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Protocol for the Vietnam Veteran Mortality Study

July 1983

Office of Reports and Statistics
Statistical Policy and Research Service
Washington DC 20420

A PROTOCOL FOR THE

VIETNAM

VETERAN

MORTALITY

STUDY

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Biometrics Division

Office of Reports and Statistics

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Washington, DC 20420

July 1983

PREFACE

In June 1980, members of the Science Panel of the interagency Herbicide Orange Working Group met with VA personnel and began outlining a study of Vietnam veteran mortality. Within a short time, a protocol was written and then modified, and work was begun on assembling the data. This study design was subsequently received and substantially revised by the Science Panel of the newly constituted Agent Orange Working Group in March of 1982. This revised study was christened the Vietnam Veteran Mortality Study (VVMS), and work began immediately on redesign and funding of this "new" study. Approximately one year later, the study is underway, and the need has become apparent to document the revised VVMS. This document is the first protocol written for the Vietnam Veteran Mortality Study and incorporates the background and experience of the investigators up to the pilot study phase.

Biometrics Division
Office of Reports and Statistics
Veterans Administration

July 1983

ACKNOWLEDGEMENTS

This report is dedicated to the memory of Dr. Amy J. Kuntz, co-investigator, who died February 15, 1983. Amy's depth and breadth of vision helped plan and support the Vietnam Veteran Mortality Study from its inception. Her untiring dedication and devotion account to a large extent for the progress to date on the study. We shall all miss her.

We should also like to acknowledge the help of other co-workers. Mr. Donald Stockford and Mr. Johnnye Taylor of the Biometrics Division have helped us in the data collection phase of the study. Dr. A.J. Singh and Mr. Robert W. Schultz, of the Office of Reports and Statistics, have supported us fully from the beginning of the study with encouragement and necessary personnel. Dr. Barclay Shepard of the Agent Orange Project Office and his staff have provided the resources to undertake the study. In particular, we single out Mrs. Elaine Morrow, Mr. Layne Drash, and Drs. Hobson and Young of his staff.

William Frank Page, Ph.D., Principal Investigator

Susan C. Gee, M.S., Co-Investigator

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CHAPTER 1.

BACKGROUND & BRIEF HISTORY OF PROJECT

BACKGROUND

Concern about the health of Vietnam era veterans (persons who served in the armed forces during the period 1964-1975) has become widespread. Although the psychological consequences of Vietnam service have generated interest, the greatest concern centers around the effects of Agent Orange, in part because it contained as a contaminant dioxin (2,3,7,8-tetrachlorodibenzo-p-dioxin or TCDD). Agent Orange, a defoliant containing a concentrated formulation of the two herbicides 2,4-dichlorophenoxyacetic acid (2,4-D) and 2,4,5-trichlorophenoxyacetic acid (2,4,5-T), was sprayed over roughly 8 percent of South Vietnam from 1962-1972 in the Air Force Operation Ranch Hand.

The health effects of Agent Orange and dioxin are unclear. According to the AMA Council on Scientific Affairs Advisory Panel on Toxic Substances (1), long-term effects, except for persistent chloracne, have not been seen. Concerning the relationship of phenoxy herbicides and cancer in man, Coggon and Acheson (2) conclude that it is yet impossible to estimate with any precision the risk of soft tissue sarcoma due to phenoxy herbicides. Since Coggon and Acheson's review, Smith et al. (3) have made public the

results of their case-control study of New Zealand workers, showing no association between soft tissue sarcoma and occupations with the greatest likelihood of exposure to phenoxy herbicides and chlorophenols. Also, Riihimaki et al. (4) detected no increase in cancer mortality of Finnish herbicide applicators, finding no deaths due to lymphomas or soft tissue sarcomas. A comprehensive review of literature on phenoxy herbicides and health effects includes more than 1,000 references (5).

There are numerous studies now ongoing, proposed, or completed that deal with Vietnam veteran health. With respect to morbidity, ongoing studies include the follow-up study of Ranch Hand personnel and a study of birth defects risk among Vietnam era veterans who are fathers, and proposed studies include studies of ground troops exposed to herbicides and of veteran twins, one of whom served in Vietnam and one of whom did not. The government of Australia has recently released the results of a case-control study of birth defects (6), showing no significant increase in risk for fathers who served in Vietnam, and is planning a morbidity study of Vietnam veterans.

Turning to Vietnam era veteran mortality, preliminary data on mortality from the follow-up study of Ranch Hand personnel and matched controls have shown no significant differences with respect to mortality (7), although sample sizes were small. The Australian Standing Committee on Science and the Environment was unable to reach a conclusion about increased cancer mortality rates among Vietnam veterans (approximately 49,000 Australian veterans served in Vietnam), although the Committee concluded that there was a need for further monitoring of the mortality rate among Vietnam veterans.

With regard to ongoing and planned studies of Vietnam veteran mortality, the Ranch Hand follow-up will continue to report mortality, and the study of ground troops exposed to herbicides includes a mortality follow-up component. Another study, conducted jointly by the New York State Department of Health and the Veterans Administration, is looking at the relative frequency of causes of death, comparing Vietnam service veterans with comparable non-Vietnam service veterans and also veterans versus non-veterans. Although limited to deaths in New York state (excluding New York City), this study will provide proportionate mortality ratio (PMR) data for a large number of deaths; results are due to be published in the near future. The Vietnam Veteran Mortality Study (VVMS) fits into this group of ongoing studies. As planned, the study will offer national data on a very substantial number (60,000) of Vietnam era veteran deaths, and should provide a clear picture of PMR's comparing Vietnam service and non-Vietnam service veterans.

BRIEF HISTORY

In June 1980, members of the newly-created Agent Orange Office of the VA and members of the interagency federal Herbicide Orange Working Group met with Drs. Page and Kuntz of the Biometrics Division, Reports and Statistics Service (now the VA Office of Reports & Statistics). The group outlined the plan of a study which would use existing VA records from the BIRLS file (Beneficiary Identification and Records Locator Subsystem) together with Department of Defense data to study mortality of Vietnam veterans. Within a week, a draft protocol was prepared by Drs. Page and Kuntz and submitted to the others for approval. On the

whole, the group was pleased with the overall study design and Drs. Page and Kuntz began to check out some of the details in their plan. For the next year or so, Drs. Page and Kuntz began to assemble the necessary computer files to do the study. Their plan was basically a cohort study, using VA reports of death to follow-up, via computer matching, a cohort of roughly 6 million Vietnam era veterans.

In November 1981, Dr. Page made a presentation to the American Public Health Association outlining the methodology of the Vietnam Veteran Mortality Study (VVMS) as described above. He also made a presentation to the newly reconstituted Agent Orange Working Group (the new administration had restructured the old group and appointed new members to the group). The new Science Panel of the Agent Orange Working Group was basically unaware of the efforts of Drs. Page and Kuntz, and one of their members had in the meantime proposed a study very much like the VVMS. The study proposed by Drs. Page and Kuntz was not well received by this new Science Panel, and the members of the panel had several changes to propose. In the end, the original design, a cohort mortality follow-up, was changed to a proportionate mortality ratio (PMR) study. This process, which included a total redesign of the study and submission to and approval of the new Science Panel, took about six months. Since the conduct of the new study involved significantly more money , there was a need to develop budget packages and to seek funding. By the end of fiscal year 1982, monies had been found and obligated for the study (roughly $1.25 million), and RFP's had been written to let contracts to do the data collection.

As of March 31, 1983 (mid-fiscal year 1983) the contracts had been let for the data collection, and pilot studies were begun.

Current plans are for the data collection to be completed by March 1984 and for study results to be published by December 1984.

CHAPTER 2.

PROJECT OVERVIEW

The Vietnam Veteran Mortality Study is a study to assess mortality patterns of U.S. servicemen in the Army or Marines who served during a portion (1965-1973) of the Vietnam era (1964-1975). The study will compare the mortality patterns of those servicemen who served in Vietnam with the mortality patterns of those who did not serve in Vietnam. Because there are no precise estimates of the population at risk, the study will provide only proportionate mortality ratio (PMR) data.

The study has sampled roughly 60,000 deaths of veterans who served in the Vietnam era, approximately one-third of whom served in Vietnam. This study population has been selected from Veterans Administration (VA) files, based on the assumption that the reporting of deaths to the VA is very complete (this assumption is being studied for us by the Medical Follow-up Agency of the National Academy of Sciences). For each of the 60,000 deaths, two kinds of information are being collected: information on military service from the military personnel record, and information on death from the death certificate.

With respect to military service information, Westat, Inc., the military personnel record contractor, is sending the identifying information on the VA BIRLS file to the National Personnel Records

Center in St. Louis. The information will be matched against the NPRC's automated register of military personnel records to find the location of the physical record stored by NPRC. Manual searching is being done when the automated search fails to turn up the military personnel record location. In theory, all military personnel records for veterans who have died should be stored at NPRC. Once it has been located, the military personnel record is being abstracted to provide data such as duty in Vietnam, dates served in Vietnam, paygrade, education, unit assignment, military occupational specialty code, etc. The abstracting process includes a quality control system which reabstracts a portion of the records of each coder.

With respect to death certificate information, the VA's information in the BIRLS file has particular utility. Not only does the BIRLS file indicate the fact of death (and of course the fact that the deceased was a veteran), but the record also points to the location of a VA claims folder. The VA claims folder will typically contain a death certificate if a death benefit claim has been filed. Thus we are using the record locator function of BIRLS to help locate claim folders and death certificates.

The actual procuring of the death certificate is a bit more complicated, because the VA claims folder containing the death certificate may be stored in one of several locations. Active claims folders (C-folders) are stored in VA Regional Offices (VARO's), while inactive C-folders are retired from VARO's to Federal Archives and Records Centers (FARC's), which are under the direction of a separate government agency, GSA. Fortunately, BIRLS keeps track of this retirement procedure, but the division of the C-folders into two types of locations (both VARO's and FARC's are

spread geographically across the country) complicates the location process. Moshman Associates, Inc., the contractor for the death certificate information, has overall responsibility for the death certificate location process, and for requesting death certificates from state vital statistics systems when the certificate cannot be found in VA claims folders.

