially when dealing with

military issues, or the government of, or within, a particular state in the Union. There is a relationship, however, between the federal and state governments referred to as federalism. Federalism can sometimes create a tension between the federal and the state levels of governments because each of the 50 states and their subordinate governments possess substantial, independent legal authority which is still subject to the supremacy of federal authority, to the extent it exists in regard to certain matters. Often, the authorities overlap and the astute leader and clinician will embrace that overlap and facilitate a sense of teamwork at all opportunities despite any counter influences. Just as parochialism exists among the Army, Navy, Air Force, and Marine Corps, so too do parochial attitudes exist between different levels of government. Overcoming these attitudes is a challenge.

SOURCES OF LAW

The defining document of our legal system is the US Constitution. It is the source of all legal authority for the federal government and state governments. Each state has its own constitution, and subordinate levels of government often have their own legal sources of government such as a charter or statute. Since they all differ, their style of government may be different as well, yet all fall under the authority of the US Constitution. The US Constitution is truly the supreme law of the land, except that the 10th Amendment specifically states:

The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.

In other words, if the US Constitution does not contain a provision dealing with a certain matter, that matter is reserved to the states; those powers are often referred to as "police powers." There is no mention of public health in the US Constitution, so, as a result, public health has normally been the primary responsibility of the states, and public health law has normally been a creature of state and local governments. Despite that responsibility, the federal government has often asserted its authority over public health-related activities through its interstate commerce, taxation, and spending powers under Article I, Section 8, of the US Constitution. These powers explain such policies in the past as national speed limits

and tobacco taxes, seemingly local matters controlled or influenced by the federal government—a source of tension under the concept of federalism.

Statutes and regulations are outgrowths of the US Constitution and the respective state constitutions. The constitutions give the US Congress and the various state legislatures the power to pass laws in the form of statutes. Federal agencies and state agencies then write regulations that implement the statutes. These statutes can affect public health at the federal, state, and local levels. For example, Congress passed statutes that created the US Public Health Service with its authorities and powers. It also created explicit regulatory agencies like the Food and Drug Administration or the Occupational Safety and Health Administration (OSHA) and nonregulatory agencies like the Centers for Disease Control and Prevention (CDC). State legislatures also created agencies with regulatory and nonregulatory powers and those same state legislatures delegated similar regulatory authority to lower levels of government to create entities such as departments of public health which possess similar regulatory powers but only within their local jurisdictional limits. This mix of federal, state, and local laws and regulations can be a challenge for the leader or clinician who finds him or herself on a federal military installation surrounded by several local and state jurisdictions. Everyone may or may not be operating in the same or similar manner in regard to public health, yet each is certainly in compliance with federal law, except that military installations must comply with their respective agency and department regulations as well. A daunting challenge? Yes, but not an impossible one if everyone from all the levels of government come together to work through the issues.

A summary of the sources of law would not be complete without mention of the common law. Local, state, and federal courts determine the guilt of accused criminals, resolve private law disputes between individuals, and review actions of agencies enforcing civil laws such as those addressing public health. In general, lower courts follow the decisions of higher courts, and state courts review state laws to determine if they violate the state or federal constitutions. Federal courts review the constitutionality of state and federal laws, and the US Supreme Court's decisions bind all state and federal courts. The federal courts and most state courts use common law precedent which is critical, especially when it involves decisions that affect public health matters. That precedent established by some decision will then bind us in terms of what we can or cannot do in a public health scenario.

JACOBSON V MASSACHUSETTS, A LANDMARK CASE

Many would regard *Jacobson v Massachusetts* (197 US 11 (1905)) as the most famous case in public health law and the foundation of public health common law. This 1905 US Supreme Court case concerned an order based on a state statute compelling vaccinations of residents against smallpox after a recent smallpox outbreak in Massachusetts. The Cambridge Board of Health ordered the vaccinations. Mr Henning Jacobson refused the vaccination and refused to pay the \$5.00 fine. The US Supreme Court decided that:

Upon the principle of self-defense, of paramount necessity, a community has the right to protect itself against an epidemic of disease which threatens the safety of its members.

With its decision in support of the law, the US Supreme Court began our modern constitutional analysis of disease control law which includes:

- ♦ Use of police powers for public health concerns.
- ♦ Delegation of certain authorities to health agencies and other government subdivisions.
- ♦ Use of actions limiting liberty for well-established public health interventions.

More importantly, though, the case addressed the balancing of public good vs individual rights, a concept which leaders and clinicians will have to understand as they face future public health matters.

ETHICS AND THE LAW

...laws are often broadly framed, leaving much room for administrative discretion about when to use public health authority and about which intervention is more ethically appropriate when more than one alternative course of action is legally permissible.³

Public health law provides authority, limitations on state power, and incentives and disincentives for behavior. It is very formal, focusing on statutes, regulations, and court decisions as previously described. Unfortunately, law does not always cover every situation or every issue which arises. Sometimes, less formal actions and decisions must be taken based on norms, values, professional codes, and previous experience. In other words, sometimes the law will simply not have the clear answers to the questions posed and a more informal but deliberate approach is necessary. Therefore, ethics help in filling the gaps not specifically addressed within the law.

Federal executive branch employees must conduct themselves within the parameters of executive branch ethics.

AN INTRODUCTION TO PUBLIC HEALTH LAW FOR LEADERS AND CLINICIANS

In the military, the *Joint Ethics Regulation*⁴ supplements the general executive branch rules. However, ethics rules for government employees are really standards of conduct; norms and morality go beyond these defined standards. Norms and morality address the rights and wrongs that are widely shared by society. Some are universal, while others are particular to certain communities. They are not absolute. Sometimes they conflict and then require balancing. In many ways, balancing norms and moral claims is similar to the process leaders and clinicians use when balancing public good versus individual needs; it could be characterized as a public health cost-benefit analysis. Instead of quantifiable health gains or losses, leaders and clinicians identify, weigh, and balance the moral interests that are at stake.

This reflection and balancing is not easy and often people take different ethical approaches such as utilitarianism, liberalism, or communitarianism, to name a few. Since ethical reflection, deliberation, and analysis is difficult, codes of ethics have been developed over the years. A code provides a statement of moral norms to guide professionals within their practice and professional lives. A code lays a foundation of trust between professionals and those they serve. For example, federal executive branch employees follow the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR §2635). Another example relevant to public health officials is the Principles of Ethical Practice of Public Health developed by the Public Health Leadership Society.⁵

COMMON PUBLIC HEALTH ISSUES

While the modern health officer must be an educator and a statesman, rather than merely a police officer, many of his duties are still necessarily concerned with law enforcement...Health officers must be familiar not only with the extent of their powers and duties, but also with the limitations imposed upon them by law.⁶

Emergencies

Generally, emergency declarations are issued after a public health event begins. Some states have adopted statutes that provide very detailed standards for actions in a public health emergency. Some declarations limit police powers while others are silent, which may give local health departments broad powers under a state's police powers. The US Constitution gives the President broad powers to manage national security threats like bioterrorism, and the President can also react to a state's request for emergency support. The Federal Emergency Management Agency can then assist local authorities by providing emergency housing, water, and other supplies and loans. Of great interest is the development of

Emergency Management Assistance Compacts (EMAC) between the states. These contracts, administered by state emergency management agencies and activated by governor-declared emergencies, allow states to share personnel and other resources across state boundaries. Instead of a federal-state relationship, EMACs create a state-state relationship which can be established with or without federal assistance.

Surveillance, Reporting, and Personal Privacy

In the spirit of federalism, state and local governments conduct most communicable disease surveillance, investigation, and intervention under their police powers, while the federal government has the responsibility in controlling diseases related to goods moving in interstate commerce, such as food. Both ideally cooperate when disease threats cross state lines and authorities overlap.

Reporting disease is not a new concept. State and local governments report this information to the CDC, which acts as a national clearing house for state disease reports looking for patterns, tracking emerging diseases, and advising states. However, the CDC does not regulate state or local government public health entities. The OSHA also requires reporting and tracking of occupational diseases based on its authority legislated as allowed under the Commerce Clause (Article I, Section 8, Clause 3) of the US Constitution.

There is no common law physician-patient privilege. Such a privilege was created by state laws in the 1950s. There was no general right of medical privacy until passage of the Health Insurance Portability and Accountability Act of 1996 (Pub L No. 104-191, 110 Stat 1936) enacted on August 21, 1996. The final regulation, the Privacy Rule, was published in December of 2000. However, personal privacy is not absolute when it comes to public health. In 1977, the US Supreme Court found in *Whalen v Roe* (429 US 289 (1977)) that public health reporting of narcotics prescriptions to the New York State Health Department did not violate any constitutionally protected rights. States can require access to records as a condition for medical and facility licensure. The federal government also requires access to records as a condition for participating in federal payments programs. Finally, even when individuals or businesses are not regulated by a state or the federal government, a court order may grant access to information otherwise inaccessible.

Environmental Health

Leaders and clinicians also must consider environmental matters when considering public health. Are environmental law and public health law 2 separate legal disciplines? Yes, but they often overlap and must be

considered together. Until the early 1900s, almost all environmental health regulation was done by state and local governments. Since the 1960s, the federal government has taken the lead with laws such as the Clean Air Act (Pub L No. 88-206, 77 Stat 392 (1963)), the Clean Water Act (Pub L No. 92-500, 86 Stat 816 (1972)), and the Comprehensive Environmental Response, Compensation, and Liability Act (42 USC §9601-9675 (1988)). These laws may in fact preempt state laws. Then again, the federal laws set minimum standards which are implemented and enforced by the states. In some instances, the state standards may be stricter than the federal standards or incorporate a wider scope. In addition, federal agencies such as the Environmental Protection Agency, the Department of Agriculture, the Agency for Toxic Substances and Disease Registry, and state environmental departments along with large city and county health departments have roles in the regulation of environmental public health. Many players are involved in the mix and cooperation among them is vitally important.

Occupational Health

As with environmental health, occupational health law often finds itself separate from public health law, but the two cannot help but overlap. When there is workplace injury, states have worker's compensation laws that are administered by state agencies rather than the courts to provide limited compensation to employees. The federal equivalent is the Federal Employee's Compensation Act (5 USC 8101 et seq (1916)) which provides workers' compensation to civilian federal employees for workplace injuries. However, the US Congress recognized that worker's compensation laws did not create sufficient incentive to reduce occupational injury, so it created OSHA and the National Institute for Occupational Safety and Health (NIOSH), which is part of the CDC and researches and funds programs to reduce work-related injury. As part of the Department of Labor, OSHA sets and enforces standards for workplace safety and health. The NIOSH provides scientific input for OSHA regulations.

CONCLUSION

This article has briefly touched the surface of public health law, but hopefully it has given the reader a sense of the extent and depth of this incredible area of the law. Like the public health sector itself, this area of the law is constantly growing and constantly changing. Public

health law is by no means static. It is a challenging area of law which is regularly, invariably addressing new issues. The necessity for public health and legal professionals well-versed in both the substance and nuance of public health law is growing, with no end in sight.

