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13. ABSTRACT (Maximum 200 words) Does military service, in particular operational deployment, result in a higher risk of chronic illness among military personnel and veterans? The Millennium Cohort Study, the largest Department of Defense prospective cohort study ever conducted, will attempt to answer this question. The probability-based sample of 140,000 military personnel will be surveyed every 3 years during a 21-year period. The first questionnaire, scheduled for release in summer 2001, will be sent to 30,000 veterans who have been deployed to southwest Asia, Bosnia, or Kosovo since August 1997 and 70,000 veterans who have not been deployed to these conflict areas. Twenty thousand new participants will be added to the group in each of the years 2004 and 2007 to complete the study population of 140,000. The participants will have the option of completing the study questionnaire either on the paper copy received in the mail or through the World Wide Web-based version, which is available at www.MillenniumCohort.org . This will be one of the first prospective studies ever to offer such an option. The initial survey instrument will collect data regarding demographic characteristics, self-reported medical conditions and symptoms, and health-related behaviors. Validated instruments will be incorporated to capture self-assessed physical and mental functional status (Short Form for Veterans), psychosocial assessment (Patient Health Questionnaire), and post-traumatic stress disorder (Patient Checklist-17). Information obtained from the survey responses will be linked with other military databases, including data on deployment, occupation, vaccinations, health care utilization, and disability. In addition to revealing changes in veterans' health status over time, the Millennium Cohort Study will serve as a data repository, providing a solid foundation upon which additional epidemiological studies may be constructed.					
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The Millennium Cohort Study: A 21-Year Prospective Cohort Study of 140,000 Military Personnel

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Does military service, in particular operational deployment, result in a higher risk of chronic illness among military personnel and veterans? The Millennium Cohort Study, the largest Department of Defense prospective cohort study ever conducted, will attempt to answer this question. The probability-based sample of 140,000 military personnel will be surveyed every 3 years during a 21-year period. The first questionnaire, scheduled for release in summer 2001, will be sent to 30,000 veterans who have been deployed to southwest Asia, Bosnia, or Kosovo since August 1997 and 70,000 veterans who have not been deployed to these conflict areas. Twenty thousand new participants will be added to the group in each of the years 2004 and 2007 to complete the study population of 140,000. The participants will have the option of completing the study questionnaire either on the paper copy received in the mail or through the World Wide Web-based version, which is available at www.MillenniumCohort.org. This will be one of the first prospective studies ever to offer such an option. The initial survey instrument will collect data regarding demographic characteristics, self-reported medical conditions and symptoms, and health-related behaviors. Validated instruments will be incorporated to capture self-assessed physical and mental functional status (Short Form for Veterans), psychosocial assessment (Patient Health Questionnaire), and post-traumatic stress disorder (Patient Checklist-17). Information obtained from the survey responses will be linked with

other military databases, including data on deployment, occupation, vaccinations, health care utilization, and disability. In addition to revealing changes in veterans' health status over time, the Millennium Cohort Study will serve as a data repository, providing a solid foundation upon which additional epidemiological studies may be constructed.

A Cohort Study for the New Millennium

The 1999 Institute of Medicine report, *Measuring Health*,¹ recommended that the Department of Defense begin systematically collecting population-based data to evaluate the health of service personnel throughout their military careers and after separation from military service. The Department of Defense, in its report to Congress titled *Effectiveness of Medical Research Initiatives Regarding Gulf War Illnesses*,² also identified the need for a coordinated effort to determine whether deployment-related exposures are associated with postdeployment health outcomes. The Millennium Cohort Study is a response to these two recommendations. In this report, we describe the development of the Millennium Cohort Study, including its objectives and epidemiological methods, and we discuss its potential value in improving the health of present and future military populations.

Study Design Process

A multiservice and multiagency team was created to devise a comprehensive study encompassing all branches of military service, including Reserve and National Guard personnel. Beginning in December 1999, investigators from the U.S. Army, Navy, Air Force, and the Department of Veterans Affairs collaborated to determine the study objectives, the target populations, the survey contents, and to plan study execution.