Once located, the death certificate will be abstracted by Moshman Associates to provide data such as date and place of death, underlying cause of death, and multiple causes of death, as well as usual occupation and industry. Cause of death will be coded according to the eighth revision of the International Classification of Diseases Adapted (ICDA-8) for use in the United States, and will be coded in such a manner as to be comparable with national vital statistics. The abstracting process includes a quality control system which reabstracts a portion of each coder's work.

After military service and death certificate information has been collected (the data are being collected simultaneously from both sources), the two types of data will be merged and analyzed. The data will provide information to calculate PMR's adjusted for factors such as age, race, education, and rank in service. Various analytical approaches are being studied, including classical PMR analyses as well as categorical data analyses.

The remaining sections of the protocol deal in greater detail with the definition and selection of the study population, sample size estimates and power calculations, the data collection process, and plans for analysis.

CHAPTER 3.

DEFINITION AND SELECTION OF STUDY POPULATION

OVERVIEW

In this chapter we discuss the definition and selection of the Vietnam Veteran Mortality Study population. The goal of the definition and selection process is a study population of a suitable size and composition to allow a proportionate mortality ratio (PMR) analysis to be successfully undertaken. In this chapter we discuss the following items: identifying veteran deaths, selecting the study population, determining the study population size, and sampling the study population.

IDENTIFYING VETERAN DEATHS

In this section we discuss the process of identifying veteran deaths. We begin briefly with an alternative we considered and then dismissed, and then we concentrate the remaining discussion on the identification process actually used in the study, focusing on its strengths and weaknesses.

The goal of the veteran death identification process is to assemble as complete a roster of veteran deaths as possible, keeping in mind trade-offs in data quality, timeliness, and costs.

Moreover, it is not enough to assemble a simple roster, but that roster must also facilitate the capture of the necessary study information, and in particular must be easily linkable to death certificates and military records. This last requirement has important practical ramifications.

The most natural strategy for identifying veteran deaths is one that was ultimately rejected on practical grounds -- the strategy of ascertaining veteran deaths through vital statistics systems. The basic flaw in the strategy is simple: one cannot count on having veteran status recorded on all death certificates in all the necessary vital statistics systems. For instance, veteran status is not coded in the national vital statistics system, which forces one to go to the individual states. The individual states may or may not have collected veteran status and may or may not have coded it and entered it into a computerized system, and the study is too large to go about identifying deaths in state vital statistics systems through a manual process. More important, the quality of a veteran status indicator might be quite variable, and we know of only one study of the quality of this indicator (8). Finally, there are few available links, once the death certificate is found, to enable one to gather military service information. If the social security number (SSN) is recorded on the death certificate, that SSN may be used to match the death certificate to military records, but often military records are not indexed by SSN but by military service number. Thus, for practical reasons we must dismiss the idea of using vital statistics systems for the ascertainment of veteran deaths.

Fortunately, there is a practical alternative way to identify veteran deaths. The Veterans Administration (VA) pays a lump sum

death benefit to beneficiaries of eligible veterans. Up until October 1, 1981 the group of eligible veterans was quite large and included the veterans who served during the Vietnam conflict. Subsequent changes to legislation have reduced the number of veterans whose beneficiaries would be eligible for death benefits .

The VA maintains an automated system to identify and keep track of veteran beneficiaries. The system includes records for veterans receiving benefits such as compensation and pension, loan guaranty, and education, as well as records for veterans whose beneficiaries receive a death benefit. This system, BIRLS, is used to ascertain veteran deaths.

The BIRLS file offers the following advantages in ascertaining veteran deaths : (1) it is thought to be relatively complete in its roster of veteran deaths, (2) it has a built-in linkage, through the VA claims folder, to the veteran's death certificate, and (3) it collects the kind of information that facilitates linkage to the military record system. Each of these points will now be discussed in turn.

As noted above, prior to October 1981 eligibility for the VA lump-sum death benefit was quite widespread. Anecdotal evidence indicates that application for the death benefit was also quite widespread; funeral directors were said to be uniformly knowledgeable about the existence of the benefit and quite thorough in making application for the benefit for the family. The evidence of completeness of veteran death reporting to the VA is not just anecdotal. A very important study by Beebe and Simon (9) showed that up to 98% (for World War II veterans) of independently ascertained veteran deaths were known to the VA. This study was undertaken prior to the existence of the automated BIRLS file, but

used a manual file comparable in many ways to the BIRLS file. There seems to be good reason to assume that the computerized BIRLS file is just as complete as the manual VA file.

Nevertheless, the completeness of veteran death reporting on the BIRLS file is too crucial an issue to be left to assumption. A contract has been let to the Medical Follow-up Agency of the National Research Council/National Academy of Sciences to redo their earlier study, this time focusing on Vietnam era veteran death reporting on the computerized BIRLS file. In addition, we mention that the BIRLS file has been used and continues to be used as an important resource for mortality follow-up (10-12).

The second advantage of the BIRLS file is its built-in linkage to death certificates. The BIRLS file, as its name suggests, is a records locator system. The record in question is the VA claims folder or C-folder. The C-folder holds the paper record of a veteran's claim for benefits, and in the case of the application of a beneficiary for death benefits, the C-folder should contain some kind of notification of death. In almost all instances, we believe, this notification is the official death certificate. Thus, using BIRLS, it is possible to locate the C-folder for a particular veteran known to be dead (BIRLS has a field to record date of death and the recording of the date of death stops the payment of other veterans benefits), and having located the folder, to retrieve the death certificate. This death certificate linkage is discussed in more detail in Chapter 4.

The final advantage of the BIRLS file is the data it contains to facilitate linkage to a veteran's military record. The most important information is identifying information, and BIRLS can contain all or some of the following : name, social security

number, military service number, date of birth, dates of military service, and branch of service. Entrance to the military records system is normally gained through its automated index known as the register, and this register contains basically the name, identification number, and branch of service of a veteran. Unfortunately, there is only one identification number and it may be either the social security number or the service number (the veterans in this study include those who served in the era when the service number was being changed to the social security number). There are various ways of getting around this difficulty, including using BIRLS data to search for both name and social security number and name and service number, when available. These issues are discussed more completely in Chapter 4.

In conclusion, the BIRLS file will be the source from which veteran deaths are identified. Current information indicates that this system should be a substantially complete roster of Vietnam era veteran deaths, and this assertion is being studied by an independent group under contract. Use of the BIRLS file to assemble the roster of veteran deaths has other benefits in addition to its alleged completeness -- it allows interface with death certificates located in VA claims folders and with military records archived by the military services.

SELECTING THE STUDY POPULATION

General Discussion

In this section, we discuss the rationale and the method of selecting the study population of Vietnam era veteran deaths. We begin with a few preliminary remarks on the rationale of selection, and then move to a detailed description of the algorithm which determines which records from the BIRLS file (see preceding section for a discussion of the BIRLS file) were selected to be included in the study population.

The goal of the selection process is to assemble a group of suitable Vietnam era veteran deaths that is large enough to enable a PMR analysis. There are two important objectives in this goal -- on the one hand we are interested in as complete a roster as possible, and on the other hand we want as error-free a roster as possible. These two objectives must be kept in mind since we are assembling the study population from a data file which we know is not error-free. For this reason, the selection process will be a two-stage process. In the first stage we will select as complete a roster of possible Vietnam era veteran deaths as possible. In the second stage we will edit this file to obtain as accurate a roster as possible. In this edit stage we are faced with incomplete, missing, conflicting, and erroneous data, and must, nevertheless, make a final decision as to whether or not a particular record is to be included in the study population.

Determining the proper edits is, therefore, a difficult process. There will be many cases where one is unable to determine unequivocally whether a particular record belongs in the study population, due to missing, erroneous, or inconsistent data. A

"tight" edit, which tosses out these questionable cases, may actually exclude subjects which properly belong in the study. Conversely, a "loose" edit will include in the study subjects who are not in the scope of the study.

The edit process will attempt to exclude from the study population only those records for which the subjects have only a remote chance of being Vietnam era veteran deaths. However, in order to make sure these edits were not in error, a sample of subjects excluded from the study will be included in the pilot test as a "quality control" sample. The records will be located for these subjects and a definitive answer will come from the military service record. At the end of the pilot test we will know what proportion of excluded study subjects actually should have been included in the study, thus providing some idea of the bias created by wrongly excluding them.

Before moving to the detailed selection and edit processes, let us first define the study population in more general terms. First, we are concerned only with veterans who served either in the Army or in the Marines. The reasoning for this choice is that the meaning of Vietnam service would seem to be clearest in these two groups. For both Army and Marines, Vietnam service meant service in-country; there was close contact with the environment of Vietnam (we will note also when service was in parts of Southeast Asia other than Vietnam). For Navy and Air Force, the context of the service in Vietnam may not be so clear; it may be very difficult to determine whether Navy personnel, who were considered to have Vietnam service if they served on a ship stationed in the territorial waters, ever actually set foot in the country. The same is the case for Air Force personnel who might have flown

missions over Vietnam and yet might not have been stationed in Vietnam. Thus the study is limited to the Army and the Marines in order to have a clear meaning of service in Vietnam .

Second, we are concerned with excluding deaths related to combat. It is clear that combat deaths would occur in the Vietnam service group and not in the non-Vietnam service group and would be a source of incomparability between the two groups. Deaths which are indirect outcomes of combat are less easy to ascertain. For that reason we are excluding all deaths in service up through 1973 (the end of the combat period in Vietnam). By "in service" death we mean any death that occurred while the veteran was in military service, regardless of the cause. The operational definition is thus straightforward -- a death is an in service death if the date of death and the date of discharge from military service are equal. Selecting out all in service deaths for the Vietnam era up through the end of combat removes a possible source of incomparability between the Vietnam and non-Vietnam service groups.