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Using the Army Medical Cost Avoidance Model to Prioritize Preventive Medicine Initiatives

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An ounce of prevention is worth a pound of cure.
Benjamin Franklin

In today's fiscally constrained environment, Benjamin Franklin's words could not be more relevant. As budgets shrink, the importance of prioritizing resources to yield the greatest effect is paramount. Demonstrating the effectiveness of newly proposed programs or program modifications is a challenging task that demands objective data in order to make informed decisions. Statistical data can be a powerful tool to demonstrate the potential of a medical prevention program, however, the available statistics have limited application to specific prevention programs. Typically, information from the Bureau of Labor Statistics (BLS) is used to support a global preventive medicine program's potential. The available information from BLS is limited to the number of lost work days due to injuries and illnesses for general occupations.¹ The BLS information is dependent on reporting and does not include lost time cost and permanent disability cost. Information, such as that from the BLS, is aggregated in such a manner that the assumptions and limitations required to use it degrades the usefulness of the data, resulting in limited utility. For example, BLS-presented data on nonfatal injuries and illness requiring time away from work is categorized by general occupational (ie, laborers, nursing assistants) and injury category (overexertion, falls, slips, trips) to report the top occupation and injuries in the workforce. The BLS provides the number of lost work days but no associated costs for medical treatment or lost time. These metrics captured from workers' compensation and employer reporting data do not provide the user the capability to accurately predict costs. There are a variety of return on investment (ROI) models available which are simply performance measures that analyze the efficiency of an investment. In a business sense, it is one way of comparing profit or loss compared to the amount invested. Two key elements are required to accurately apply a ROI model to the avoidance of medical costs: the total medical costs associated with an injury or illness, and the total mitigation or prevention costs. The Medical Cost

Avoidance Model (MCAM) ICD-9* Analysis Tool was developed to meet the challenging need for an ROI model that captures the full spectrum of medical costs.

THE MEDICAL COST AVOIDANCE MODEL ICD-9 ANALYSIS TOOL

The Health Hazard Assessment Program, a program within US Army Institute of Public Health, has developed a MCAM ICD-9 Analysis Tool that bridges the gaps among medical cost components (medical costs, lost time, disability, etc.) and provides the user with a comprehensive tool to demonstrate ROI for prevention programs. The MCAM is a web-based tool now available on the US Army Public Health Command website.³ The ICD-9 Analysis Tool of the MCAM was designed with prevention program developers in mind and provides the medical costs associated to specific ICD-9 codes.² When a patient is seen by a healthcare provider, the visit is documented through the use of one or more ICD-9 diagnosis codes, which is associated with a specific treatment cost.

The MCAM ICD-9 Analysis Tool links cost data from 3 primary sources to calculate total medical costs: the Military Health System (MHS) (medical treatment and fatality costs), the Army Military-Civilian Cost System (AMCOS) (personnel cost for lost time), and the US Department of Veterans Affairs (VA) (permanent disability cost). Medical treatment data from the MHS includes outpatient and inpatient treatment provided to eligible personnel in military and civilian treatment facilities. The MCAM uses data from the active duty Army population from fiscal years (FY) 2010, 2011, and 2012.

Each of the MCAM cost components defined in Table 1 are summed to produce the total medical cost (C_t) using the simple calculation: $C_t = C_c + C_h + C_l + C_f + C_d$. The MHS data are the backbone for the ICD-9 Analysis Tool, while the ICD-9 code itself is the common link in

*The International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) is the official system of assigning codes to diagnoses and procedures associated with hospital use in the United States.²

determining total medical cost from medical treatment, lost time, fatality, and disability. The methodology used to capture these medical costs is summarized below.

Medical Treatment Cost. The medical treatment cost (known in the model as clinic and hospital cost) is derived from the average cost per diagnoses by calculating the average number of clinic visits or hospital stays and the average cost per clinic visit or hospital stay per ICD-9 diagnosis.

Lost Time Cost. The lost time metric for each clinic visit and hospital stay is calculated using the assumptions that a direct care clinic visit at a military treatment facility requires 2 hours; a purchase care clinic visit at a civilian provider requires 4 hours, and each day in the hospital equates to 8 hours of lost time from work. These assumptions were developed through interviews with military healthcare providers. A disposition is recorded in the MHS at the conclusion of a clinic visit or hospital stay for direct care and inpatient purchased care. The 3 dispositions captured per ICD-9 diagnosis code in support of the lost time portion of the MCAM are: (a) assignment to quarters (bed rest), (b) convalescent leave, and (c) limited duty assignment (reduced productivity). A timeframe is assigned with each disposition and linked to the averaged adjusted military personnel salary from the AMCOS Lite database.⁴ The military personnel salary is adjusted to reflect the full burden of the lost time cost, including costs of other benefits and entitlements such as retired pay accrual and medical support cost attributed to each Soldier outside of the base pay. The method of capturing lost time by specific ICD-9 codes is unprecedented. Linking lost time directly to ICD-9 diagnoses captures information on injuries and illnesses that otherwise go unreported.

Fatality Cost. Fatality costs are also derived from disposition data in the MHS. Each fatality per ICD-9 diagnosis is assigned \$500,000, which is the combined maximum amount of Servicemember's Group Life Insurance (SGLI) and the death gratuity benefit paid to the survivors of a Soldier who dies while on active duty. The SGLI is a VA program that provides group life insurance to members of the uniformed services. Service members are automatically insured under SGLI for the maximum amount of \$400,000 unless they elect to reduce the insurance coverage.⁵ The death gratuity is a one-time, nontaxable payment of \$100,000 to help surviving family members deal with the financial hardships that accompany the loss of the service member.⁶

Disability Cost. The ICD-9 diagnoses are associated to VA disability compensation through a mapping tool

developed by the Veterans Health Administration (VHA).⁷ The VA disability compensation is a tax-free monetary benefit paid to Veterans on a monthly basis.⁸ The amount paid is dependent on the severity of the disability as rated by the specific Veterans Administration Schedule for Rating Disabilities (VASRD) coding.⁹ The mapping used in the MCAM correlates ICD-9 codes to the 4-digit VASRD code in order to determine the permanent disability costs. It is important to note that not all ICD-9 diagnoses result in a permanent disability.

THE MCAM IN ACTION: AN ICD-9 ANALYSIS FOR THE SAFE PATIENT HANDING AND MOBILITY PROGRAM

Healthcare providers are at a high risk for musculoskeletal disorders (MSD) because they are required to manually move patients. According to the BLS, nursing-related professions have among the highest rate of workplace injuries. In 2012, the BLS reported that

In healthcare and social assistance,...MSDs made up 42[%] of cases and had a rate of 55 cases per 10,000 full-time workers. This rate was 56[%] higher than the rate for all private industries and second only to the transportation and warehousing industry.¹⁰

However, the true number of musculoskeletal injuries related to manually handling patients is unknown because there is a high rate of underreporting in nursing staff. According to Hart, about one in 4 (25%) nurses and one in 3 (33%) radiology technicians who have experienced on-the-job injuries did not report those injuries to their employer in at least one instance.¹¹ The most common reasons cited for not reporting injuries among both groups of hospital employees are: injuries are a part of the job; it's not worth making a report because nothing will happen; and not having enough time.¹¹ The musculoskeletal injuries suffered by healthcare workers can result in early retirement and lifelong disability resulting in a loss of experienced clinical providers. An estimated 12% to 18% of nursing personnel leave the profession annually due to chronic back pain, and another 12% consider a job transfer to reduce their risk of back injury.¹²

Table 1. The MCAM Medical Cost Components, Definitions, and Descriptions.

Cost Component	Definition	Description
C _c	Clinic cost	Outpatient treatment
C _h	Hospital cost	Inpatient treatment
C _l	Lost time cost	Time away from work due to clinic visits, hospital stays, assignment to quarters, convalescent leave, and the limited ability to perform.
C _f	Fatality cost	Insurance and gratuity pay
C _d	Disability cost	VA compensation disability

USING THE ARMY MEDICAL COST AVOIDANCE MODEL TO PRIORITIZE PREVENTIVE MEDICINE INITIATIVES

The Ergonomic Program of the US Army Public Health Command developed Safe Patient Handling and Mobility Programs (SPHMP) for the US Army Medical Command to reduce the incidence of musculoskeletal disorders related to patient handling in civilian and military healthcare providers. The SPHMP program elements were designed through collaboration with the VHA, a leader in research and innovation regarding safe patient handling practices worldwide. The SPHMP is a well-coordinated programmatic approach to implementing a new standard of practice that is designed to focus on the patient's care and clinical outcomes while minimizing staff injury. The SPHMP is a multifactorial model that includes ergonomic patient handling and movement site assessments, education and training, and the facility wide installation of safe patient handling equipment, policy and unit champions. Additionally, the 2010 Facility Guidelines Institute (FGI) *Guidelines for Design and Construction of Healthcare Facilities*¹³ requires that patient handling and movement assessments (PHAMA) be conducted for new construction and renovation to identify appropriate patient handling equipment requirements for each area and to determine the space and construction needs to incorporate safe patient handling equipment.

The majority of the cost required for SPHMPs is safe patient handling equipment costs. In addition to the 2010 PHAMA requirement, the FGI published a white paper which included guidance on appropriate ceiling lift coverage.¹⁴ Traverse ceiling lifts are recommended for the majority of inpatient rooms in acute care settings and are preferable to floor-based lifts due to their usability, convenience, and space-saving accessibility. Ancillary equipment such as patient lift slings are stored in patient rooms and are laundered with general linens. In contrast, floor-based patient lift equipment has a large footprint and is frequently kept in storage closets away from patient rooms. In a study by Marras, the use of ceiling lifts resulted in safe forces on the lumbar spine while use of floor-based equipment had potential to increase forces acting on the lumbar spine to unacceptable levels.¹⁵

Generally, traverse ceiling lifts can range from \$5,000 to \$10,000 per unit depending on manufacturer, weight capacity, and design features. Additional costs include ancillary equipment such as repositioning sheets and slings. The estimated cost for a 200 bed hospital to install ceiling lifts is \$750,000, which includes the installation of ceiling lifts and supporting equipment for approximately half of all inpatient rooms as well as physical therapy, radiology, operating room, emergency department, and other ancillary areas. For the purposes of this article, \$750,000 will be considered the project costs.

Collins reported that SPHMPs reduce workers' compensation injury rates by 61%, lost workday injuries rates by 66%, restricted workdays by 38%, as well as the number of workers suffering from repeat injuries.¹⁶ The VHA has been successful in increasing patient and staff satisfaction while decreasing modified duty days (70%), lost time for injuries (18%), and the number (30%) and severity of injuries among patient handlers by implementing a SPHMP.¹⁷ In addition to the health outcomes for both patient and provider, it is important to demonstrate the cost effectiveness and return on investment for the costs associated with implementation of these programs. The ICD-9 Analysis Tool² can provide the medical cost avoidance to support the implementation of SPHMPs.

THE ICD-9 ANALYSIS TOOL USER INTERFACE

The ICD-9 Analysis Tool user interface is straightforward and requires only minimum information from the user to provide the total medical cost avoided. The user is required to name the project, select the ICD-9 code either through the drop down list for the 3 digit filter or through the text filter, and provide the number of cases expected to be avoided with the number of years of the given project. Model background information and input guides are available by clicking on the question mark buttons on the user interface as shown in Figure 1. The total medical cost avoidance is delivered by clicking the Calculate Cost Avoidance button (outlined in red in Figure 1). The Details link provides a pop-up window itemizing the cost components. A full report is produced by clicking the Print Results button.