After initial protocol development, the study was extensively reviewed by a number of experts and review panels. The American Institute of Biological Sciences evaluated the Millennium Cohort Study in June 2000 and determined the study to have excellent scientific merit. In June 2000, a scientific steering and advisory committee, composed of five leading academic research experts and three representatives from veteran service organizations, reviewed the questionnaire and study design and made recommendations to the investigators to improve the study.

Finally, investigators obtained the following institutional approvals for the study protocol: the Naval Health Research Center's Scientific Planning and Review Committee in September 2000; its Committee for the Protection of Human Subjects in November 2000; the Uniformed Services University of the Health

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Sciences' Institutional Review Board in January 2001; the U.S. Army Research Institute of Environmental Medicine's Institutional Review Board in March 2001; and the institutional review board from the Seattle Epidemiologic Research and Information Center, Department of Veterans Affairs Puget Sound Health Care System, in July 2001.

Objectives

The Millennium Cohort Study's primary objective is to determine if risk factors related to military service, such as service occupational specialty, deployment history, service type, and other exposures, are associated with the development of chronic disease. Secondary objectives include examining characteristics of military service associated with common clinician-diagnosed diseases and with scores on several standardized self-report health inventories for physical and psychological functional status.

Study Population

The study population has been generated from a statistical sample of all regular active duty, National Guard, and Reserve military personnel of the Army, Navy, Air Force, and Marine Corps to be generalizable to the entire military force. The 2001 cohort will be stratified into 30,000 study participants who have been deployed after August 1997 to southwest Asia, Bosnia, and Kosovo and 70,000 study participants who have never been deployed to these areas. Reserve, National Guard, and female service personnel will be oversampled (Fig. 1). This probability-based sample of 100,000 study participants has been based on service rosters as of October 1, 2000, provided by the Defense Manpower Data Center (Monterey Bay, California) and will represent approximately 3.7% of the 2.7 million persons in uni-

form. In 2004 and again in 2007, additional probability-based samples of 20,000 U.S. active duty, National Guard, and Reserve military personnel will be added to the study. These personnel will have at least 1 year and not more than 2 years of service at the time of recruitment into the study. Service academy cadets and midshipmen will not be included in the 2004 and 2007 cohorts because of their high rates of attrition. Figure 1 reflects the expected number of potential participants that must be targeted to enroll the initial 100,000 individuals into the study.

Data Collection Instrument

The initial survey instrument consists of 67 items, some having multiple components: basic demographic features (7 items); the 36-item Short Form for Veterans of the Medical Outcomes Survey³ to assess physical and functional status (12 items); the Patient Health Questionnaire⁴ to provide a psychosocial assessment (14 items); medical conditions diagnosed by a clinician (1 item); self-reported symptoms (1 item); the Patient Checklist⁵ to screen for post-traumatic stress disorder (1 item); alcohol use (10 items)⁶; tobacco use (6 items); alternative medicine use (1 item); occupational classification (5 items); life events and occupational exposures (4 items); average hours of sleep (1 item); and various contact information questions (4 items). Both the paper and World Wide Web-based survey instrument afford respondents an opportunity to list concerns not otherwise solicited. The standardized instruments (Short Form for Veterans, Patient Health Questionnaire, and Patient Checklist) were selected because of published data on their reliability and validity and their use in previous veterans studies. The paper survey instrument was created using mark-sense Teleform Elite software (Cardiff Software, Vista, California) to automate survey