Third, we want to limit the study population to Vietnam era veterans, and BIRLS does not always have military service dates. Therefore, records with missing service dates are included in the study if the year of birth is 1935-1957 (actually BIRLS records only the last two digits of a year). These birth years were chosen to include veterans with a high probability of having served in the Vietnam era, yet without including too many veterans who might have served earlier or later.

In summary, the study population in general terms consists of records with an indication of death on BIRLS as being Army or Marine (or branch unknown) veterans of the Vietnam era (1965-1973). In-service deaths up through 1973 are excluded from the study, and

in cases where there are missing military service dates, year of birth '35-'57 is used as a proxy for Vietnam era service.

Detailed Description

We are now ready to detail the selection process from the BIRLS file. It is important to remember throughout this discussion that we are dealing with an administrative data file which may contain missing, incomplete, or erroneous data. A good deal of the complications in the selection algorithm are due to the problems caused by missing and and incorrect data.

We now outline the selection process. In the first stage all records of deaths of persons with any possibility of having Vietnam service are selected from BIRLS, including records of persons with missing service dates but with birth year 1935-1957 inclusive. This first tier of selection is much too broad a definition, as we will shortly see, but the strategy for the first stage was to not eliminate any possible study subjects. In the second stage we further refine the selection by requiring either Vietnam era service or birth year 1935-1957, inclusive. By Vietnam era service we mean any indication of Vietnam era service on the BIRLS file. Specifically, either the enlistment or separation dates on the BIRLS file must fall between 1964 and 1975, or enlistment must be before 1964 and separation after 1975, but before 1982. The selection by birth year is made only if there are no service dates.

In the last tier of selection we exclude certain subjects. As discussed previously, all in service deaths through 1973 are excluded. In addition, all subjects are excluded who have a known branch of service which was not Army or Marines. Also excluded are enlistment dates after 1973. This edit was made in order to

conform to the Department of Defense definition of Vietnam era. And finally death years out of range (before 1964 or after 1982) are excluded unless the birth year equals the year of death, indicating an error on the record.

The results of the selection process leave us with two files: the original file has been partitioned into "selected" and "unselected" files. From the roughly 800,000 deaths extracted from BIRLS we have determined that about 185,000 are probable Vietnam era veteran deaths. The selection process has been complicated by the fact that data on the BIRLS file may be missing or erroneous. Hence, it is important that we include a double check on the selection process itself. Specifically, we will include a random sample of the excluded records in the pilot test. By including these records in the pilot test, we will see whether indeed the excluded subjects should have been excluded. In any cases where we find that a group of subjects was excluded from the study when a significant portion of these subjects should have been included, we will be able to add that group of subjects back into the study.

The classes of subjects excluded from the study fall into five groups. Group 1 are those excluded because BIRLS said that their branch of service was not Army or Marines. To the extent that BIRLS may have erred, some Army and Marine subjects may have been incorrectly excluded from the study. Group 2 includes those subjects with a death year out of range (and also those subjects on whose records the death year was not equal to the birth year so that it is unlikely the two were confused). Again errors on BIRLS could have incorrectly excluded subjects. Group 3 includes subjects who have service dates recorded on BIRLS, but for whom those service dates are outside the Vietnam era. Group 4 are the

subjects with in service deaths through 1973. In these cases BIRLS errors could occur in either the separation date or the date of death, resulting in an improper exclusion. Group 5 includes those subjects with missing service dates and a birth year out of range. For this group, it is quite possible that we could inadvertently exclude older Vietnam era veterans whose service dates were merely unrecorded on BIRLS.

One additional complication that should be mentioned here is a complication regarding the recording of dates on BIRLS. The BIRLS file only records two digits for the year, and thus does not record the century. Although this would not seem to be a problem at first glance, there are some difficulties. We have, for example, doubtlessly included a certain number of Civil War veterans in the study, since our service dates are '64 to '75 with death prior to '82. Moreover, any World War I veteran with an enlistment or separation date of '17 which was transposed to '71 could enter the study if he met the other selection criteria.

In conclusion, the selection process used in defining the study population for the Vietnam Veteran Mortality Study is a complicated process. It has been complicated by the fact that the selections are made from an administrative file which can contain less than perfect data. The result of the selection process will produce some errors, both improper inclusion of study subjects and improper exclusion of study subjects. The first errors cause no problem, for once the military record has been abstracted, improper subjects can be identified and excluded from the analysis. The second type of error, improper exclusion of study subjects, is much more difficult to control; we have deliberately included a sample of "excluded" subjects in the pilot test in order to check on the

levels of error in the exclusion process. Any such errors can be remedied after the pilot test and before the full study begins.

SAMPLING PROCEDURES

After the selection and edit steps were performed on the BIRLS records, roughly 185,000 records were left as probable Vietnam era veteran deaths. This included possible duplicates. From this group approximately 60,000 records were selected by simple random sample and allocated into four "batches" of roughly 15,000 each. Each batch is a separate random subsample, and the batches will be processed separately in order to spread out the data collection. However, since the batches are random subsamples, the results of the individual batches could be analyzed separately once that portion of the data collection is completed. The first batch has furnished the material for both the military personnel record and death certificate pilot studies. As mentioned previously, roughly 500 records which did not pass the second edit stage (i.e., they were probably not Vietnam era veteran deaths) were selected as a "quality control sample"; these records were added to the first batch of 15,000 records.

CHAPTER 4.

SAMPLE SIZE AND POWER CALCULATIONS

The sample size for the mortality study was determined by considering the power of the statistical tests of the study hypotheses. These hypotheses concern the frequency of occurrence of specific causes of death on the death certificate among those veterans with and without Vietnam service. The power of a statistical test refers to the probability that a true difference in mortality rates will be judged statistically significant in a given sample. The observed difference in mortality rates is affected both by the misclassification that occurs in either the exposure or the outcome variables as well as by the variability due to sampling. Both of these effects will be discussed below with respect to their impact on the sample size needed, beginning with the misclassification issue.

With respect to misclassification, we have two important concepts: (1) whether the misclassification is "random," and (2) whether the misclassification is "excessive." In general, if the misclassification is random and not excessive, then the larger the sample size, the greater the power, although even random non-excessive misclassification will have the effect of lowering power. Let us define the terms "random" and "excessive."

The term "random" is used to mean that the probability of misclassification of the outcome variable is independent of the classification or misclassification of the exposure variable. The term "not excessive" is used to mean that: (1) the proportion of truly exposed is greater among the group that is observed (thought to be) exposed than among the group that is observed to be unexposed, and (2) the misclassified with a negative outcome are a smaller proportion of those with a negative outcome than the properly classified with positive outcomes are of those with positive outcomes. These conditions are satisfied if, for example, all misclassifications are held to less than 50%.

If these two assumptions are violated, unusual and untoward effects can occur; for example, the observed difference and the true difference may actually have opposite signs. This is a much more serious situation than the case where the misclassification is random and non-excessive, for then the observed difference is still of the same sign as the true difference and is merely decreased in magnitude.

In the mortality study the exposure variable is duty in Vietnam, and the meaning of misclassification is straightforward, namely, we can misclassify by labeling a veteran with duty in Vietnam as having had no duty in Vietnam, or vice versa. With respect to the outcome variable, cause of death, misclassification will be taken to be the miscoding of the cause of death on the death certificate to another category. For a given cause of death of interest, one can consider a dichotomous variable defined as 1 if the cause of death is the cause of interest and 0 if this is not the case. By using this scheme, it is clear that misclassification

can also occur in either of two directions -- 0's can be misclassified to 1's or 1's to 0's.

It is reasonable to assume that service in Vietnam is measured with very low error. We are not using a proxy measure of service in Vietnam -- the military personnel record is the absolute standard. The only misclassification errors should be random and quite small.

Similarly, it is reasonable to assume that there is no misclassification of cause of death. Proper quality control of the coding process should ensure an extremely low coding error, so as to be the same as that of the U.S. statistics which are being used as the basis for the sample size calculations. Therefore, there is no misclassification, vis-a-vis the death certificate cause of death. This assumption is not to be confused with the misclassification of cause of death on the death certificate itself, i.e., the writing down of the wrong thing on the death certificate. This is discussed in Appendix E.

Despite the fact that we have made a case for assuming that there should be almost no misclassification, our sample size calculations will be made with non-zero estimates of misclassification proportions regarding the probability of misclassifying service in Vietnam. In addition to these primary sample size calculations, we include an analysis of the effect of more excessive misclassification. These latter calculations are provided in the spirit of a "robustness against misclassification" analysis. We now turn to the actual calculation of the sample size.

PARAMETERS FOR SAMPLE SIZE CALCULATION

Various parameters need to be specified in order to determine the sample size needed for a study to achieve a given power, the probability of finding differences, based on service in Vietnam. The parameters needed are: (1) the relative risk, which is the ratio of the probability of the outcome (disease status) among those with service in Vietnam (exposed) to the probability of the outcome among those with no service in Vietnam (unexposed); (2) the probabilities of misclassifying the service in Vietnam; (3) the proportion of veterans with duty in Vietnam; and (4) the proportion of veterans expected to have the disease on their death certificate. From these data the formulae given in Appendix B calculate the likelihood (power) of actually finding a statistically significant difference between those with and without service in Vietnam when the true difference is at least as great as the specified relative risk.

We begin by discussing the relative proportions of the various causes of death among Vietnam era veterans. Table 1 shows the estimates of the number of deaths for Vietnam era veterans for the period 1966-1980 for selected causes of death. These are deaths that would be expected to occur in civilian life after discharge from service, and exclude deaths occurring in military service. The estimates are based on U.S. male death rates and on Veterans Administration Vietnam era veteran population estimates for 1965-1979 by five-year age groups.