A recommended starting point for using the MCAM's ICD-9 Analysis Tool is to determine the number of cases expected to be avoided per year and the number of years the program is anticipated to be in effect. Our example for the Army Healthcare Specialist (military occupation specialty (MOS) 68W) begins with a 3-year (FY 2010-FY 2012) data analysis of ICD-9 and MOS from the MHS using the MHS Management Analysis and Reporting Tool (M2). Table 2 presents the average case count, average cost per case, and accumulated incidence of selected ICD-9 diagnoses in active duty Army Healthcare Specialists for an unnamed medical facility. The Healthcare Specialists are a population of enlisted Soldiers working in medical facilities who are subject to performing tasks associated with manual transfer of patients. The data in Table 2 was derived by catchment area Defense Medical Information System ID Code for a hospital identified as "Hospital X." The data includes inpatient and outpatient treatment performed through direct and purchased care. The ICD-9 codes identified in Table 2 were selected because they are injuries commonly associated with patient handling.

Figure 1. MCAM ICD-9 Analysis Tool user interface.

THE ICD-9 CASE ANALYSIS REPORT

Theoretically, the medical treatment cost presented in Table 2 provides some medical cost savings on its own, however, it only presents a portion of the cost. The lost time associated with the treatment is often the largest cost component. We assumed that 25% of the case count for the 2 ICD-9 codes with the highest case count from Table 2 was attributed to patient handling. We entered 45 cases for ICD-9 code 7242 (lumbago) and 17 cases for ICD-9 code 7245 (backache NOS (not otherwise

specified)) for cases avoided per year. We entered 10 for the total years because the expected life for a ceiling lift is 10 years. The cost of the equipment (\$750,000) was entered as the project cost.

The ROI estimated by the ICD-9 Analysis Tool for the SPHMP is \$13,499,480, approximately 18 times the amount invested. The user is provided a summarized report (Figure 2) that itemizes the cost components for each ICD-9 code entered. The ROI is the net grand total located at the bottom line of the report. A one-year cost is also provided in each report. The report can be printed directly from the application.

There are no calculated costs for the disability and fatality components in this example. As noted on the bottom of each MCAM ICD-9 Case Analysis report, both of these components will remain zero until the number of avoidable cases entered exceeds certain thresholds. The disability costs are based on the prevalence of the most probable VASRD associated with the queried ICD-9 diagnosis among the Army veteran population.

Table 2. Back Injuries for Active Duty Healthcare Specialists* at Hospital X.				
ICD-9	Description, Short	3 Year Average (FY 2010 - 2012)		
		Case Count	Average Cost/Case	Incidence [†]
7241	Pain in thoracic spine	37	\$364	2.87
7242	Lumbago	181	\$451	14.06
7244	Lumbosacral neuritis NOS [‡]	23	\$1,228	1.75
7245	Backache NOS [‡]	66	\$318	5.10
7248	Other back symptoms	27	\$332	2.10

*Military Occupational Specialty 68W
[†]Accumulative incidence per 100
[‡]NOS indicates not otherwise specified.

USING THE ARMY MEDICAL COST AVOIDANCE MODEL TO PRIORITIZE PREVENTIVE MEDICINE INITIATIVES

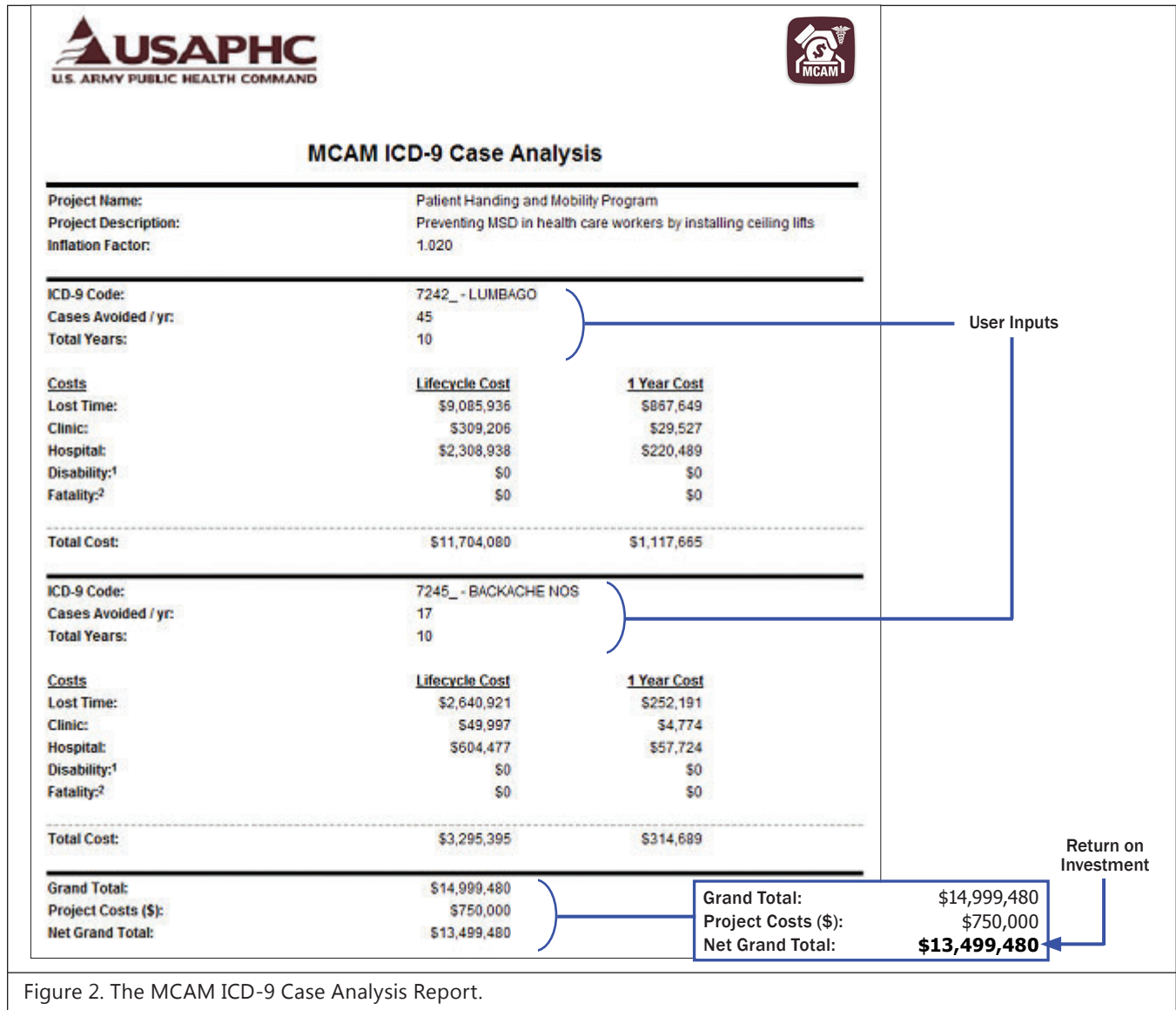


Figure 2. The MCAM ICD-9 Case Analysis Report.

Fatality costs are based on the incidence of fatality for the queried ICD-9 diagnosis in active duty Army personnel. Not every ICD-9 diagnosis will result in disability or a fatality.

SUMMARY

The MCAM's ICD-9 Analysis Tool provides preventive medicine program developers with a powerful tool to demonstrate ROI. Previously disjointed cost components have been brought together in the MCAM to calculate the total medical cost avoided. Users are required to make 4 data entries. In response, the user receives the highly coveted medical cost avoidance that should be realized. The SPHMP example demonstrates how simple it is to use the MCAM to determine the expected ROI.

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The Public Health Specialist Program at the Medical Education and Training Campus

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The Medical Education and Training Campus (METC) was established as part of the 2005 Base Realignment and Closure Commission legislation requiring the Air Force, Army, and Navy to collocate enlisted basic and (most) specialty medical training at Joint Base San Antonio Fort Sam Houston, Texas. The METC achieved initial operating capability on June 30, 2010, becoming fully operational on September 15, 2011. Currently, METC has 9 academic Departments and 51 programs. More than 21,000 Air Force, Army, Navy, Marines, Coast Guard, and international students graduate from METC each year. An average of 7,000 students are on campus at a given time.

The Public Health Specialist Program, along with the Behavioral Health Program, falls under the Department of Public Health. Originally named the Preventive Medicine Program, the name was changed to the Public Health Specialist Program in the fall of 2013 to better align the training with civilian equivalents. The program graduates Army Preventive Medicine Specialists (Military Occupational Specialty 68S) and Navy Preventive Medicine Technicians (Navy Enlisted Classification Code HM-8432). The first class of the Preventive Medicine Program graduated on October 26, 2011. Since then, more than 1,000 students have graduated from the program at METC.

In 2013, the program initiated a major curriculum overhaul to improve the quality of the training by updating courses, better incorporating technology into instruction, and realigning some courses. The new curriculum is scheduled for implementation in the summer of 2014. This article describes both the current and revised curriculum for the Public Health Specialist Program at METC and discusses the benefits of the program for students, faculty, and the military services.

OVERVIEW

The Public Health Specialist Program consists of a consolidated phase as well as service-specific tracks. Each course begins with the consolidated phase, during which Army and Navy students are together for 400 hours of

training, covering a variety of topics required by both services. Once the consolidated portion of the training is complete, the students separate into service-specific tracks to receive instruction on requirements unique to the Army and Navy respectively. Army students have 208 instructional hours in the Army-specific portion of their training, while Navy students have 544 instructional hours in their service-specific training. Under the current curriculum, the American Council on Education recommends that award of 9 undergraduate credit hours for Army students and 12 hours for Navy students.

The program faculty consists of 2 Army officers (one Entomologist and one Environmental Science and Engineering Officer), one Navy Environmental Health Officer, 9 Army noncommissioned officers (NCOs), and 7 Navy NCOs. The Program Director is either an Army or Navy officer, as the position alternates between the services.

There are 7 courses within the consolidated portion of the training: Introduction to Preventive Medicine, Medical Threat, Food Service Sanitation, Aspects of Water, Entomology, Operational Preventive Medicine, and Deployment Environmental Surveillance Program. Introduction to Preventive Medicine provides students with a brief overview of Preventive Medicine and sets the stage for the remainder of the training. The Medical Threat course prepares students to prevent and reduce disease and injury in operational settings and to communicate preventive medicine issues in a briefing format. Food Service Sanitation prepares students to inspect food service operations and provide consultation to food service staff to correct deficiencies. As part of the Food Service Sanitation Course, students have the opportunity to earn the ServSafe certification from the National Restaurant Association. During Aspects of Water, students learn to test water for a variety of uses, interpret those results, and make appropriate recommendations to ensure that water is safe for its intended use. The Entomology course introduces students to the basics of pest control and vector borne disease prevention. Upon successful completion of this course, students earn Department

of Defense Pesticide Applicator Certification in the following Environmental Protection Agency pest control categories: Right-of-Way Pest Control; Industrial, Institutional, Structural, and Health-related Pest Control; and Public Health Control. The Operational Preventive Medicine course concentrates on specific preventive medicine measures, including operational risk management procedures used during disaster and humanitarian relief missions, base camp assessments, and medical threat assessment. Finally, the Deployment Environmental Surveillance Program prepares students to perform air, water, and soil surveillance, and document potential adverse health exposures in an operational environment.