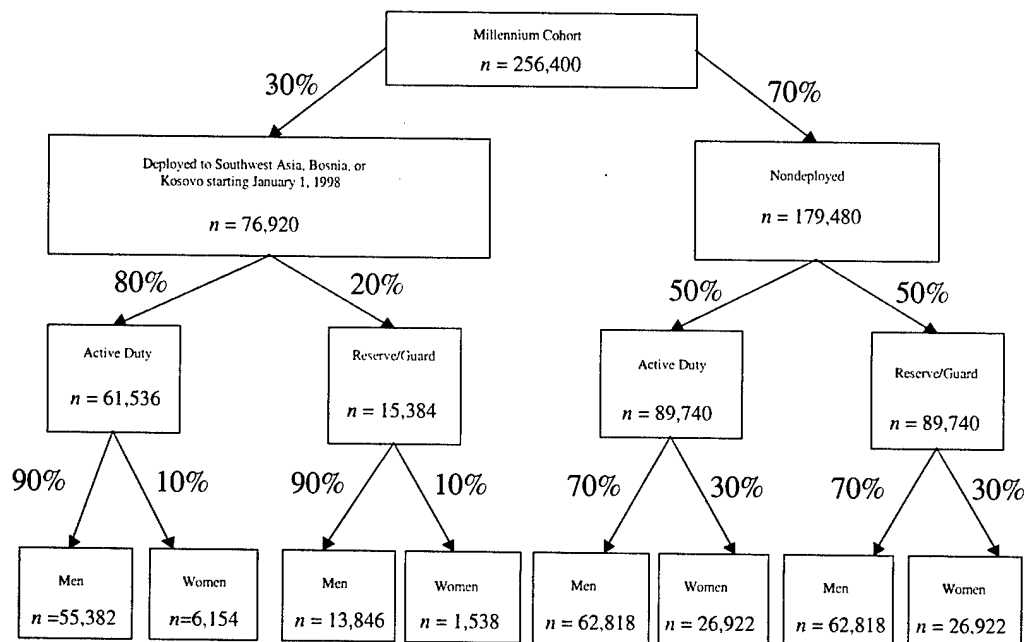


Fig. 1. Sampling strategy. An initial sample of 256,400 service men and women will be drawn from regular active duty, Reserve, and National Guard rosters as of October 1, 2000, in an attempt to achieve the 100,000 target population size. Thirty percent of this population will have been deployed to southwest Asia, Bosnia, or Kosovo after January 1, 1998, and 70% will have never been deployed to these areas. Women and Reserve/National Guard personnel will be oversampled.

review and to help reduce data entry error. To maximize data quality, the survey instrument was modified based on multiple service-wide focus groups as well as the results of an early pilot survey of 1,000 respondents (2,564 surveyed).

Study Execution

The Millennium Cohort Study questionnaire will be sent via the U.S. Postal Service to participants every 3 years. Standard techniques^{7,8} used in the postal survey process will be used. These techniques consist of sending a presurvey introductory postcard, cover letter with survey, postcard reminders, and up to two repeat survey mailings if necessary (Fig. 2). The presurvey introductory postcard serves two purposes. First, it alerts the participants to the forthcoming survey. Second, it allows the investigators to inexpensively gather current address information for subjects who have recently moved after data extraction. The questionnaire, a cover letter, and a consent form describing the study will then be sent by first-class U.S. mail. A tracking service and address locator databases will be used to find correct addresses for undelivered mail.

Mail Tracking

All outgoing and incoming mailings related to this study will be individually identified by a bar code containing a computer-generated random number that is unique for each potential study participant (subject identification number) and a mail item code. Using bar code readers linked to a mail-tracking

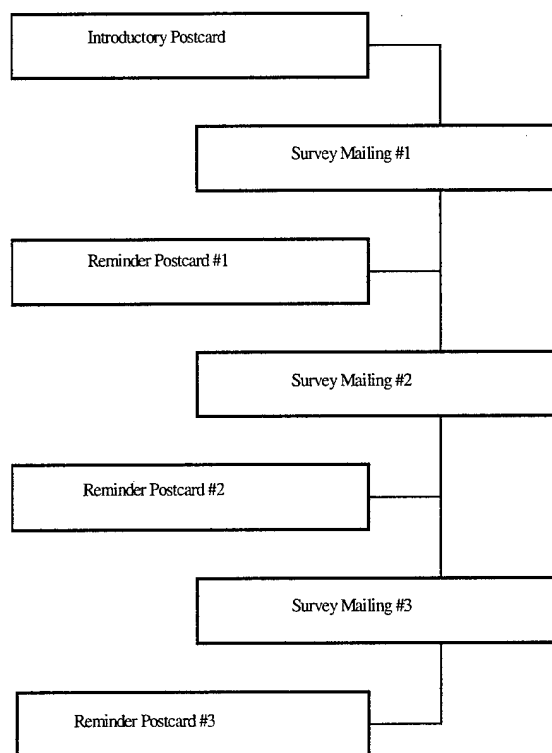


Fig. 2. The postal survey process throughout the course of this study. An introductory postcard will be mailed out and then followed by up to three questionnaire mailings, each followed with a reminder postcard.