Estimates for all causes -- trauma, neoplasms, heart disease, cirrhosis, and all diseases -- are based on U.S. male death rates for 1976. Estimates for the selected malignant neoplasm causes are

based on combined U.S. male death rates for 1974-1976. Except for the deaths for specific neoplasm diagnoses, the numbers are rounded to the nearest thousand and the number of deaths per 10,000 is rounded to the nearest hundred. The code numbers in parentheses after the cause of death are from the World Health Organization's International Classification of Disease, Adapted, version 8.

There are several reasons why these estimates only approximate the number of veteran deaths. For one, they use the U.S. vital statistics for the period 1976, or 1974-1976, as the estimator for the death rates, while the veteran deaths being estimated and the veteran population used span the period 1966-1980. Also, the tabulated U.S. rates may overstate actual U.S. death rates because of the U.S. Census undercount, which is highest among young black males. This undercount causes the death rates to appear to be higher than they are because the Census population estimates are used as denominators in the computation of U.S. death rates. If the denominator is smaller than it should be, the death rate will be higher than it should be. Furthermore, the race and age distribution within the five-year age groups may be different for the U.S. male population than for the veteran population. Also, the mortality study is concerned with deaths among the Army and Marine Corps Vietnam era veterans, who are probably slightly younger than the total Vietnam era cohort, so that the estimates for certain causes may vary slightly from those presented.

Lastly, there are two countervailing differences between the veteran cohort and U.S. males of similar age that would affect their death rates. On the one hand, the veteran population was screened for health problems prior to induction, making this group a potentially healthier one than the general population (13). On

the other hand, veterans may die shortly after discharge from combat-related causes to which the rest of the population is not exposed. The estimates will be less precise to the extent that these factors change the death rates.

TABLE 1
Estimates of Deaths by Cause for Vietnam Era Veterans
1966-1980
(Excludes deaths occurring during military service)

Cause of Death	Estimates of Numbers of VEV Deaths		
	All VEV	Per 10,000 VEV Deaths	Non Vietnam Service in Sample of 50,000 VEV Deaths
All Causes	203,000	10,000	33,500
Trauma	110,000	5,400	18,213
Suicide	20,000	1,000	3,375
Other trauma (including accidents)	90,000	4,400	14,838
All diseases	93,000	4,600	15,287
Neoplasms (140-239)	22,000	1,100	3,574
Benign eye,brain (224-225)	99	5	16
Multiple myeloma (203)	176	9	29
Liver (155)	235	12	39
Connective tissue (171)	250	12	41
Lymphosarcoma (200)	711	35	118
Hodgkins disease (201)	1,140	56	188
Malignant brain etc (191, 192)	1,543	76	255
All other neoplasms	17,846	895	2,888
Heart disease (410-414, 420-429)	28,000	1,400	4,556
Cirrhosis (571)	6,000	300	1,036
All other diseases	37,000	1,800	6,175

Estimated deaths for several malignant neoplasm diagnoses are given in Table 1 above. These have been identified as possibly of special interest in the PMR study. The rarest of these is multiple myeloma for which it is expected that there would be nine deaths for every 10,000 Vietnam era veteran deaths. Liver neoplasms are the next rarest with 12 deaths per 10,000 deaths.

POWER CALCULATIONS

Figure 1 shows the relationship between power and the expected number of deaths in the unexposed cohort, using the assumptions noted below. The points identified on the curves are the specific causes of death at the expected number of deaths for a sample size of 50,000 Vietnam era deaths as shown in Table 1. It is assumed here that the proportion of the sample with service in Vietnam is 33%, that there is essentially no misclassification of those who did not serve in Vietnam, and that there is a five percent probability of overlooking the service in Vietnam. The lowest curve represents the probability of finding a statistically significant difference at the 0.05 level when the true relative risk is 1.50. The next curve is for relative risk of 2.00 and the third, 2.50.

The calculations for the curves shown in Figure 1 were done using the following formula. In this formula the term r, observed relative risk, is calculated from the assumed true relative risk using the misclassification probabilities above and the formula in Appendix C on misclassification.

$$\text{Power} = \text{Probnormal}\{-\text{Probit}(1-a)+2*\text{sqrt}(EXP)*(\text{sqrt}(r)-1)/\text{sqrt}(1+K)\}.$$

Where

(1) a = the probability of a type I error; i.e., the probability that a difference will be asserted to be found when it is not there,

(2) EXP = the expected number of cases in the unexposed cohort,

(3) R = the observed increased relative risk of disease in the exposed cohort,

(4) K = the factor by which the unexposed exceeds the exposed cohort in size,

(5) Probnormal(z) is the probability that a random variable with mean 0 and variance 1 will be less than z,

(6) Probit(b) is the inverse for the probnormal; i.e., the value of the normal distributed random variable with a mean of 0 and a variance of 1 for which the probability of being less than that value is b, and

(7) sqrt is the square root function.

Note that if EXP is the expected number of deaths in the unexposed cohort, then the expected number of diseased in the exposed cohort is (R*EXP)/K. This formula is derived in Appendix B.

FIGURE 1. POWER AND EXPECTED NUMBER OF DEATHS IN NON-EXPOSED GROUP (SEE TEXT FOR ASSUMPTIONS)

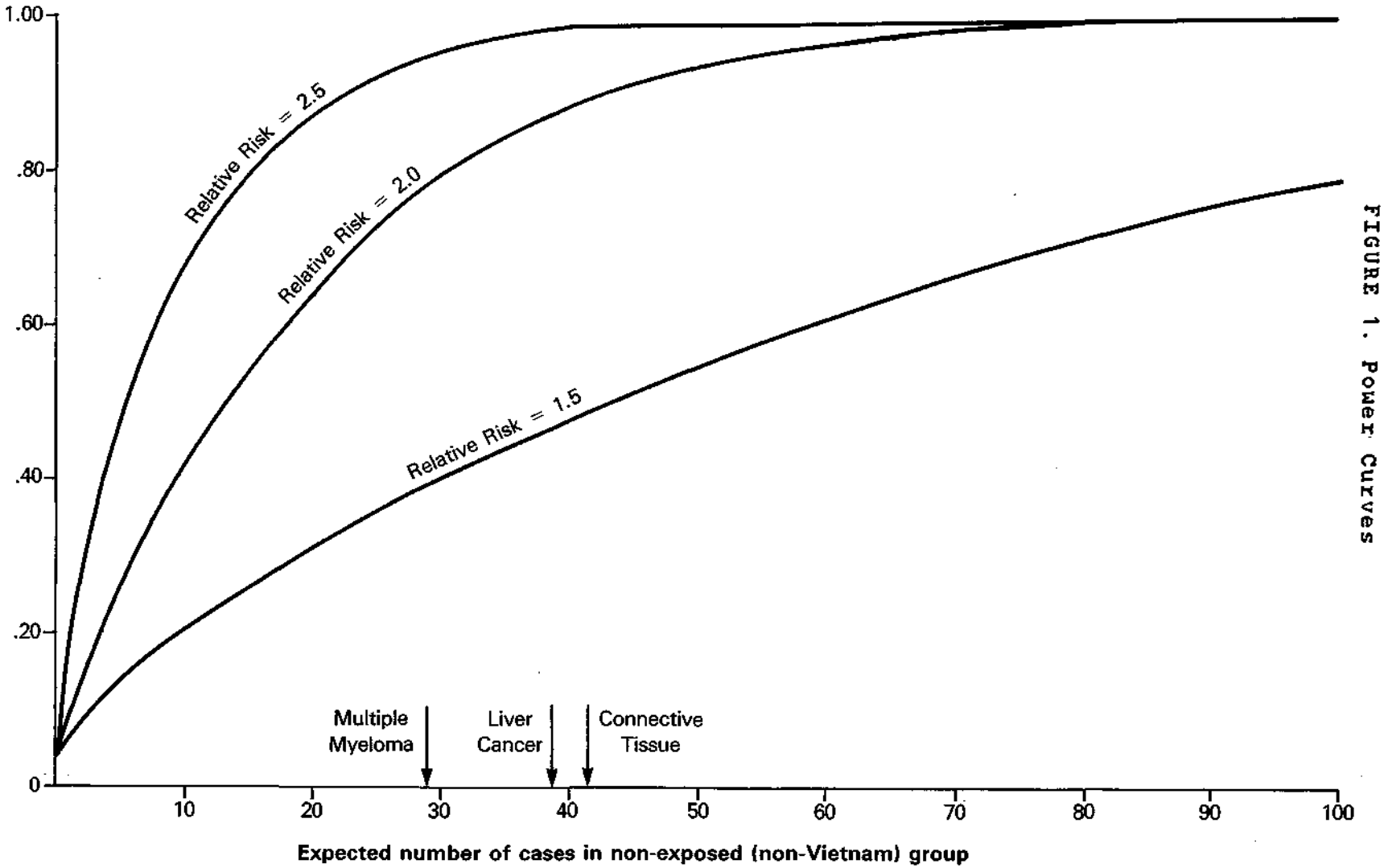

FIGURE 1. Power Curves

ROBUSTNESS OF MISCLASSIFICATION

In this section we examine the robustness of the sample size estimates in comparison with larger amounts of misclassification. Because the issue of power is most troublesome in disease categories where frequencies are small, this "robustness analysis" selects out only two relatively rare disease categories, multiple myeloma and liver cancer for analysis.