The Army-specific training consists of Army Public Health, Health Physics, Industrial Hygiene (IH), and a Situational Training Exercise (STX). Army Public Health provides students with an understanding of Army programs related to health and wellness, including the Military Vaccine (MILVAX) program, sexually transmitted disease prevention, and epidemiological investigations. The Health Physics course provides students an introduction to chemical, biological, radiological, and nuclear event response. In the IH course, students learn the fundamentals of industrial hygiene. Upon successful completion of IH, students receive certification in Basic Industrial Hygiene from the Army Medical Department Center and School (AMEDDC&S). The final event for Army students is a capstone STX. The STX is scenario driven and requires students to draw from all of the courses they have taken to address a variety of preventive medicine problems and deliver a briefing summarizing their findings and recommendations to mitigate health threats in the given scenario.

The Navy-specific training consists of Public Health Administration, Communication, Biostatistics, Epidemiology, Microbiology, Parasitology, Immunization Programs, Occupational Safety and Health, Shipboard Preventive Medicine, Environmental Sanitation, and a Final Evaluation Exercise (FEX). Public Health Administration provides Navy students with a basic understanding of how Preventive Medicine fits into Navy Medicine. The Communication course lays the groundwork for students to effectively communicate public health messages in their future assignments. Biostatistics gives students an introduction into the fundamentals of statistics. Epidemiology covers the principles of disease investigation, reporting, and prevention. The Microbiology course examines the impacts that microorganisms have on humans and the environment. Parasitology introduces students to parasites that can affect human health and their epidemiology. The Immunization Programs course provides students with an understanding of the MILVAX program

and prepares them to manage immunization programs in their future assignments. Occupational Safety and Health provides an introduction to the Navy's Occupational Safety and Health Programs. Shipboard Preventive Medicine covers potable water supply requirements for operational forces afloat and the procedures for wastewater treatment and disposal for forces afloat. Environmental Sanitation covers sanitation and infection control, both ashore and afloat. The FEX is the capstone event for Navy students. The FEX is scenario driven and requires students to synthesize the information that they learned throughout the program to address real-world situations, preparing written and oral products for evaluation.

REVISED CURRICULUM

In the summer of 2014, the Public Health Specialist program will begin teaching the revised curriculum, which is designed to increase the individual Soldier or Sailor's readiness to perform their mission upon graduation. While many of the individual courses have the same titles in the revised curriculum, the entire program was carefully reviewed for accuracy of content, currency of materials, and synchronization between test questions and lesson objectives. Ensuring that the program addresses requirements outlined in the Army Critical Task List (CTL) for Preventive Medicine Specialists and the Navy Job Duty Task Analysis (JDTA) for Preventive Medicine Technicians was a major consideration in developing the new curriculum. Once the training requirements for Army and Navy students were identified from the CTL and JDTA, they were cross-referenced to determine which can be taught in a consolidated environment and those that are so unique to one of the services that they must be taught in the service-specific portions of the course. In addition, the new curriculum seeks to target higher levels of learning in both the cognitive and psychomotor domains than presented by the earlier curriculum. This will increase the level of difficulty in many of the courses and help to ensure that better prepared students are graduating from the program.

Under the revised curriculum, the order of courses within the consolidated phase was shifted to generate a better flow and some content was moved from the service-specific portion of the training to the consolidated portion to reduce redundancy. As a result, the consolidated portion of the program will increase from 400 to 460 instructional hours; the Army phase will decrease from 208 to 180 instructional hours; and the Navy phase will decrease from 544 to 516 instructional hours. The comparison of the current and revised curriculum in terms of hours spent in each course and the order of courses is presented in the Table. After implementation, the new curriculum will be presented to the American Council

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on Education for review to determine the number of undergraduate credits earned by Army and Navy students.

Under the revised curriculum, Military Public Health and Communication are added to the consolidated portion of the training. Military Public Health brings material previously taught in each of the service-specific portions of the program together to provide Army and Navy students an overview of public health in the military, and better sets the stage for the courses that they will take throughout the rest of the program. The Communication course is moved from the Navy-specific portion of the program to the consolidated phase to provide both Army and Navy students with the fundamentals of preparing and presenting briefings, a critical skill for success throughout the program as well as in their careers. In an effort to better streamline the program, the Medical Threat and Operational Preventive Medicine courses are combined into a single course named Operational Preventive Medicine. The order of courses was adjusted in the new curriculum to create a more natural flow with courses that build on each other grouped together. The order of courses is shown in the Table.

The Army Public Health course is removed from the Army-specific training under the revised curriculum, with the tasks previously taught in that portion of the curriculum moved to the Military Public Health course in the consolidated phase. Health Physics and Industrial Hygiene remain in the Army-specific portion of the curriculum, with students still receiving the Basic Industrial Hygiene certification from the AMEDDC&S following completion of the latter course. The STX now conducted on Ft. Sam Houston will transition to a Field Training Exercise (FTX) which will be conducted at Camp Bullis, Texas.

The Navy-specific portion of the course is slightly shorter under the revised curriculum, with the Communication course shifted to the consolidated curriculum. Furthermore, the new curriculum will incorporate Shipboard Pest Management, which has not been previously taught at METC, into the Shipboard Preventive Medicine course. In order to better prepare our Sailors for their missions afloat, the Navy-specific training will incorporate a field trip to Corpus Christi Naval Air Station to give Sailors an opportunity for hands-on training in some of the tasks that are unique to Shipboard Preventive Medicine.

COMMENT

Consolidated training at METC presents a wide array of benefits to the students, instructors, and the military services. In order to maximize the benefits of an education at METC, curriculum should be developed that incorporates consolidated training as much as possible while balancing the unique needs of each service. The Public Health Specialist Program presents an effective, high-quality, academic program that strives to exploit the advantages of training within the METC environment.

By far, the greatest advantage of the consolidated Public Health Specialist Program at METC is that it prepares our students from very early in their careers to understand and work with individuals from other services. During Operations Iraqi Freedom and Enduring Freedom, military preventive medicine personnel worked in an increasingly joint environment. For many of our service members, the first time that they were exposed to another service culture was in the high stress, deployed environment. The establishment of METC enabled this experience to become part of the early indoctrination of our service members into military medicine.

During the consolidated portion of training, Army and Navy students begin each day reciting in turn the *Soldier's Creed* and the *Sailor's Creed*, and singing both

Current and Revised METC Public Health Specialist Program Curricula.		
Phase	Current Curriculum	Revised Curriculum (Effective summer 2014)
Consolidated	Introduction to Preventive Medicine Medical Threat Food Service Sanitation Aspects of Water Entomology Operational Preventive Medicine Deployment Environmental Surveillance Program	Introduction to Preventive Medicine Military Public Health Communication Food Service Sanitation Aspects of Water Deployment Environmental Surveillance Program Operational Preventive Medicine Entomology
Army-specific	Army Public Health Health Physics Industrial Hygiene Situational Training Exercise	Health Physics Industrial Hygiene Field Training Exercise)
Navy-specific	Communication Public Health Administration Biostatistics Epidemiology Microbiology Parasitology Immunization Programs and Vaccines Shipboard Water Sanitation Occupational Safety and Health Environmental Health Final Evaluation Exercise	Public Health Administration Microbiology Biostatistics Epidemiology Parasitology Immunization Programs and Vaccines Occupational Safety and Health Environmental Sanitation Shipboard Preventive Medicine Navy Final Evaluation Exercise

Anchors Aweigh and *The Army Goes Rolling Along*. Throughout the first 3 months of training, students work together across services on projects, in study groups, and as teammates. They are taught by members of each service, getting different perspectives and experiences to draw from in their own careers. By the completion of the consolidated courses, they are a cohesive team in which students better understand the culture of each service and are prepared to work in joint environments in the future.

Faculty members also benefit from the consolidated nature of the program for many of the same reasons. Regardless of the uniform that an individual instructor wears, all instructors in the program are responsible for teaching and mentoring both Army and Navy students at the start of their careers in preventive medicine. Working together as a team, the instructors learn to communicate effectively within each service culture. By the time program faculty depart METC, they have a solid understanding of both the similarities and the differences of the military services and are themselves better prepared to serve in joint environments in the future.

Given the benefits of the consolidated training in the Public Health Specialist Program to both students and faculty, it is clear that the nature of the program will ultimately benefit the services by helping to develop Sailors

and Soldiers who have a less parochial view of their role within the military. As more service members graduate from the academic programs at METC and begin their careers in Military Medicine, the benefit of consolidated training will continue to grow. By developing curricula that seeks to reduce service-specific channeling as much as possible, the Public Health Specialist Program at METC is one small piece of the larger effort to improve integration of the capabilities and interoperability of military services across the full spectrum of Military Medicine.

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Medical Education and Training Campus Public Health Specialist Program students performing entomological surveillance. Photo courtesy of Ms Lori Newman, JBSA Fort Sam Houston Public Affairs Office.

Managing Public Health in the Army Through a Standard Community Health Promotion Council Model

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ABSTRACT

Context: Public health processes in the US Army remain uncoordinated due to competing lines of command, funding streams and multiple subject matter experts in overlapping public health concerns. The US Army Public Health Command (USAPHC) has identified a standard model for community health promotion councils (CHPCs) as an effective framework for synchronizing and integrating these overlapping systems to ensure a coordinated approach to managing the public health process.

Objective: The purpose of this study is to test a foundational assumption of the CHPC effectiveness theory: the 3 features of a standard CHPC model—a CHPC chaired by a strong leader, ie, the senior commander; a full time health promotion team dedicated to the process; and centralized management through the USAPHC—will lead to high quality health promotion councils capable of providing a coordinated approach to addressing public health on Army installations.

Design: The study employed 2 evaluation questions: (1) Do CHPCs with centralized management through the USAPHC, alignment with the senior commander, and a health promotion operations team adhere more closely to the evidence-based CHPC program framework than CHPCs without these 3 features? (2) Do members of standard CHPCs report that participation in the CHPC leads to a well-coordinated approach to public health at the installation?

Conclusions: The results revealed that both time ($F_{(5,76)}=25.02, P<.0001$) and the 3 critical features of the standard CHPC model ($F_{(1,76)}=28.40, P<.0001$) independently predicted program adherence. Evaluation evidence supports the USAPHC's approach to CHPC implementation as part of public health management on Army installations. Preliminary evidence suggests that the standard CHPC model may lead to a more coordinated approach to public health and may assure that CHPCs follow an evidence-informed design. This is consistent with past research demonstrating that community coalitions and public health systems that have strong leadership; dedicated staff time and expertise; influence over policy, governance and oversight; and formalized rules and regulations function more effectively than those without. It also demonstrates the feasibility of implementing an evidence-informed approach to community coalitions in an Army environment.

The United States Army uses a community coalition approach called community health promotion councils (CHPC) as a strategic platform to manage the Army Public Health System. The Army is organized across functional chains of command. The Army Public Health System has subject matter experts on various public health concerns in these different systems. Assets can be found as a part of the medical system, the installation management system, or as a part of tactical operations at the mission level. Each of these systems plays a part in managing the overall public health system for the Army installation. The driving force for the standardization of integrating the Army's Public Health System through

the CHPC is *Army Regulation 600-63*.¹ It defines health promotion as:

...any combination of health education and related organizational, political, and economic interventions designed to facilitate behavioral and environmental changes conducive to the health and well-being of the Army community.^{1(p6)}

Community health promotion councils are designed to manage a coordinated approach to local public health at Army installations and integrate health promotion and disease prevention into the Army's business practices. Because CHPCs are essential to the Army's strategy to

address public health concerns, there is a strong need to document and evaluate the evidence supporting their effectiveness.² Therefore, this study:

1. Describes the need for a CHPC model to coordinate the Army public health system.
2. Outlines the CHPC model and the evidence that informs its development.
3. Reports the results of initial studies of CHPC effectiveness.
4. Establishes an agenda for future research.