database, research staff will be able to rapidly scan incoming undelivered mailings and respondent mailings to determine the proportion of incorrect addresses, the proportion of survey respondents, and the response to study incentives (e.g., beverage coasters, key chains, and magnets). In the case of nonresponders, repeat mailings of surveys will continue until one of the following occurs: a completed survey is received, the candidate explicitly declines to participate, or the candidate does not respond after three questionnaire mailings without evidence indicating that all surveys were not delivered to the subject.

Survey Reliability and Validation

After candidates have consented to participate and respond to the survey, 1% of them will be asked to complete a similar but shorter survey instrument to assess the reliability of selected questions. Additionally, self-reported hospitalization data will be validated by linkage to the Department of Defense's electronic hospitalization databases. Similarly, various Department of Veterans Affairs databases will be examined for health care utilization. These electronic records archive clinical diagnoses in the International Classification of Diseases, 9th Revision, Clinical Modification format.⁹

Sampling of Nonrespondents

In addition to resampling a small percentage of respondents, we will also attempt to reach 3% of nonrespondents by telephone. Computer-assisted telephone interview techniques will be used to characterize the nonrespondents.

Data Linking and Statistical Analyses

The Department of Defense Center for Deployment Health Research directly manages or has access to numerous established military data sets (Table I).¹⁰⁻¹³ These data sources will be linked to survey data and enhance the ability to conduct comprehensive evaluations of the medical outcomes of interest. In addition, the Department of Veterans Affairs has agreed to provide mortality and other health care utilization and disability compensation data that will augment the investigators' capacity to capture health outcomes in longitudinal follow-up (Table II).¹⁴⁻¹⁶ Self-reported and objective electronic data will be examined for health outcomes of interest by demographic and deployment subgroups. Demographic covariates available for multivariate modeling will include age, gender, race/ethnicity, marital status, education level, rank/rate, occupation, service branch, and length of service. In addition, health habits, health care utilization history, immunization history, and deployment history will be available from the survey and other sources to uniquely describe exposures of military concern. Outcomes of interest are expected to be extensive but will include common chronic diseases, such as diabetes, heart disease, and cancer. Other outcomes that may be uniquely accessible from the periodic surveys include chronic multisymptom illnesses and more subtle changes in functional status. Interest in these diagnostically challenging outcomes continues to grow more than a decade after the Persian Gulf War experience.^{1,2}

Data will be linked using unique personal identifiers; identi-

TABLE I
SOURCES OF SUPPLEMENTAL MEDICAL AND ADMINISTRATIVE DATA

Database	Information Provided
Civilian Health and Medical Program of the Uniformed Services	Contains one record for each claim voucher for care by a civilian provider. Care is rendered to dependents who are not Medicare eligible. The files contain historical data from December 1979.
Defense Enrollment Eligibility Reporting	The central source for Department of Defense personnel information. The database is used to determine medical benefits eligibility, insurance, immunizations, and patient information. The data set is thought to be 93% accurate for the addresses of military personnel, and the accuracy continues to improve.
Defense Outplacement Referral System	National resume and referral network to help separating Department of Defense personnel transition into civilian life.
Department of Defense Birth Defects Registry ¹⁰	Established at Naval Health Research Center, San Diego, in January 1999. The registry uses a hybrid system of active and passive surveillance of Department of Defense dependent births.
Health Enrollment Assessment Review	Created to assist in identifying individuals and groups of individuals who require proactive interventions and personnel whose clinical and preventive services are not current or have never been performed. Also describes a patient's risk factors, his or her chronic medical conditions, and whether the enrollee falls into the high resource utilization category.
Master Crosswalk File ¹¹	Provides "crosswalks" between military occupational codes of the four military services and the Coast Guard and their civilian counterparts as defined by the standard occupational classification codes, occupational employment statistics codes, census codes, Office of Personnel Management codes, and classification of instructional programs codes.
Military operation rosters	As the Department of Defense deploys large groups of military personnel for sustained periods, participants are recorded by various services and compiled in databases at the Defense Manpower Data Center in Seaside, California.
Recruit Assessment Program ¹²	The Recruit Assessment Program will represent a collection of baseline demographic, medical, psychological, occupational, and risk factor data from U.S. military personnel at the time of their entry into military service.
Standard Ambulatory Data Record	Department of Defense database of military outpatient visits since October 1, 1997.
Standard Inpatient Data Record	Department of Defense database of all military hospitalizations since October 1, 1998.
Total Army Injury and Health Outcomes Database ¹³	A comprehensive database developed to study injury and illness among Army soldiers may be used to study particular injury or disability outcomes among the Army subgroup of the Millennium Cohort Study.