Table 2 shows the effects of varying the misclassification rates on the power of the study to detect differences for two of the rarer diseases (multiple myeloma and liver cancer) when given certain values for the true differences and given the misclassification of the service in Vietnam. The derivation of the formulas used in this analysis may be found in Appendix C. In particular, Table 2 shows the power (the probability of detecting a difference in the frequency of occurrence of these two diseases, in a sample of 50,000 Vietnam era deaths at a nominal significance level of 0.05) for three different assumed actual relative risks, for two different proportions of the cohort actually in Vietnam, and for eight selected rates of misclassification. The first column, exposed misclassification, is the proportion of the truly exposed who are (mis)classified as unexposed. The second column, unexposed misclassification, is the ratio of the number who were not exposed but were (mis)classified as exposed to the number truly exposed. The misclassification values that were used were 0, 5, 10 and 15 percent for exposed to unexposed, and 0 and 10 percent for the ratio of the unexposed misclassified as exposed to the truly exposed. The proportions of the sample exposed were 28% and 38%.

TABLE 2
Percent Probability of Detecting a Difference in the Frequency of Occurrence of Two Diseases for a Sample Size of 50,000 Deaths
(All values except relative risk are percentages)

Exposed Misclassification	Unexposed Misclassification	Relative Risk											
		1.75				2.00				2.50			
		Multiple Myeloma		Liver Cancer		Multiple Myeloma		Liver Cancer		Multiple Myeloma		Liver Cancer	
		Vtn	Serv	Vtn	Serv	Vtn	Serv	Vtn	Serv	Vtn	Serv	Vtn	Serv
		28%	38%	28%	38%	28%	38%	28%	38%	28%	38%	28%	38%
0	0	60	66	71	77	79	84	88	92	96	98	99	99
0	10	57	64	68	74	76	82	86	90	95	97	99	99
5	0	56	61	67	72	74	79	85	88	94	96	98	99
5	10	53	58	64	68	72	76	82	86	92	95	98	98
10	0	52	56	63	67	70	74	81	84	91	93	97	98
10	10	49	52	60	63	67	70	78	80	89	91	96	96
15	0	49	51	59	61	66	68	77	79	88	89	95	96
15	10	45	47	55	57	62	63	73	74	85	86	93	93

It is quite likely given the figures in Table 2 that a study of 50,000 deaths will produce data which will identify differences in the frequency of occurrence even for causes of death which are rare. For example, if the true relative risk is 2.5 there will be a probability of at least 85% of finding a statistically

significant difference at the 0.05 level of significance. The 85% figure is the "worst" case: when misclassification is relatively high (15% of those with service in Vietnam being misclassified as having no service in Vietnam, and the equivalent of 10% of those in Vietnam being those with actually no service in Vietnam), and the percent with service in Vietnam is quite low - 28%. For a relative risk of 2.0 the power drops to 62% for multiple myeloma in the "worst" case; however, the power for detecting differences in prevalence of liver cancer deaths is still 73%. If the two types of misclassifications can be kept at 10% or less, then the power for multiple myeloma will be 70% or more unless both misclassifications are ten percent or more. As the true relative risk drops to 1.75, the power falls off accordingly. Even in this case, however, the power will be close to or over 70% if the misclassification is low or the exposure proportion is moderately high. The high end of the service in Vietnam percentage, 38%, is not unreasonable. In fact, a recent survey of veterans (14) found that 44% of the Army and Marine Corps veterans of the Vietnam era served either in Vietnam, Laos, or Cambodia, or waters in or around those countries, or in missions flying over these countries. A sample size of 50,000 would appear to have a reasonable probability of detecting different prevalences of causes of death between those who served in Vietnam and those who did not.

The nominal level of 0.05 significance is the actual level of significance if only one hypothesis is tested. As more diseases are tested, then the level of significance increases, that is, the chance increases of finding a difference in the sample which does not reflect a true difference increases.

OVERSAMPLING

A sample size of 50,000 then was chosen for this study since it is the smallest sample which gives the necessary power for detecting differences in death rates for the causes of interest. However, a sample of 60,000-65,000 will need to be selected from the BIRLS file in order to provide a sample of 50,000 for analysis. Losses to the initial sample have two fundamental causes. One is the inability to locate records. This involves the inability to locate some VA claims folders, some military records, and some death certificates. It is expected that death certificates will, in most cases, be found in the VA claims folders. For those which are not, the death certificate will be sought from the state where the death occurred. Nonetheless a few death certificates will remain missing. Losses from these sources are expected to be small.

Larger losses from the initial sample are expected because of the errors on the BIRLS records. The errors of concern here are in the branch of service and the period of service fields. In the case of branch of service we expect to find that perhaps as many as 30% are missing. Of this 30%, 50-60% will probably actually be Army or Marine Corps veterans. Thus, 10-15% of the records initially selected for the sample will be ineligible for the study because they will come from the wrong branch of service. In this case the record, which is included in the initial sample, is excluded when it is identified as not from the Army or Marine Corps. Some records on the BIRLS file which appeared to belong to the Vietnam era actually do not, due to errors in recording period of service. Other records do not contain period of service and were included if the birth year (1935-1957) indicated a likely

Vietnam era veteran. These records will be excluded when the period of service is correctly identified and found not to belong to the Vietnam era.

CHAPTER 5.

INFORMATION SOURCES AND DATA COLLECTION

In this section, we will discuss how we will obtain information on Vietnam service from military service records and cause of death data from death certificates. In addition, we discuss collecting data from both sources on demographic, socioeconomic and other characteristics we believe might be confounding variables. Two contracting firms have been hired to work with Veterans Administration personnel in the data collection phase of this study. Moshman Associates, Inc. will have the responsibility of abstracting data from death certificates, and Westat, Inc. will be responsible for collecting military service record data.

DEATH CERTIFICATE INFORMATION

Historically, wartime veterans have been entitled to a death benefit from the VA. In order to get this benefit when the veteran dies, the person or organization responsible for the funeral expenses of the deceased veteran must submit proof of death and proof of veteran status. Usually the death certificate is submitted as proof of death. The items used as proof of death and veteran status are retained in the veteran's claims folder (C-folder), which is kept at the appropriate VA regional office if

the file is active or is sent to a Federal Archives and Records Center (FARC) if there has been no activity on the file for two years.

Locating File Folders

The veterans' claims folders are located in one of 58 VA regional offices, the VA records processing center in St. Louis, or in one of 16 FARC's. The BIRLS system (see Chapter 3) has a location indicator which identifies the VA regional office or FARC in which a folder may be found.

We plan to create computer listings and computer-generated cards four times during the course of the study. The computer listings along with the set of computer-generated cards will contain the deceased veteran's name, claim file location number, and social security number. Each of the four batches created will be for approximately one-fourth (15,000) of the study sample. We will send the lists and cards created from each run to the appropriate VA regional offices and FARC's. Personnel in the VA regional offices and FARC's will locate the claims folder, photocopy the death certificate, if available, and return the photocopy attached to the computer-generated card to Moshman Associates, Inc. The purpose of the four computer runs is two-fold. First, the requests for searchofg claims folders will be spread out evenly during the study period, and by giving expected return times for each of the four mailings, we should avoid last minute return of photocopied certificates. In addition, by creating four different listings, the up-to-date VA regional office or FARC location given in the BIRLS system may be utilized.

Appropriate VA and GSA officials have signed a memorandum of understanding to allow GSA personnel to pull claims folders and photocopy death certificates in FARC's. Also, officials at VA regional offices have been sent a circular explaining the purposes of the study and study procedures.

We have identified two possible problems in connection with this phase of the study. They are:

(1) No death certificate is found in the folder, or

(2) No claims folder is found.

If there is no death certificate in the folder, personnel should look for other evidence of death. A DD Form 1300, Report of Casualty, may be substituted for the death certificate. If this is not available a VA Form 23-6547, Excerpts From Death Certificates, will be filled out and forwarded to the contractor; this form gives the date and place of death of the veteran. Identifying information on VA Form 23-6547 will enable Moshman Associates to contact state vital statistics offices directly to obtain copies of death certificates. In the event there is no evidence of death in the claims folder, the computer-generated card will be so noted and returned to the contractor.

If no claims folder is found at the VA regional office, personnel should check BIRLS to see if the claims folder is located at another VA regional office. If this is the case, the computer-generated card should be forwarded to the proper station. If the claims folder has been retired to a FARC, personnel at the VA regional office should note this on the card and return it to the contractor. When normal search procedures fail to locate the missing folder, the contractor will be notified.

The contractor will send a list of those veterans whose death certificates are not found to each of the 50 states in an attempt to obtain the death certificates.

Death Certificate Data Requested

For the deceased veterans in the study, the VA is requesting that the contractor abstract the following information from the death certificate:

Demographic and Other Variables (Excluding Medical)

- veteran's name
- social security number
- sex
- date of birth
- age at last birthday
- birthplace
- date of death
- county and state of death
- marital status
- race
- usual occupation
- kind of business or industry
- county and state of residence
- veteran status (when available)

Medical Variables

- all causes and conditions at death
- whether or not the death was an accident

whether or not the death was a suicide

whether or not the death was a homicide

existence of an autopsy

All medical conditions are to be coded according to the Eighth Revision of the International Classification of Diseases adapted for use in the United States. However, ICD-9-CM morphology codes will be used for any histological information recorded on the death certificate relating to malignancies. These codes are not available in the Eighth Revision but are compatible with it.

A discussion of the quality of the medical certification on the death certificate is in Appendix E.

Death Certificate Contractor Responsibilities

The death certificate contractor, Moshman Associates, will be conducting work in three phases. In the first phase, which has been completed, Moshman Associates presented plans for conducting the death certificate portion of the study. Management of the death certificates, coding procedures (including quality control), editing, plans for a pilot study, and data presentation are covered in the Phase I report submitted to the Veterans Administration contracting officer's technical representative (VA COTR).