THE NEED FOR ARMY COMMUNITY HEALTH PROMOTION COUNCILS

Within most public health systems, the various components are typically owned and operated by different organizations such as schools, hospitals, and community health departments. Integration among these elements in the public health system is defined by their ability to agree on overall objectives, freely share information, and plan and implement complementary activities in the context of an agreed upon overall health response plan.³ Research shows that effective coordination among stakeholders in public health allows public health systems to achieve their mission, address health problems and respond to economic and performance demands.⁴ For example, integrating stakeholders within a public health system resulted in a dramatic rise in funding for single-disease or population-group-specific programs such as immunizations, malaria, and HIV/AIDS.⁵

Conversely, a fragmented approach to public health leads to duplication of services, conflicting recommendations to fix problems, medical errors, misunderstanding or lack of awareness of the true causes of problems, increased costs, public health errors, and ultimately poorer population health.⁶ The Institute of Medicine reports that failures in system capabilities are often a result of how public health services are organized and delivered across communities.^{7,8} Systemic errors occur, including poor reporting and communication of population health trends rather than technical failures.^{9,10} These concerns led the field of public health to a wide-spread acknowledgement of a need for strong and integrated services within public health systems.¹¹

Research demonstrates that integration within a public health system is largely driven by the extent to which there are clear processes and a strong governing body regulating the interaction of agencies and organizations. Further, effective governance involves bringing constituents together and facilitating their actions within the system to accomplish system-wide goals. The system

should document and disseminate how the various components of a public health system function; provide their constituents with information about the evidence supporting programs, policies, services, and the effectiveness of other public health practices; and ensure the access of target populations to those services.¹² The information collected through the public health system and its governing body allows the effective allocation of resources, maximizes the collective impact of public health practices within the system, and allows public health stakeholders to methodically identify system strengths and weaknesses.¹³

Similarly, Army installations operate with interdisciplinary, complex systems that affect the health and well-being of the Army communities. For example, Army installations are governed through traditional, functional chains of command. Generally, these functional lines are mission or tactical operations (war-fighting, Soldier training and development, strategic operations); garrison operations (programs, services, facilities); and medical operations (healthcare services). The functional areas create many unique and overlapping systems within the overall Army public health system. The functional chains of command have the tendency to stovepipe and create natural silos. This is an efficient approach to ensuring leadership and accountability in achieving specific, clearly-defined missions. However, it creates obstacles and inefficiencies in addressing complex public health issues that require a multidisciplinary approach.

An example: suicide is a major, current public health concern in the Army. However, the ability to prevent suicide in the Army is within the purview of multiple commands and Army agencies. The Medical Command (MEDCOM) employs behavioral health providers that treat behavioral health disorders among Soldiers,¹⁴ the Army G1 (the Chief of Staff for Manpower and Human Resources) develops and administers a suicide prevention program and other programs that affect risk factors associated with suicide, such as the Army Substance Abuse Program,¹⁵ and the Army G3/5/7 (the Director of Strategy, Plans, and Policy) administers Comprehensive Soldier Fitness, a program designed to train Soldiers to become more psychologically resilient.^{16,17} These programs have complementary missions, but had no formal forum to coordinate their approach to suicide prevention at an installation level.¹⁸ Therefore, Army installation CHPCs evolved to bring representation from different stakeholders to the same table to develop efficient, coordinated approaches to public health concerns without reducing the autonomy of existing systems or disturbing the functional chain of commands in the Army organizational structure. In other words, the goal of the

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CHPC is to build a public health infrastructure and public health system that efficiently and systematically promotes health and prevents disease within the existing Army organizational structure on an installation.

Standard Community Health Promotion Council Model		
Chaired by the senior commander	Organized and managed by the health promotion team	Centrally managed by the US Army Public Health Command

Figure 1. Three critical features of a standard community health promotion council.

The standard CHPC model, illustrated in Figure 1, is marked by 3 critical features. First, the CHPC is chaired by the highest level of leadership on an Army installation (the installation's senior commander). The senior commander champions and leads the CHPC, and provides the authority to influence the programs, policies, and environments that affect the health of the installation's population. Second, the CHPC is organized and managed by a health promotion operations team. The health promotion operations team consists of a health promotion officer (HPO) and a health promotion research assistant (HPRA). The health promotion operations team consists of members of the senior commander's full time staff and is responsible for facilitating the CHPC and ensuring it is consistent with Army regulations and meets the standards developed by the Army Institute of Public Health of the USAPHC. The health promotion team provides subject matter expertise on the public health process to the senior commander's staff and ensures coordination and fidelity to the standard process. This includes ensuring that the CHPC identifies health needs through systematic data collection, sets priorities through a health promotion strategic plan, oversees the development and implementation of health promotion programs and policies to address these priorities, and oversees the evaluation of the effectiveness of programs and policies. The third critical feature of the standard CHPC model is centralized management through the USAPHC. The USAPHC is a subordinate command to MEDCOM and oversees the administration of public health in the Army. It also collaborates with other Army oversight agencies such as the US Army Forces Command, US Army Training and Doctrine Command, the Army Materiel Command, the Army Installation Management Command, as well as other Army senior leaders such as deputy chiefs of staff of the Army and assistant secretaries of the Army to address the Army's public health concerns. Through centralized management, HPOs, CHPCs, and senior commanders are able to remove barriers to healthier communities through USAPHC's influence over programs and policies that are set at higher, strategic levels of the Army. Furthermore, USAPHC's direct oversight of the CHPCs ensures that the CHPCs adhere to an evidence-informed program framework.

Currently, USAPHC funds health promotion officers and health promotion research assistants at Army installations that adhere to the standard CHPC model. The HPOS and HPRAs are located at 12 posts across the continental United States: Aberdeen Proving Ground, MD; Fort Bliss, TX; Fort Bragg, NC; Fort Carson, CO; Fort Campbell, KY; Fort Drum, NY; Joint Base Lewis-McChord, WA; Fort Polk, LA; Fort Hood, TX; Fort Irwin, CA; Fort Riley, KS; and Fort Stewart, GA. Fourteen other installations in this evaluation have established CHPC processes but do not have a designated health promotion officer or health promotion research assistant.

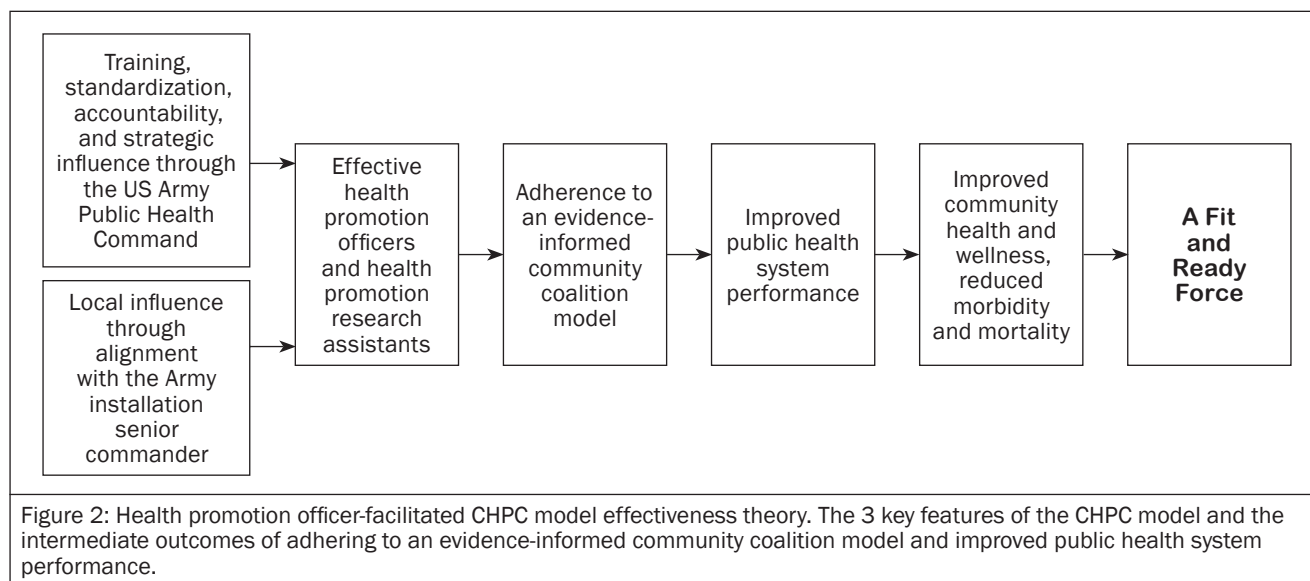
EVIDENCE IN FORMING THE CHPC MODEL AND PROCESS: COMMUNITY COALITIONS

The CHPC standard model is rooted in community coalition action theory¹⁹ and other research on effective community health coalitions. A community coalition is defined as:

...an organization of individuals representing diverse organizations, factions or constituencies within the community who agree to work together to achieve a common goal.^{20(p1)}

The functions of community coalitions are generally to increase capacity through collaboration, help communities build social capital to apply to social and health issues, and to serve as catalysts for change and movement towards desired outcomes (eg, policy change).²¹

The community coalition approach grew out of multiple lines of research. For example, public health research indicates that public health problems are complex and rooted in a society's social and ecological context and should be addressed from multiple directions by multiple actors in the community. Therefore, community coalitions aim to create synergy and opportunities for collaboration to address public health problems across multiple sectors.²² Community coalitions seek to empower communities to advocate for their own health and wellness, which is consistent with research demonstrating that a population's health is more likely to improve when the community itself is engaged and invested in the community coalition process.²³ Furthermore, better health in a community is more linked with the community health system characteristics (eg, health behaviors and environmental factors in the community) than the performance of the healthcare system (eg, accessibility of healthcare).²⁴ Finally, community coalitions that aim to advocate for policy changes are supported by research demonstrating that the most effective strategies to improve the public's health result from changes in policy.²⁵



Research on community coalitions indicates that coalitions can positively affect health indicators such as lead poisoning, adolescent pregnancy, infant mortality, motor vehicle accidents, and tobacco use. For example, the Community Trails Project (a collaborative partnership) contributed to a 10% annual reduction in alcohol involved automobile crashes.²⁶ Also, the Community Intervention Trial for Smoking Cessation contributed to increased quit rates among light to moderate smokers.²⁷ Additional case studies from 20 community coalitions indicate that they have a strong and positive impact on organizational change including leveraging financial resources, developing programs, changing policy, increasing collaboration, increasing community engagement, involvement, and strengthening an organization's health promotion structure.²⁸

Not all community coalitions are equally effective.²⁸ Research consistently finds that the effectiveness of community coalitions is affected by multiple factors. For example, a review of 26 studies concerning community coalition effectiveness found that 5 factors predicted community coalition success in at least 5 studies. These factors include formalization of rules and procedures, leadership style, member participation, membership diversity, agency collaboration, and group cohesion.²⁹ Coalition leadership is a recurring predictor across several reviews. For example, a study of 10 coalitions formed as a part of the America Stop Smoking Intervention Study for Cancer Prevention highlights the importance of good coalition leadership.³⁰

These case studies revealed that task-focus, good communication, quality action plans, and dedicated staff time were related to measures of community coalition

effectiveness such as membership satisfaction, successful action plan implementation, and resource mobilization.³⁰ Other studies suggest that coalition success is facilitated by a supportive organizational climate, ability to affect community norms, power to influence policy, and ability to develop and advocate for primary prevention resources within the community.³¹ Finally, diverse membership, a clear strategic vision, effective conflict resolution processes, a theory-driven approach to the community coalitions, the ability of coalitions to evaluate their effectiveness, and dedicated and competent staff all contribute to the success of community coalitions.²¹

The 3 critical features of the standard CHPC model ensure that many of the indicators of coalition and public health system effectiveness are present in the Army CHPC model. The Army CHPC model is well-positioned to have an affect on policy. The senior commander at an Army installation has the authority to develop, disseminate, and enforce policies that affect the public health. For example, a senior commander at one Army installation learned that Soldiers were experiencing adverse effects from polypharmacy (the prescription of 5 or more medications) because providers were not receiving warnings when placing prescriptions through the electronic profile and pharmacy system.³² The senior commander used the CHPC to convey this issue to the Army hospital commander who ensured warnings to prevent polypharmacy were added to the system.