fiers will be stripped before analyses to ensure the privacy and security of all data provided by participants. Outcomes will be modeled using multivariate techniques. Methods that adjust for temporal bias and attrition from the services, such as Cox proportional hazard modeling, will be used when appropriate. The investigators, using input from the Scientific Steering and Advisory Committee, will tailor specific analyses to the outcomes of concern.

Maximizing Participation

A major challenge in conducting cohort studies is maximizing participation, both initial enrollment of study subjects and preventing losses to follow-up. In addition to the use of repeat mailing and incentives, Millennium Cohort Study research staff members have actively sought the support of military and veterans service organizations. In August 2000, a special study

TABLE II
DATABASE SOURCES AVAILABLE THROUGH THE DEPARTMENT OF VETERANS AFFAIRS¹⁶

Database	Information Provided
Beneficiary Identification and Records Locator System	Provides the Social Security number and the state in which death occurred from all veterans whose survivors apply for a death benefit. It is updated quarterly and contains 8.3 million records. It is thought to capture 95% of veteran deaths.
National Patient Care Database	Combines several Department of Veterans Affairs databases, including the Patient Treatment File and the Outpatient Clinic File.
Outpatient Care File	Provides information regarding principal diagnosis and location of all Department of Veterans Affairs—provided episodes of outpatient care. Contains more than 20 million records per year with weekly updates.
Patient Treatment File	Contains up to 10 discharge diagnoses and 5 procedure codes for all Department of Veterans Affairs—provided hospital care with weekly updates.
Veterans Information Systems Technology	A comprehensive clinical and administrative database that contains laboratory, radiology, and pharmacy data.

briefing was given to military and veterans service organization representatives in the Washington, DC, area. A number of these organizations have subsequently agreed to endorse and help publicize the study. Finally, the study investigators developed a Millennium Cohort Study logo that is printed on all study correspondence, questionnaires, and incentives to promote a sense of fraternity among study participants and prompt higher participation rates. Other methods of maintaining contact with participants and keeping them involved in the study will continue to be explored.

The Millennium Cohort Study World Wide Web Site

The Millennium Cohort Study research staff created a World Wide Web site as another means of encouraging participation and engendering a high level of interest in the study. The World Wide Web site (www.MillenniumCohort.org) will serve as a method of receiving data as well as a system of releasing information to study participants and the general public. Study volunteers will be informed of the World Wide Web site in the initial postcard mailing and in subsequent mailings. The World Wide Web address is also listed on the incentives and the study letterhead. Subjects may provide mailing address changes and/or their e-mail address to receive periodic study communications. Additionally, the World Wide Web site will provide updates on study progress and findings to participants. Participants will be able to contact the study coordinator via the World Wide Web site or through e-mail to ask questions or offer suggestions. Thus, the World Wide Web site will serve as a continuous and relatively inexpensive means of keeping study participants involved and interested throughout the course of the study.

Perhaps most importantly, the World Wide Web site will provide the participants with the option to complete an on-line questionnaire rather than the mailed paper questionnaire. The use of a "digital signature"^{17,18} (the subject identification number along with the last 4 digits of the Social Security number) will prevent individuals other than study subjects from completing the survey. The on-line questionnaire adheres to the same format as the paper version, allowing participants to answer questions in very much the same manner as they may be accustomed to doing with the paper surveys. After the participant completes and submits the questionnaire, the data are transmitted via secure electronic means to the Naval Health Research Center and incorporated into the study database.