Phase I

A brief summary of plans reported in the Phase I document is given below:

Management of Certificates - The Veterans Administration plans to give Moshman Associates four tapes, each containing one-fourth

of the study sample. These tapes contain names and other identifying information on the veterans in the study sample. Each tape corresponds to the one-fourth of the study sample being sent to the VA regional offices and FARC's (see Locating File Folders section). Moshman Associates will check the tapes for any duplicate names and social security numbers and will bring this to the VA COTR's attention for reconciliation. Moshman Associates plans to use these tapes to set up a master list to keep track of the certificates being sent to them. They will notify the VA COTR if any VA regional offices or FARC's return a large number of illegible certificates or fail to send a large number of certificates without noting the reason on the computer-generated card provided to them (see Locating File Folders section). Moshman Associates plans to request death certificates from states when they are unable to obtain them from a VA regional office or FARC.

When the contractor begins to receive death certificates, VA Forms 23-6547 and illegible copies will be removed for special handling. The remaining certificates will be sorted by state of death and batched in groups of 500. Each batch will be assigned a batch number and each certificate a sequential accession number. The batch number, sequential accession number, a VA ID number, the state of death, date of receipt and source of receipt (VARO or FARC) will be entered onto an automated data file in order to keep track of where the certificate is during all stages of processing.

Coding Procedures - Moshman Associates plans to use the National Center for Health Statistics (NCHS) instruction manual, "Demographic Classification and Coding Instructions for Death Records" (1981), as a guide for coding the demographic items on the death certificate. The 1970 Federal Information Processing

Standard (FIPS) codes will be used to assign codes to both the residence of the decedent and the place of death. NCHS recommended this to Moshman Associates due to the fact that the 1982 manual based on the 1980 census has not been in use for a sufficient period of time to resolve all problems with it.

Moshman Associates will be using a manual on occupation-industry codes developed by the Bureau of the Census to code the deceased veteran's occupation.

The contractor will hold a two-day training session for the demographic coders on the project. Included in this training session will be a review of the coding scheme for each item on the death certificate and a practice session of coding actual death certificates.

The contractor feels that no formal training will be required for nosologists who have been performing this task for many years and were involved in the development of the procedures at NCHS. However, the nosologists will be instructed in the use of ICD-9-CM morphology codes for any histological information recorded on the death certificate for any malignacy.

A coder production schedule will be set up (based on the results of the pilot study) and batches of certificates will be assigned to individual coders. Each individual coder will code his batch of certificates and return them to the supervisor, who will verify that all certificates in the batch have been coded and returned. The supervisor will then select a random sample from each coder's batch for demographic coding verification. Batches with an error rate greater than five percent will be rejected and the entire batch will be recoded. As the demographic coding of batches becomes acceptable, the batches will be given to the

nosologists for medical coding. The medical coding will undergo 100 percent verification. Throughout the coding process, the status of each batch will be entered onto the automated data file set up to keep track of the certificates.

Keytaping, Editing, and Data Presentation - As the coding is completed on the death certificates, keytaping of the certificates will take place. Based on the results of a pilot test, it will be decided whether or not 100 percent verification of the keytaping is necessary.

Computer programs are being developed to detect errors in the range and format of variables keyed and to check for inconsistencies in the data. Finally, the data tape created will be checked against the master file to ensure that all certificates that were found were processed. Errors detected in the editing procedures will be corrected and a final automated version will be given to the VA COTR along with the photocopied certificates and microfiche copies with both arranged in sequential accession number order.

Phase II

A pilot study is planned to test the procedures given in the Phase I report. About 3,000 of the first 15,000 requests sent to the VA regional offices and FARC's will be processed completely before processing other requests. This will enable the contractor to test all procedures outlined in the Phase I report, to determine production times and help set up coding and other schedules. In addition, the pilot test is expected to aid the contractor in setting up quality control measures, including determining the intial sample sizes needed to be submitted for coding verification.

Phase III

Phase III is the production phase. During this phase procedures formulated in Phase I and modified during the pilot study will be implemented for the entire study sample.

MILITARY SERVICE RECORD INFORMATION

The General Services Administration (GSA) maintains the National Personnel Record Center located in St. Louis, Missouri. Military personnel records including those from the Vietnam era are kept at this depository.

Locating File Folders

Although the military records themselves are not automated, there is a computerized system (the register) for locating the personnel records. According to personnel at the center, almost all of the Vietnam era records can be located by using this register. In order to use the register, the veteran's name, branch of service, social security number, birth date and, when available, service number need to be provided. We will furnish this information to the military service records contractor, Westat, Inc., on four computer tapes. Each tape will contain necessary data for a computer match on one-fourth of the study sample (15,000). The computer match of the data on each of these tapes with the data on the register will allow the contractor to obtain the file location number which identifies the exact location of the record at the center. These records can then be pulled by GSA personnel and provided to Westat, Inc. in order that Westat, Inc. can abstract and code the military experience information.

Appropriate VA and GSA officials have signed a memorandum of understanding (Appendix C) to allow GSA personnel to locate and provide Westat with the military records of deceased veterans in the study.

Retrieving the records and then abstracting them will be done somewhat simultaneously so that a large number of records are not withdrawn from their permanent location for a long period of time. That is, as records are found, they will be sent immediately for abstracting and then returned. When records are not available, requests will be resubmitted. Some records will not be found. Information from VA claims folders may be used when this occurs.

Military Service Record Data Requested

Some veterans in the study sample will have served in the Navy or Air Force. This happens because the sample chosen from the BIRLS system included those with unknown branch of service.

Data items being collected for all veterans in the study include:

veteran's name
branch of service
military service number
location of military service records (registry numbers)

These items may be obtained from the registry without seeing the military service records. Additional items being collected for all those identified by military service records as having served in either the Army or Marine corps are the following:

social security number

date of birth

sex

race

date first active duty began

paygrade at beginning of first active duty

place of residence when first entered service

date of latest separation

paygrade at latest separation

type of discharge for latest separation

conduct code at latest separation

education at latest separation

military occupation speciality code (MOSC) at latest separation

total time on active duty (years and months)

For Army and Marine corps veterans who served in Southeast Asia (Vietnam, Cambodia, Laos, and Thailand) the following information will be collected on each Southeast Asia tour of duty:

country of service

date assignment began

date assignment ended

MOSC

principal duty

unit

Military Service Record Contractor Responsibilities

The military service record contractor, Westat, Inc., will be conducting work in three phases. In the first phase, which has been completed, Westat, Inc. presented plans for conducting the military service record portion of the study. Records location and verification, the service record abstract, quality control measures, field training, final computer files, and pilot study plan are all discussed in the Phase I report submitted to the VA contracting officer technical representative (VA COTR).

Phase I

A brief summary of plans reported in the Phase I document is given below:

Records Location and Verification-The Veterans Administration has provided Westat, Inc. with a tape containing one-fourth of the study sample. Three more tapes will be provided throughout the study containing the remainder of the deceased veterans in the study sample. The tapes contain the name, branch of service, service number, social security number, date of birth, and dates for one or two periods of service for each deceased veteran in the study. The information on these tapes is taken from BIRLS (see Chapter 3). Westat, Inc. has prepared a tape from the VA tape in the format required by NPRC for search in NPRC's location system (the register). The Westat, Inc. tape contains the veteran's name, service number, branch of service and sequence study identification number assigned to each case. Westat, Inc. will create similar tapes from the remaining three tapes the VA furnishes.

NPRC will match service or social security numbers with entries on the locator files (i.e., the registry). Finding Aid Reports

(FAR's) will be printed indicating "not found" or "found". For the found records, items from the locator file will be printed (name, branch of service, record file location number). The sequential study ID number will also be noted. In addition, a tape image of these FAR's will be produced.

The FAR's "found" cases will be matched with the VA tape provided to Westat, Inc. to identify any discrepancies in the names and/or branches of service. Computer listings will be generated cross-indexing name, sequential study ID number, and record location number. The lists will indicate the location status (found, found-discrepancy, not found), branch of service, and other identifiers taken from the VA tape: date of birth, service and social security number, and service dates. The list will be in registry number order, matching the order in which the FAR's are printed, and will be used as the master control for requesting service records, for entering results of further searches, and for noting the final disposition of each case.

For cases "not found" in the NPRC computer registry, a match on an identification number not previously matched (service number or social security number) will be attempted. If this fails, the NPRC mantains a microfiche index image of the computer registry entries which can be manually searched. By doing this, Westat, Inc. can be more selective among all persons with matching names.

Finally, the VA COTR will be notified of all cases for which a record can not be located or for which a record remains out-of-file. At this point, the VA claims folder may be retrieved and used to help resolve discrepancies in an attempt to locate the correct service record.

Once the correct service record is verified, the required data will be abstracted.

Service Record Abstract - An abstract has been developed and modified by the pilot study. The form and instructions are in Appendix D.

Quality Control - Three types of quality control will be implemented by Westat, Inc. : (1) system control, (2) record location and verification, and (3) data quality.

The system quality control will allow Westat, Inc. to account for the status of each case in the sample at each step in processing and to assure that all appropriate steps have been taken. In order to do this, Westat, Inc. will maintain a computer-based management control system (MCS). As a back-up for this system, notations will be made on the FAR's. Since a FAR is printed for each case in the sample, the FAR can be used as a control for record retrieval and completion of the abstract. A third mechanism to be used is case listings. These will contain all identifiers and results of the NPRC registry search (see Records Location and Verification).

Some quality control measures for the record location and verification have already been discussed (see Records Location and Verification). As records are received by Westat, Inc., the name and registry numbers will be checked with the FAR to verify that the correct record has been received. Also, labels will be printed containing the sequence ID, VA identifiers, and record location number (if found). These will be placed on the abstract forms as cases are assigned to the abstractors to provide a reference for verification with the information in the service record.

Procedures for controlling the accuracy and completeness of data which are manually abstracted are: (1) the field supervisor will review each abstract for completeness and obvious errors; (2) a percentage of abstracts in each batch will be checked against the service record (if there are frequent and/or consistent errors, a 100 percent check of the batch will be made); (3) a comparison abstract will be completed by another abstractor for a percentage of the cases; (4) a computer edit will check abstracted data for acceptable values and consistency among items; and finally, (5) keyed data on selected items will be verified against the abstract for a percentage of cases.