The Army CHPC model also places a strong emphasis on formalization of rules and policies and can ensure these rules are executed through centralized management. Each standard CHPC is required to execute the prescribed model with specific deliverables, including

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reports of change in public health programs, practices, and policies; annual survey of CHPC effectiveness; report on adherence to the program framework; annual strategic plan; annual marketing plan; annual working group action plans; annual community profile; annual community resource guide; and quarterly program status reports. Health promotion officers provide these deliverables to centralized managers at the USAPHC who ensure the installation health promotion team adhere to the program framework and *Army Regulation 600-63*.¹ Another characteristic of effective coalitions, staff dedication time and expertise, is the primary reason for the HPO position. The HPOs are hired based on their competence in Army culture, leadership, and business management skills, and are trained to appreciate their public health role in improving community health as they collaborate with local and USAPHC public health professionals in areas of surveillance, community health, program planning, implementation, and evaluation.

In summary, the standard CHPC model has several of the core components of an effective community coalition; dedicated staff time and support, formalized rules and procedures, oversight to ensure quality action plans, and power to affect policy and advocate for primary prevention resources through the senior commander. Nonetheless, there are currently no published studies testing the effectiveness of the standard CHPC model. Because the standard CHPC is becoming a key strategy for promoting health and preventing disease and injury within Army populations, additional study to evaluate the model is critical. In an effort to evaluate the standard CHPC model, USAPHC is establishing a process for evaluating and monitoring the model to ensure quality, satisfaction, fidelity, and impacts. The next sections establish the study design, participants, and results.

The purpose of this study is to test a foundational assumption of the CHPC effectiveness theory: the 3 features of a standard CHPC model—a CHPC chaired by a strong leader, ie, the senior commander; a full time health promotion team dedicated to the process; and centralized management through the USAPHC—will lead to high quality health promotion councils capable of providing a coordinated approach to addressing public health on Army installations.

METHOD

Evaluation Questions and Study Design

The study employed 2 evaluation questions:

1. Do CHPCs with centralized management through the USAPHC, alignment with the Senior Commander, and a Health Promotion Operations Team adhere more

closely to the evidence based CHPC program framework than CHPCs without these 3 features?

2. Do members of standard CHPCs report that participation in the CHPC leads to a well-coordinated approach to public health at the installation?

The study addressed the first question with a single factor (CHPC type), 2-level (standard CHPC vs. nonstandard CHPC) evaluation design with CHPC program adherence as the outcome variable. A past evaluation of CHPC effectiveness conducted by the Office of the Secretary of Defense for Health Affairs showed that the effect of the critical features of the standard CHPC model was moderated by the amount of time a CHPC had been established.* Therefore, the amount of time a CHPC had been operating was included as an additional predictor of program adherence.

The study addressed the second question through a survey that measured members' perceptions that the CHPC led to a more coordinated public health system.

Instruments

Program adherence was measured through an instrument called the "structure process evaluation tool" (SPET). The SPET is a 58-item self-assessment for CHPC leadership (HPOs, centralized HPO managers, and CHPCs) to measure the extent to which the CHPC is meeting the requirements set forward in *Army Regulation 600-63*.¹ It includes items such as "Does the installation have a CHPC that meets quarterly?" and "Does CHPC membership include representatives from each of the following: medical tactical, community, local?"

Perception of public health coordination is measured through the CHPC Effectiveness Survey. The Effectiveness Survey is a 20-item assessment administered yearly to CHPC members to assess the extent to which they perceive the CHPC as achieving its objectives and member satisfaction. In this assessment, participants respond to items regarding member satisfaction such as "in general, how would you rate the overall functioning of the HPO position at your installation" on a scale from 1 (Strongly Disagree) to 5 (Strongly Agree).

However, only 5 of these items are directly relevant to members' perceptions that the CHPC is achieving a more coordinated public health system. Therefore, only these items were analyzed to address evaluation question 2. The items include:

*Internal military document not readily accessible by the general public.

- The CHPC identified gaps in existing resources for needs/risks.
- The CHPC uses data to identify community needs/risks.
- The CHPC assesses existing resources for overlaps.
- The CHPC develops action plans for identified priorities.
- The CHPC facilitates relationships and networking between garrison, medical and tactical assets.

Participants and Procedure

The SPET and Effectiveness Survey are completed annually between July and September of the Army fiscal year by all HPOs or a member of the CHPC (for installations without the standard CHPC model). The results of the SPET were aggregated across 6 years (2007-2012) and represents responses from 11 installations with the standard CHPC model and 18 installations without the standard CHPC model. There were a total of 83 (N=83) responses to the SPET. The CHPC Effectiveness Survey was completed once per year for 6 years (2007-2012) by the CHPC membership only where there is a standard CHPC model (N=454). This study was reviewed by the US Army Public Health Review Board and all tools and methods were validated as approved methods of public health practice. The study did not require Institutional Review Board approval as all methods and data collected were a part of standard public health practice for community health promotion councils in the US Army.

RESULTS

Evaluation Question 1

Ordinary least squares regression was used to determine the extent to which the 3 critical features of the CHPC model and time operating positively predicted program adherence. The results revealed that both time ($F_{(5,76)}=25.02$, $P<.0001$) and the 3 critical features of the standard CHPC model ($F_{(1,76)}=28.40$, $P<.0001$) independently predicted program adherence. Contrary to prior research, however, the relation between adherence to the standard CHPC model was not moderated by the time that had elapsed since the CHPC began meeting ($F_{(1,76)}=0.06$, $P=.81$).³³ These results are displayed in Figures 3 and 4.

Evaluation Question 2

Data from the CHPC Effectiveness Survey were analyzed with descriptive statistics measuring the extent to which members perceived the standard CHPCs as achieving the

goal of integrating the Army installations' local public health systems. The survey results indicated that members responded on the positive side of the scale. In other words, members generally agreed that participating in the standard CHPC model is associated with a more coordinated approach to addressing public health at the installation. Figure 5 presents the results of this analysis.

COMMENT

These results provide preliminary evidence that the Standard CHPC Model may lead to a more coordinated approach to public health and may assure that CHPCs follow an evidence-informed design. This data supports the standard CHPC Model where the Army senior commander provides strong leadership; the health promotion team drives the process with expertise and coordination; and centralized management ensures a standardized approach to policy and procedure execution is maintained through evidence of delivery. This is consistent with past research demonstrating that community coalitions and public health systems that have strong leadership,

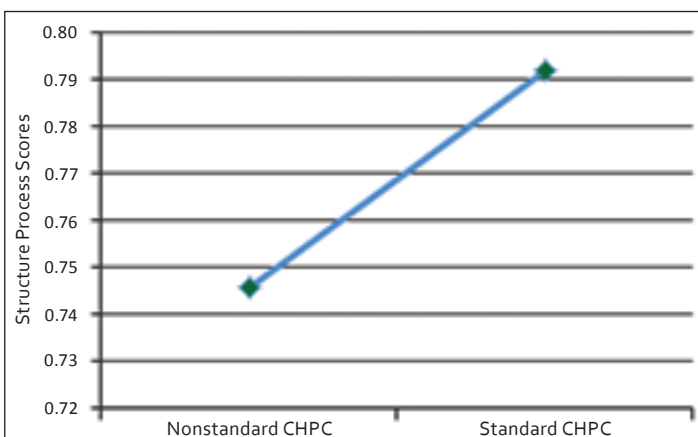


Figure 3. Structure process score plotted by type of community health promotion council, demonstrating the effect of a senior commander aligned and centrally managed health promotions operations team (standard CHPC) on program adherence.

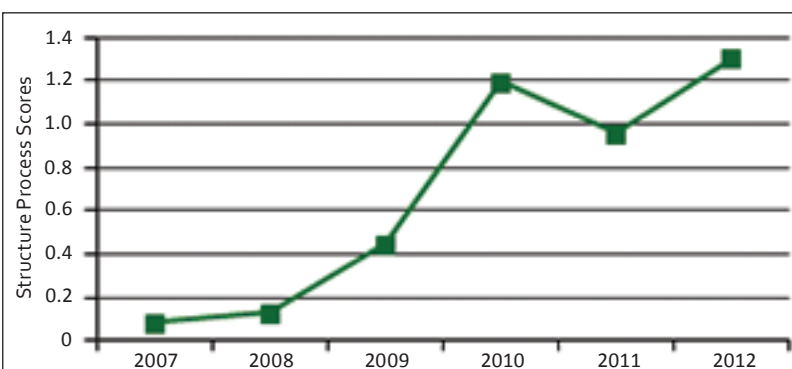
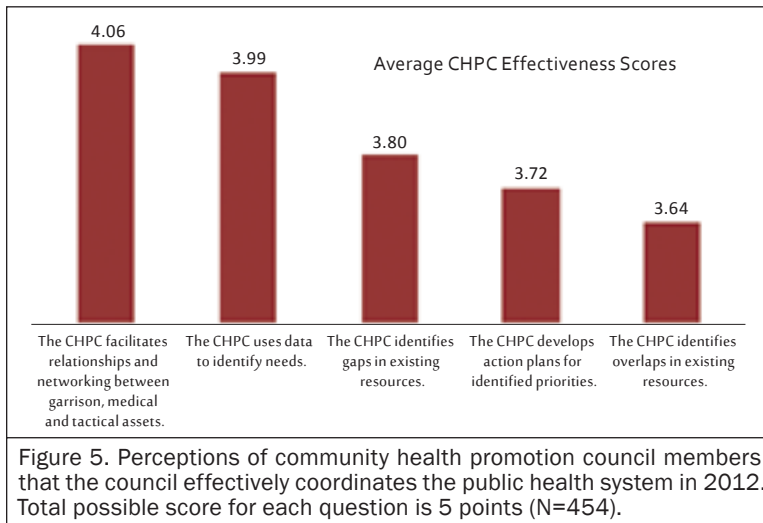


Figure 4. Community health promotion council structure process scores plotted by year, demonstrating the relationship between the time the CHPC is operating and adherence to an evidence-informed model.

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dedicated staff time and expertise, influence over policy, governance and oversight, and formalized rules and regulations function more effectively than those without.^{3,4} It also demonstrates the feasibility of implementing an evidence-informed approach to community coalitions in an Army environment. The Army model is not only supported by methodologies described in the literature, the evidence from the process validates those same methodologies and contributes to the body of knowledge on the effect of coalitions on public health process management in communities.