The Potential Value of a Large-Scale Military Cohort Study

Numerous Gulf War veterans began reporting various medical symptoms soon after the end of fighting in Operation Desert Storm. Many of these veterans attributed their illnesses to deployment-related exposures in the Persian Gulf. At that time, the Department of Defense had little or no systematically collected predeployment health data to compare with postdeployment health assessments. The Millennium Cohort Study takes an important step in support of force health protection by providing predeployment health data, previously lacking, on a large cohort of military service personnel and follow-up for health outcomes during a 21-year period. These essential data will

assist researchers and military leaders in understanding the health impact of future military deployments more completely than in the past. In turn, this better understanding may affect deployment policies as well as prevention and treatment programs, possibly influencing veterans' benefits for the future.

The longitudinal cohort study design method is a natural choice for a study of this importance and magnitude. The cohort study offers several advantages over other study designs. In particular, cohort studies are valuable when the exposure or exposures being examined are rare.¹⁹ This advantage is especially relevant to the unique roles and duties presented by the military population. Cohort studies also allow for the examination of "multiple effects of a single exposure."¹⁹ For example, the Nurses' Cohort Study, initiated in 1976 to examine the use of oral contraception, has been useful in providing information about several different conditions such as breast cancer, ovarian cancer, and heart disease in women.^{19,20}

The ability to examine the relationship between exposure and the time before disease presents itself is an important strength of the cohort study as well.¹⁹ Prospective cohort studies reduce the chance of participant recall bias inherent in most retrospective study designs. Furthermore, prospective cohort studies that examine data sources such as medical and deployment records supplemented with participant questionnaires, like the Millennium Cohort Study, provide a more complete method of collecting information on exposures.¹⁹ The cohort design method also allows for investigators to periodically resurvey the study population, allowing flexibility in assessments based on newly discovered scientific advancements.¹⁹ As noted previously, the Millennium Cohort Study takes advantage of this design feature by surveying the selected cohort every 3 years for a total of seven questionnaires within the 21-year study period.

The nature of the cohort study, providing the most direct measurement of the risk of disease development by prospectively collecting and studying exposure and outcome data over time, has been responsible for numerous public health advancements. The Millennium Cohort Study has the potential to contribute new and important information to the field of preventive medicine and public health, benefiting both military and civilian populations alike, just as other landmark cohort studies have done. Two seminal longitudinal prospective cohort studies, the Framingham Heart Study²¹ and the Nurses' Cohort Study,²⁰ have been able to provide valuable insight with regard to the identification of risk factors for diseases of public health importance. The Framingham Heart Study, through its tracking of a cohort of 5,127 men and women living in a single community, identified risk factors for cardiovascular disease that greatly enhanced our scientific understanding of the association between lifestyle factors and the occurrence of adverse outcomes from coronary artery disease. The Nurses' Health Study was initiated to examine the health effects of the use of contraception among women. By leveraging the cohort design, this study had since provided invaluable information on reproductive system cancers and other women's health issues.

In a similar manner, the Millennium Cohort Study has the potential to uncover unanticipated exposure-disease associations in a relatively young, healthy, screened population that might otherwise remain unrecognized. This information will not only benefit the military but will likely benefit civilian popula-

tions as well, just as the Framingham and Nurses' Cohort studies benefited more than just their study populations. Most members of the Millennium Cohort Study population will become civilians during the course of follow-up, further highlighting the applicability of study findings in both military and civilian sectors.

Millennium Cohort Study data will likely serve as a foundation for other epidemiological studies, just as in the Framingham Heart Study and Nurses' Health Study. While many of these efforts will be managed by military research teams, the Millennium Cohort Study data will likely be used by civilian research teams as well. Because of its potential impact on preventive medicine practice, the Millennium Cohort Study is an important and exciting project for the new millennium. The study's successful implementation is critical, and its results may resonate in public health for years to come.

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