Field Training - A three-day training session will be conducted for the abstractors. Field manuals which contain forms and step by step procedures for each technical field activity, as well as material on the study objectives and organization, confidentiality of information and administrative procedures, will be issued in advance. The training will proceed from structured group exercises to individual practice with actual service records.

Final Computer Files - In addition to data items abstracted (see Appendix D), the final computer file will contain the sequence ID number and the original data items on the VA tape provided to Westat, Inc..

Pilot Study Plans - After matching the Westat, Inc. tape formated from the VA tape against the register, Westat, Inc. plans to abstract: (1) 100-150 records for Army veterans, and (2) 100-150 records for Marine veterans and 50 cases not found by NPRC, or found with names not matching the names provided by the VA. The pilot study will be used to test the forms and procedures and to estimate the schedule and cost of the main abstracting effort.

Phase II - Pilot Study

The pilot study of the abstract form and procedures described in the Phase I report has already been conducted at the National Personnel Records Center (NPRC) February 7-11, 1983.

As a first step, all 15,663 cases on the first computer tape given to Westat, Inc. by the VA were reformatted and submitted to the NPRC computer registry for search on one number (service or social security number). For 82 percent of the cases (i.e., 12,862), a registry number was produced. As previously mentioned, the registry number is an indication of where the record is located at the center. A sample was taken from the 12,862 records that were found. From this sample, Westat, Inc. estimates that 94 percent of the registry numbers will actually lead to the location of the correct record, three percent will probably locate a record that turns out to be for someone having an ineligible branch of service, and three percent of the registry numbers will actually lead to the location of an incorrect record.

Of the 2,801 for which no location number was found on the registry, six percent were found to be from the VA quality control sample and an additional five percent were discharged in 1964, according to the VA tape, and thus would not be eligible to be in the study. Westat, Inc. did a manual search of a sample of the remaining 2,482 not-founds. From this sample (n=89), Westat, Inc. estimates 82 percent of the computer not-found records can be found. The total manual search effort will consist of the original not-founds plus those found in the registry that turned out to be the wrong record (2,818 from the first VA tape).

After matching the Westat, Inc. formatted tape with the registry, simple random samples were selected from cases with a

single find (i.e., only one registry number was produced) and for which names on the VA tape and the NPRC registry tape were the same. One hundred and fifty Army records and 150 Marine records were selected. NPRC processed 200 FAR's by the start of the pilot study. Of these, 187 correct service records were provided. These records were abstracted in order to test abstracting procedures.

Some minor modifications were made to the abstract form as a result of the pilot test.

Phase III

Phase III is the production phase of this project. Westat, Inc. has begun this phase. The modified abstract form will be used in the production phase. Manual search procedures are still being evaluated based on the pilot study, and decisions will be made during the beginning of this phase as to how to proceed regarding this.

VA INTERACTION WITH CONTRACTORS

Throughout the projects, the contractors will be expected to make presentations of their progress, milestones obtained or missed, and problems and their proposed solutions to the VA contracting officer's technical representative. Draft reports are to be submitted to the VA COTR at the conclusion of each phase of the studies. The VA COTR will review the reports and make any corrections or suggestions he feels are necessary. These suggestions and/or corrections will be incorporated in the final versions of these reports.

PROJECT DOCUMENTATION

In addition to the Phase I, Phase II, and Phase III reports, other documents will be available. For example, Westat, Inc. has available instruction manuals given to field workers outlining study procedures, including instructions for abstracting.

CHAPTER 6.

PRELIMINARY PLANS FOR ANALYSIS OF DATA

Data collected from death certificates along with data collected from military service records will be consolidated into one file for the analysis phase of this study. Since we have no way of knowing how many veterans with or without service in Vietnam were at risk of dying, cause-specific mortality rates can not be determined. However, the proportion of deaths due to a specific cause, the proportional mortality ratio (PMR), can be determined for each of the two groups.

LIMITATIONS OF PMR ANALYSES

Some problems do exist in using a PMR type of analysis (15,16). First, an apparent excess in the proportion dying from cause "x" may be due to an overall lower mortality rate for causes of death other than "x," rather than an excess mortality for "x." This could happen, for example, if the cause specific rates for "x" were equal in two populations, yet one population had a lower overall mortality rate. Without access to the at risk population this problem cannot be untangled. Second, the sum of the proportions dying due to all the different causes always equals "one." Therefore, if cause "a" has a higher proportion in population A

than in population B, then one or more other causes will have a higher proportion in population B than in population A.

As regards the first problem, Kupper, et al. (1978) have compared various cause-specific mortality ratios and have found that the ratios of the PMR's in two populations are useful. In addition, they show that the ratio of the PMR's of two populations is equal to the ratio of their cause-specific mortality rates divided by the ratio of their overall mortality rates. The second problem can be partially addressed by computing the PMR's for all causes excluding the one(s) thought to be the cause(s) of difference. If causes of difference are eliminated, then the remaining causes should have approximately the same distribution in the two populations.

CLASSICAL TECHNIQUES

Crude PMR's

The first step in the study of Vietnam veteran mortality will be to compute PMR's for each cause of death separately for veterans who served in Vietnam, and for veterans who did not serve in Vietnam. The ratio of the PMR's for the two cohorts for each cause of death will then be calculated. As mentioned previously this is equivalent to the ratio of cause-specific mortality rates divided by the ratio of overall mortality rates for the two cohorts.

Logistic Regression PMR's

Since unadjusted PMR's do not take into account the possible effects of confounding variables on differences between the two study cohorts, erroneous conclusions might result if the analysis

stopped at that point. One plan to adjust for the effects of confounding variables such as age, race, marital status, education, branch of service, military rank, and military occupation is to fit a logistic model for each cause of death PMR including only significant variables. Duty in Vietnam will be included in each of these models as an explanatory variable.

Adjusted Denominator PMR's

All the PMR's calculated above (crude and adjusted) use the "all causes" figure as a denominator, which may cause problems if some of the causes of death are strongly associated with the risk variable, service in Vietnam. Hence, in this analysis we eliminate the causes most highly associated with service in Vietnam from the "all causes" category, and recompute the PMR's using this adjusted denominator. As above, these can be crude PMR's or adjusted PMR's.

In all the techniques discussed so far, multiple hypothesis tests will be made - one for each cause of death considered. Thus, we can expect to observe some spuriously significant results. In order to lessen this problem, we propose to group the causes of death into reasonable categories and set the nominal significance level to (alpha)/(number of cause of death categories tested), where alpha is the original significance level.

OTHER TECHNIQUES

Multivariate-Techniques

Multivariate techniques other than those discussed above are possible. A multivariate analysis could be developed which would analyze all causes simultaneously. All variables which are thought

to be confounding as well as the variable of primary interest - duty in Vietnam - would be included in the model developed. This kind of analysis would fall into the log-linear framework.

Service in Vietnam as a Continuous Variable

In addition to collecting data on duty in Vietnam, information is also being collected on the dates the veteran was in Vietnam. Thus, duty in Vietnam can be considered a continuous variable rather than a categorical one, and time spent in Vietnam could be used to calculate person-years at risk for different causes of death.

Multiple Cause-of-Death

The previous analyses have all dealt basically with underlying cause of death. Since we will be collecting all causes of death from the death certificate, there are opportunities to analyze causes of death other than just the single underlying cause. The analytic techniques already discussed could be applied in analyses of multiple causes of death.

CHAPTER 7.

STUDY LIMITATIONS

The Vietnam Veteran Mortality Study is designed to assess the mortality patterns of U.S. servicemen of the Vietnam era who served in the Army or Marines. The study will compare the mortality patterns of those veterans who served in Vietnam to the mortality patterns of those who did not serve there. It will be limited to a comparison of proportionate mortality ratios (PMR's) among these groups since no precise estimates exist for the populations being compared.

Despite the size of the study population (60,000 deaths), the VVMS will not necessarily provide definitive answers to many of the questions of interest, due to certain limitations imposed by the nature of the population being studied and of the sources of data. The following are some of these limitations.

1. Most Vietnam era veterans are still alive. Therefore, their complete mortality experience will not be available for many years. Nevertheless, with 20 years having passed since the beginning of the Vietnam era, it is now appropriate to conduct an initial mortality study which will provide a firmer base for further efforts in the future.

2. Although the sample size of 60,000 is sufficient for overall comparisons both in terms of the population and all causes of

death, it may not be adequate for analyses of subgroups of the population (e.g., those with longer time intervals between service duty and time of study), for specific causes of death, and for taking into account losses of information because of missing or erroneous military and death records. In addition, losses may occur during the tracing or follow-up procedure.

3. Since there may be differential losses in different subgroups, it is also possible that biases may be present. This may result if there are differences in the characteristics of those veterans whose records are "lost" and those whose records are found, of those veterans who are able to be followed up and those who are lost, etc.

4. Lack of uniformity in the various types and sources of death information is no doubt present and may result in some bias. In only about 75% of the cases (based on early results) is a death certificate returned. In the remaining instances, no death certificate is located in the VA claims folder, or some other form is returned. Some of these other forms do contain the cause of death, e.g., abstracts of certain states' death certificates and Department of Defense Form DD1300. Differences in the statement of cause of death on these various source documents will have to be examined and, if possible, taken into account in the analysis.

5. Statements of cause of death on certificates and other documents have certain inherent limitations, which have been shown to be present in a variety of studies of this problem. This may also introduce some bias in the comparisons. Unfortunately, it is not possible to utilize hospital records for many aspects of the study, although certain types of data may be obtained for some

segments of the population. However, hospital records may also have inherent variability and bias.

6. The study plans utilize a proportionate mortality analysis. This is no doubt the most efficient way to proceed at this stage of studying the problem. However, there are certain limitations in such an analysis. It would be most desirable to calculate estimated mortality rates even with the knowledge that such rates would be subject to error.