LIMITATIONS

The findings in this study are limited by several factors. Because the SPET is a self-report and completed by HPOs who are motivated to appear successful in developing an effective CHPC, the data from the SPET may be biased. However, this study assumes that participants in the study representing nonstandard CHPCs are also motivated to adhere to the regulations for installations CHPCs. Most likely, this bias is present in both standard and nonstandard CHPCs. At this time, the CHPC effectiveness survey is only completed at installations with a standard CHPC. Therefore, there is no way to compare whether or not standard CHPCs perform better on this survey than nonstandard CHPCs.

AN AGENDA FOR FUTURE RESEARCH

The studies support the link in the effectiveness theory between the 3 critical features of the standard CHPC model and a better coordinated approach to public health. However additional evaluation studies are needed to substantiate the effect of the standard CHPC model on community health and wellness and efficient resource

management. Reviews of past research suggest that traditional program evaluation methods are often inadequate to capture the effect of community coalitions on population health.²¹ For example, there are only 12 standard CHPCs in the Army. At the community level, there are many outside influences that affect population health and it is difficult to account for all potential confounders that may cloud the effects of standard CHPCs. Thus, traditional research designs and tests of statistical significance may be underpowered to detect the direct effect of a CHPC on community health and wellness.

However, evaluations of the effect of specific policy, program, and environmental changes initiated through CHPCs could potentially demonstrate the positive effects of the standard CHPC on population health and wellness. For example, one CHPC implemented an additional wellness service which was associated with a decrease in Soldiers' body mass index and increased help-seeking behaviors.* According to an annual report provided to USAPHC, the CHPCs implemented 1,050 similar actions and initiatives during fiscal year 2012 that aimed to improve community health and wellness and more efficiently manage public health resources at an installation. Using program evaluation methodologies to assess the impact of these individual initiatives may dramatically increase the evidence to support the effectiveness of the standard CHPC model, as well as provide greater insight into what programs, policies, and environmental changes will effect health promotion and disease prevention in the Army.

CONCLUSION

The standard Army CHPC model evolved to meet a need for better coordination within the Army public health system and presents a key strategy to achieving better health among Soldiers and their Families, retirees, and civilians. Based on past research and the studies presented here, the standard Army CHPC model is poised to positively affect the Army public health system, community health and wellness, public health resource management, and ultimately military readiness. The potential effect of the Army CHPC model, together with the opportunities it presents for interesting and revealing evaluation studies, suggest an exciting future for the study of public health management in the Army.

*Internal military document not readily accessible by the general public.

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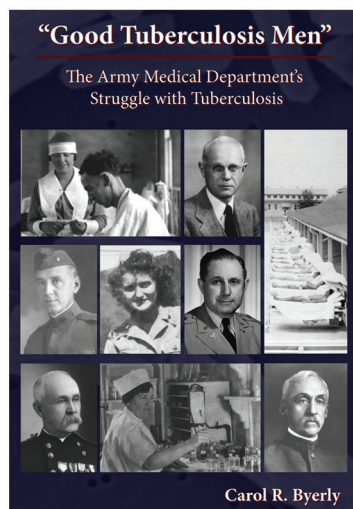
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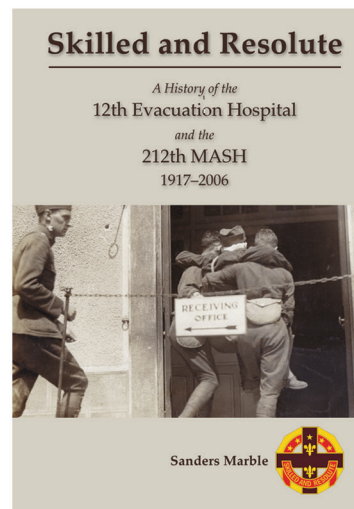
“GOOD TUBERCULOSIS MEN” THE ARMY MEDICAL DEPARTMENT'S STRUGGLE WITH TUBERCULOSIS

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Performance Excellence: Using Lean Six Sigma Tools to Improve the US Army Behavioral Health Surveillance Process, Boost Team Morale, and Maximize Value to Customers and Stakeholders

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ABSTRACT

Lean Six Sigma (LSS) is a process improvement, problem-solving methodology used in business and manufacturing to improve the speed, quality, and cost of products. LSS can also be used to improve knowledge-based products integral to public health surveillance. An LSS project by the Behavioral Social Health Outcomes Program of the Army Institute of Public Health reduced the number of labor hours spent producing the routine surveillance of suicidal behavior publication. At baseline, the total number of labor hours was 448; after project completion, total labor hours were 199. Based on customer feedback, publication production was reduced from quarterly to annually. Process improvements enhanced group morale and established best practices in the form of standard operating procedures and business rules to ensure solutions are sustained. LSS project participation also fostered a change in the conceptualization of tasks and projects. These results demonstrate that LSS can be used to inform the public health process and should be considered a viable method of improving knowledge-based products and processes.

In an effort to stay relevant and competitive, companies and organizations explore ways to streamline processes while continuing to deliver quality products and/or services to their customers. Two hallmarks of process improvement are the “Lean” principle, with its focus on speed, and the “Six Sigma” principle, with its focus on quality.^{1(p15)} Combining these principles, Lean Six Sigma (LSS) is a complementary process-improvement, problem-solving methodology used in the business and manufacturing industries to improve the speed, quality, and cost of products.^{1(p15)}

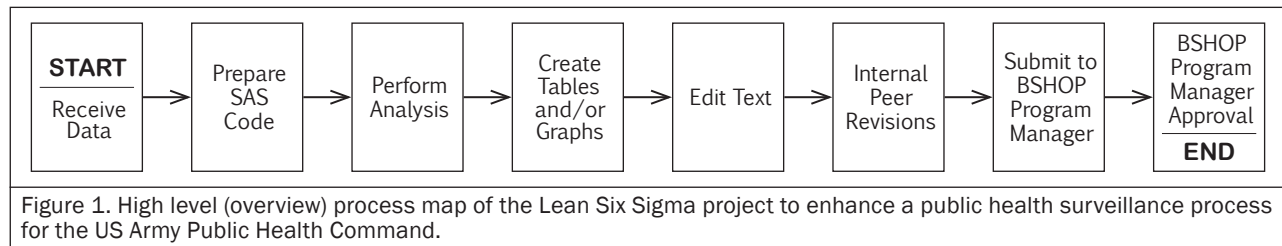
LSS is commonly associated with manufacturing entities and corporations such as GE, Motorola, Toyota, and Lockheed Martin. However, over the past decade, the LSS methodology has expanded into other organizational realms. LSS has been used to improve knowledge-based products from service organizations such as hospitals,² government offices,³ and research and development organizations.⁴ This article presents an example of the use of LSS to improve knowledge-based products in the public health sector.

In July 2008, the Army Institute of Public Health Behavioral and Social Health Outcomes Program (BSHOP) was

established at US Army Public Health Command. The mission of BSHOP is to maximize total Soldier health and combat readiness by identifying and assessing the relative impact of psychological and social threats using a mixed methodological approach. At inception, one of the primary missions of BSHOP involved routine reporting and surveillance of suicidal behavior among Soldiers using data from the Army Behavioral Health Integrated Data Environment (ABHIDE). The ABHIDE is one of the most comprehensive data sources for suicidal behavior and includes data from 27 disparate administrative data sources. The BSHOP created the Surveillance of Suicidal Behavior Publication (SSBP), which is disseminated to key military leaders including the Vice Chief of Staff of the Army, the Army Surgeon General, public health practitioners, and behavioral health providers at regional medical commands and military treatment facilities.

As the mission and scope of BSHOP expanded, it became apparent that preparation of the SSBP was a time- and resource-intensive process that prevented epidemiologists and analysts from exploring other behavioral health-related topics of public health significance. The SSBP production process had to be refined. Refining the process allows consistency in methods and provides

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time to explore not only other negative outcomes important to public health, but also to expand what can be included in the SSBP. This article describes an LSS project completed by the BSHOP Behavioral Health Surveillance Section (BHSS). Unlike other publications related to process improvement,⁵ this article describes how an industry tool was used to enhance a public health surveillance process for the US Army.

METHODS

The LSS problem-solving model is known as Define-Measure-Analyze-Improve-Control (DMAIC). Using DMAIC, LSS teams confirm the nature and extent of the problem they wish to solve, identify the true cause of the problem, develop solutions based upon data, and establish procedures for maintaining the solutions.^{1(p57)}

Before initiation, the LSS team created a project charter, a 1- to 2-page iterative document that includes the problem and goal statement, a timeline, and a list of the LSS team members. The charter was updated as the project developed through each of the DMAIC phases.

The DMAIC methodology and associated tools are discussed in detail by George et al.⁶ A brief description of each phase as it pertains to the SSBP project is presented in the following sections.

Define

The LSS team and the Project Sponsor (the BSHOP Program Manager) first determined the scope of the project, reviewed existing data to better define the problem, and set up a communication plan. The team created a high-level (overview) map of the process and established the project scope (Figure 1). The project process begins when the team receives the data to begin producing the SSBP and ends when the BSHOP Program Manager approves the publication.

Next, the team created a detailed map of the process, describing each team member's position and the tasks associated with each section of the publication. In doing so, project team members depicted the flow of the process, determined the value of specified tasks, and improved their understanding of each team member's role

and responsibilities. Like the project charter, the process map is an iterative document and was updated throughout the project as the process was refined.

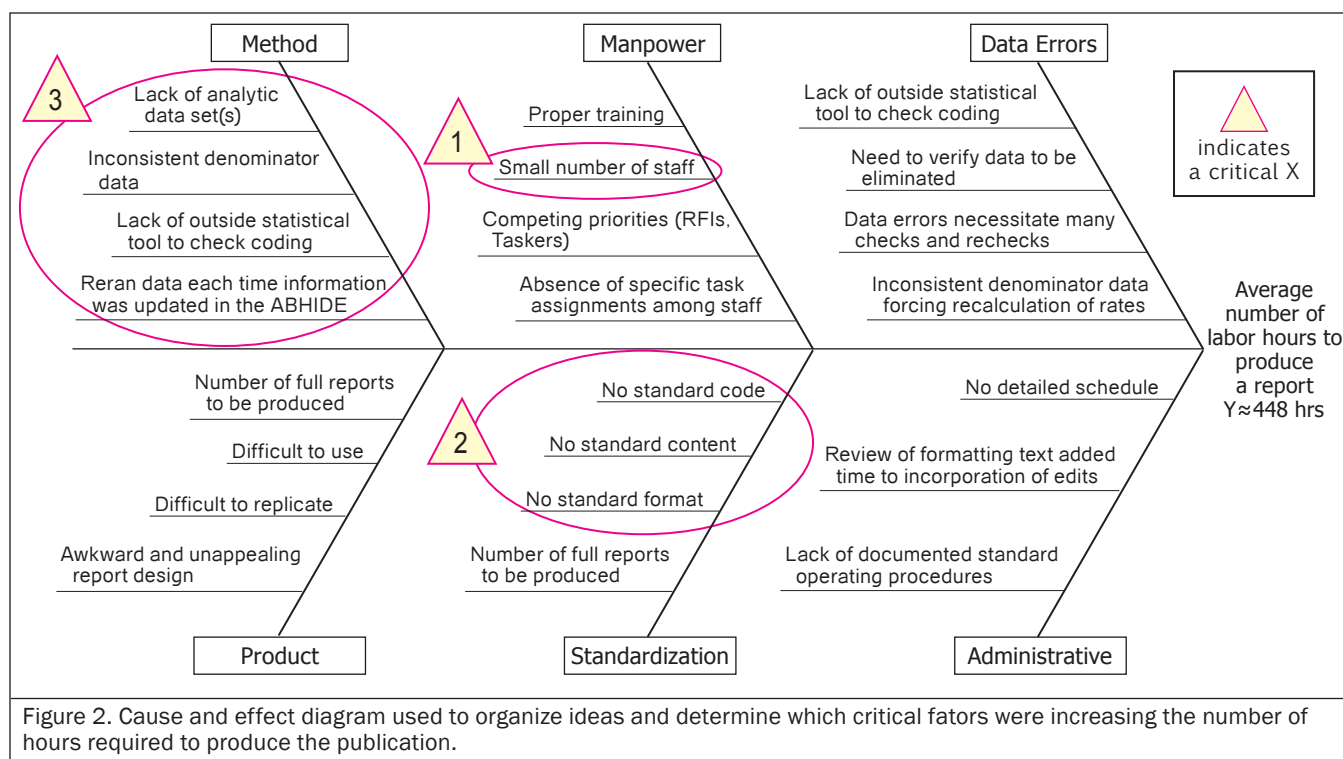
Measure

During this phase, the LSS team used baseline data and determined process performance/capability using Sigma Quality Level (SQL), a measure of process performance with respect to meeting customer requirements. A 3 SQL process meets customer requirements 93.3% (yield) of the time; a 6 SQL process meets customer requirements 99.9% of the time.^{3(p25)}

The team also developed a data collection plan to assist in the Measure phase. As part of this plan, team members recorded the number of hours they spent on each section of the publication. At the end of each publication cycle, a data technician compiled the information and created a table summarizing completion time by task and section of the publication. Operational definitions were also created to ensure clarity and consistent interpretation for each task. For example, New Code was defined as "Data analyst writes SAS code for data that has not been included in previous reports. Data analyst writes code to pull the same values in Structured Query Language to validate SAS code." (SAS v9.2 software (SAS Institute Inc, Cary, North Carolina) was used for data analysis.) Estimated financial benefits were calculated by the resource manager (RM). Estimates were based on a fully burdened labor rate (base rate +34.1% fringe benefit rate) added to overall report hours, manager review hours, and RM hours.

Analyze

During the Analyze phase, the LSS team analyzed the data collected during the Measure phase. A Pareto chart was used to specify the process steps that required the most labor hours and the most common source of defects. A Cause & Effect (C&E) Diagram, shown in Figure 2, and Matrix helped the team organize ideas and determine which critical factor(s) were increasing the number of hours required to produce the SSBP. Using the nominal group technique, the team identified and prioritized 3 root causes that had the most effect on publication production hours.



Improve

The Improve phase involved changes in the process that would reduce the number of labor hours spent producing the publication. Based upon the information obtained during the Analyze phase, the team conducted a pilot assessment to test their proposed improvement. The goal of the pilot was to demonstrate that changes in the critical factor identified as most influential would reduce the number of hours in the process while simultaneously maintaining the quality and integrity of the SSBP. Team members also developed potential solutions to other prioritized causes by brainstorming ideas, then evaluated those solutions using agreed-upon criteria.

Control

The Control phase ensured that solutions would be maintained after LSS project completion. To that end, the LSS team documented the solutions. A process control plan was created and the new and improved process performance and capability were compared to the old process performance and capability. Revised financial and operational benefits were also calculated.

RESULTS

Baseline

Four data points (previous SSBPs) were used to determine the average number of hours spent to complete a single publication (baseline). The LSS team and sponsor recognized that a larger sample size would be ideal. However, given that the section produces surveillance

publications for a rare event (suicidal behavior), 4 data points were appropriate and scientifically sound. On average, each of the previous publications took 448 (95% confidence interval, 373-523) hours to complete. This exceeded the expected standard of 308 hours which was established based on comparison with the time another organization takes to produce a similar document.

At baseline, the process was stable over time (in statistical control). However, process SQL was less than one. This indicated that the process was not capable of consistently producing the SSBP within the determined specification limits (308 hours).

Using a Pareto chart, the team determined that preparing SAS code and running statistical analyses accounted for 75% of the labor hours. Based on analysis of the C&E Diagram and Matrix, the team identified 3 root causes that needed solutions: (1) lack of personnel, (2) lack of analytic datasets and methodology, and (3) lack of standardization in SAS coding. The team agreed that focusing efforts on the SAS coding process would have the greatest effect on reducing the number of labor hours. Therefore, this part of the process was used as the pilot for the Improve phase.

For the pilot, SAS and Structured Query Language labor hours for the 1st Quarter 2012 Surveillance of Suicidal Behavior Update and the 2012 Semiannual SSBP were used as the “before” period, while SAS and Structured

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Query Language labor hours for the 3rd Quarter 2012 Update and the 2012 Annual SSBP were used as the “after” period. Results from the pilot demonstrated that the team spent 223 hours on SAS coding and Structured Query Language verification (combined) in the “before” period and 90 hours in the “after” period. Notably, the majority of the time in the “after” period was spent on code for new analyses not included in previous publications. The reduction in hours (178) during the pilot assessment demonstrated that SAS coding and Structured Query Language verification were correlated with overall production hours, resulting in a significant reduction in SSBP production hours.

Final Improvements

Project improvements resulted in a significant reduction in labor hours (-249 hours) and a significant increase in yield (+89.4%) and SQL (+3.25) as shown in the Table. The projected 7-year cost avoidance for US Army Public Health Command was \$707,045. Control measures were implemented to ensure improvements would be maintained after project completion. The team created 8 Business Rules and standard operating procedure (SOP) documents. Chief among these is the Technical Notes, which describe, in detail, epidemiologic methodologies (data sources, variables, coding decisions) used for SSBP production. The Technical Notes are updated with each iteration of the SSBP.

COMMENT

The LSS team exceeded the project goal and significantly reduced the SSBP production hours by 42% (199 hours). The results of this project are important because, to our knowledge, this is one of only a few LSS projects that applied this industry tool to the improvement of a public health surveillance system. These results demonstrate that LSS can inform the public health process and provides a viable method of improving knowledge-based processes and products.

As determined during the Analyze phase, SAS coding and Structure Query Language verification accounted for the majority of the time during the production process. The verification acted as a fail-safe to ensure coding and analysis were consistent and correct. When the SAS code became standardized and error-free, the LSS team determined this practice no longer added value.

Process improvements realized as a result of the Lean Six Sigma project .			
Metric	Before	After	+/-
Reduced number of Labor Hours	448	199	-249
Increased Sigma Quality Level	<0	3.25	+3.25
Increased Yield	<6.6%	96%	+89.4%

However, this verification process continues to be used for new SAS code. When discrepancies have been addressed and accounted for, that step is removed from the production process.

As a result of the LSS process, the team maintained the quality of the SSBP and reduced production time, while at the same time adding valuable information. This included measures from 4 datasets in the ABHIDE pertaining to deployment, drug testing, screening for the Army Substance Abuse Program, and medical problems related to sleep and to pain. These indicators are now routinely included in the SSBP.

In addition to revising and standardizing SAS coding, the format and design of the SSBP was reconfigured to better align with the overall process of analysis and reproduction. Prior to the redesign, project team members were rewriting the entire document every quarter. The new design is not only aesthetically pleasing and more appealing to the customer, it also allows easy duplication and transfer of the data from SAS outputs to the table and text. To maintain consistency, the team developed a detailed SOP describing all aspects of document design and format, such as text specification, table and figure configuration, color scheme, and font size and style.

The development of business rules also led to gains in consistency in epidemiologic methodologies and analytic processes, thereby enhancing the scientific integrity of the SSBP. These included Business Rules for Data Set Exploration and 3 Business Rules for Statistics: US Population Data Sources (US Census Data and Web-based Injury Statistics Query and Reporting System (WISQARS)), Crude and Stratified Rates, and Standardized Mortality Ratios. Other methodological advances included the following: (1) use of Health Care Effectiveness Data and Information Set rules to determine what constitutes a behavioral health diagnosis; (2) internal review of behavioral health diagnoses and their International Classification of Diseases-9 (ICD-9) codes (by the BSHOP Strategic and Clinical Integration and Evaluation Section) and external review by clinicians (colleagues and subject matter experts); (3) alignment of race/ethnicity categories with Office of Management and Budget guidelines; (4) creation of a process to resolve discrepancies in static demographic variables (gender, date of birth, race/ethnicity). The team also created a welcome packet that is used as a training tool to systematically introduce new personnel to section processes and products.

The LSS team developed and distributed a stakeholder SSBP feedback survey. Based on team discussion of feedback from the survey, the SSBP is now released

annually rather than quarterly. Data on cases of suicidal behavior that occurred during the first 3 quarters of each calendar year are analyzed but disseminated only if trends change significantly. The decrease in the frequency of reporting also enhanced interpretation of the data. In particular, the variability in the proportions from quarter to quarter resulting from the small numbers of suicidal events suggested changes that appear large but are unimportant in the context of a longer period.

In addition to the successes described above, the team realized substantial gains in team building and enhanced workplace morale. Project participation turned LSS skeptics into champions of the process and fundamentally changed the way team members conceptualized tasks and projects. As a whole, individuals now think in terms of process improvement. Statements such as “from an LSS perspective we should...” or “is this the most efficient way to...” or “what does our customer want?” are now commonplace in the work environment. The involvement of BHSS in the project also piqued interest in LSS tools and methodologies among other sections within BSHOP and resulted in 15 employees obtaining their Yellow Belt certification. There has also been an increase in cross-section collaboration, and the sharing of ideas has aided in the scholastic enrichment of individuals and teams. Support from the BSHOP Program Manager and excellent mentorship and guidance from the LSS expert from the USAPHC Strategy & Innovation Office were also integral to the success of the project.

CONCLUSION

There are 3 reasons why service-oriented organizations should consider LSS tools and methodologies when trying to improve a process, all stemming from the fact that service processes are typically slow.³ First, slow processes are subject to poor quality, which increases cost and drives down customer satisfaction.³ Second, service processes are often slow because too much work is in progress, which results in unnecessary complexity in the service or product.³ Third, in any slow process, 80% of the delay is caused by less than 20% of the activities.³ Individuals who work in service functions typically find that most of the steps in the process add no value to the product they are producing. Use of LSS to identify and quantify the steps in the process that are not of value will result in improvements³ as demonstrated by the BSHOP LSS project described here. The time and knowledge gained from this project have enabled the exploration of other behavioral health-related topics of significance, such as those added to the SSBP during the course of the project. In addition, the team has begun applying LSS tools and methodologies to other surveillance publications, including those on all-cause mortality in the US Army,

risk assessment, and sexual assault. Other programs and organizations within the Army and, more specifically, the US Army Medical Command, could use LSS tools to improve relatively simple (organization and structure of public access drives, version control for document review staffing of documents), and complex processes (patient intake process or routine medical procedures) in need of refinement. Interested parties should contact their organization's Strategy & Innovation Office for guidance to determine feasibility of a proposed project.

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