Every effort will be made to examine these limitations and their potential effect on the findings. However, it must be recognized that these limitations do impose restrictions on the inferences to be derived from the findings.

Most important of all, it must be recognized that, in this type of exploratory or "hypothesis-generating study," with these restrictions, it will only be possible to find clues that may implicate causes of death which have a greater or lesser frequency among Vietnam veterans. Such clues can then be used to plan and conduct more specific and more refined studies with less limitations in an attempt to determine more definitively the possible reasons for differences in relative frequency. In addition, it must be emphasized that the risk variable being studied - service in Vietnam - is not a specific factor, such as herbicide exposure or combat stress. Further studies will be necessary to refine the risk variables as well as to reduce the limitations.

CHAPTER 8. ADDENDUM:

MEETING OF CONSULTANTS APRIL 19-20, 1983

A group of six consultant biostatisticians and epidemiologists met at the Veterans Administration Central Office in Washington, DC, on April 19 & 20, 1983 to discuss the design and conduct of the Vietnam Veteran Mortality Study. The group was given a draft version of this protocol, and their discussions, suggestions, and recommendations on the protocol are all included in this section. The consultants in the group were the following:

Gilbert W. Beebe, Ph.D., Clinical Epidemiology Branch, National Cancer Institute, NIH, Bethesda, MD;

Chin Long Chiang, Ph.D., Professor of Biostatistics, School of Public Health, University of California, Berkeley, CA;

Joseph L. Fleiss, Ph.D., Professor of Biostatistics, School of Public Health, Columbia University, New York, NY;

Bernard G. Greenberg, Ph.D., Department of Biostatistics, School of Public Health, University of North Carolina, Chapel Hill, NC;

Abraham M. Lilienfeld, M.D., Department of Epidemiology, Johns Hopkins School of Hygiene and Public Health, Baltimore, MD;

Richard Monson, M.D., Harvard University School of Public Health, Boston, MA;

William M. Haenzel, M.A., Senior Epidemiologist, Illinois Cancer Council, Chicago, IL (invited but unable to attend);

Paul D. Stolley, M.D., Department of Medicine, University of Pennsylvania, Philadelphia, PA (invited but unable to attend).

These remarks are organized into four separate sections: sampling and the scope of the study, death certificate information, military record information, and data analysis.

Sampling and the Scope of the Study

Several of the consultants asked the fundamental question -- why sample? That is, why not request sufficient funds to include all of the roughly 185,000 identified Vietnam era deaths from the BIRLS file? Some discussion ensued about the effects of this study enlargement on the deadline for the final report (the December deadline would have to be extended), but the consensus of the group was to consider looking for additional funding to include all deaths in the study, even if the additional deaths might have to be analyzed later. Much of the rationale for this suggestion came from the realization that the power to detect differences in sub-populations of the study (e.g., specific age, branch of service, dates of death, etc.) could be quite low for rare causes of disease.

Related to this issue was a unanimous suggestion of the group to concentrate the sampling (if one must sample) in the later death years. This concern is predicated on getting the maximum information from each death, and the later deaths involve a longer "latency period" since exposure to Vietnam. Owing to time constraints, the recommended method for accomplishing this oversampling was to use random sampling in the first two batches (as is outlined in the protocol), and to do weighted sampling in the last two batches. The oversampling should concentrate on the years 1976-1981. An issue also related to having older veterans in the sample was the suggestion to lengthen the study period

definition to start at 1962 (prior to the official beginning of the Vietnam era). It was decided that the small number of troops in Vietnam at the time would not make this as useful a strategy as one might first imagine. It should be noted that although the spraying of herbicides began in the 1962-1964 period, very few persons were involved in that spraying operation and only a small area of Vietnam was sprayed; those Air Force personnel involved in herbicide spraying are already in the ongoing Air Force Health Study.

There were two differing points of view with respect to the exclusion of in-service deaths prior to 1973. One group felt that all in-service deaths should be included in the study (if the deaths could be identified as non-combat), and the other group felt that all deaths prior to 1973 should be excluded, for some of the reasons outlined above under "latency period." This issue was not resolved.

Finally, there was some concern about the large number of deaths on the BIRLS file with no military service dates, and whether the exclusion of these deaths might possibly introduce a bias. The answer to this question will have to come from the "military quality control sample" (group 5, see page 18); we will know what percentage of group 5, currently excluded from the study, was incorrectly excluded from the study. Then we will have to see how many excluded subjects this represents relative to the total study subjects , and how large a bias this improper exclusion could create.

Death Certificate Data: Quality and Completeness

One of the concerns of the consultants pertained to the formats for death information in the study. In particular, for many deaths the only death information will come from a Department of Defense (DoD) form, DD1300. The consultants felt that it was important to contact DoD experts on the DD1300 and find out how the form is filled out, when and under what circumstances it is filled out, and what information it contains. There was also a suggestion to contact DoD personnel to see what kind of rosters of in-service deaths, battle casualties, killed-in-action (KIA), and missing-in-action (MIA) they have. Despite these suggestions for further research, the consultants thought that, in general, we should use the DD1300 to ascertain cause of death when, in the coding nosologist's judgment, the cause of death data looked reasonable. In the cases when the DD1300 data are not sufficient, an attempt should be made to obtain a state death certificate. The consultants also suggested that we get in touch with the underwriters of the military life insurance programs (these programs are now run by private firms), and see what kind of information they could supply.

With respect to the gathering of death information, the consultants thought it a good idea to make some site visits to both VA Regional Offices and Federal Archives and Records Centers to check on the quality of death certificate findings. They also thought it would be a good idea to try to collect information on differential reporting of death to the VA as it might vary by cause of death (the study of the completeness of BIRLS reporting of

deaths does not plan to analyze reporting by cause of death, but some cause of death data may be available.)

There were a few miscellaneous recommendations. First, nosologists should be blind to the Vietnam duty status of the deaths they are coding. Second, hospital records should be obtained for selected causes of death where death certificate information is known to have limitations; for example, liver disease (connection with alcohol is not always mentioned on the death certificate), drug dependence, and soft tissue sarcomas. Finally, religion (an item not being collected) may be a confounding variable when analyzing data on suicide.

Military Service Data: Quality and Completeness

A central issue in the discussion of the miltary personnel abstracting process was the item on unit assignment. One group of consultants thought that collecting such data was a waste of time, and that the time and money spent on collecting that item would be better spent in getting an increased sample size. Another group thought that this was a useful item, and that the study would suffer if such data were not collected. After some discussion, it became clear that the amount of time saved in not writing down the unit assignment would probably be small, since the record would still have to be searched for dates of service in Vietnam. So the "trade-off" issue of unit assignment vs. sample size became instead the issue of increasing sample size, per se (see earlier paragraphs on the sampling and scope of the study).

As far as usefulness of the unit assignment data are concerned, two points were raised. First, in an occupational health study, one would want to have access to this information once one found an

elevated risk category. That is, one would want to be able to determine whether those veterans with a higher risk of dying of cause of death "x" all served in the same unit, or same kind of unit. Secondly, there is the possibility of using the unit assignment data to link to other files. In particular, the Agent Orange Task Force, headed by Mr. Richard Christian of the Army, is compiling a list of ground troop units categorized into three classes of probable exposure to Agent Orange: "likely highly exposed," "likely not so highly exposed," and "likely unexposed." These data from the Agent Orange Task Force could, in theory, be matched to the unit assignment data collected in this study, and thus provide PMR's for different Agent Orange exposure groups.

Another issue discussed was the issue of overseas duty for personnel who did not serve in Vietnam. The consultants felt that the fact of overseas service was a possible confounding variable in comparing Vietnam and non-Vietnam PMR's, and recommended strongly that this information be collected. Later discussion on this issue found an interest among some consultants to collect information on the actual amount of time spent overseas in military service. While this was judged a useful item, the group also acknowledged that this would be a costly item -- more costly than collecting Vietnam service information among those who served in Vietnam. Therefore, it is likely that only a simple dichotomous response will be collected for overseas duty (either "yes" or "no") for the non-Vietnam study subjects.

A few other recommendations were made. The VA Master Index, the manual predecessor of the automated BIRLS file, was discussed as a useful source of military record identification. In particular, this file could be used to verify and correct the

identification information on subjects that could not otherwise be located in St. Louis. Finally, it was judged very important to get a reliable estimate of the percentage of deaths in the sample that were actually eligible for the study. (Recall that errors and missing data on BIRLS may mean that subjects will be excluded from the study once their military personnel record has been pulled and abstracted).

The interim estimate calculated by Westat, Inc. for the records they have found so far is that 84% of the original study subjects were actually eligible for the study.

Analysis

In discussing the analysis, there was a good deal of discussion about the actual calculation of the PMR's. Specifically, the consultants suggested that using the "all causes" category for the denominator of the PMR estimates was troublesome. The suggestion was made to try to find a better "referent" category, so that the analysis would be more similar to a case-control study with a fairly common cause of death as a control. The only suggestion for such a category was the "cardiovascular death" category, and while this was not enthusiastically endorsed by all, no one could suggest a better group. It was generally agreed that "external causes" (accidents, suicides, homicides, etc.) should be excluded from the referent group, since the external causes may show some association with service in Vietnam. It was also agreed that the referent group is best picked on some biological basis, rather than based on the results of another study (such as the New York State PMR study.)

Another item concerned the use of ancillary data on the veteran population. It was strongly suggested that, despite its short-comings, estimates of the veteran population be used to calculate estimated mortality rates, even with the knowledge that such rates would be subject to error. The reason is simply that data on mortality rates are very important and it was thought that, even with the errors due to veteran population estimates, mortality rates were worth calculating.

In terms of the actual analysis itself, a minimum set of variables was suggested. The independent variable is duty in Vietnam, which should be coded as length of service in Vietnam, with the covariables age, race, branch of service, rank, date of death, and type of discharge (medical discharges should be excluded.) With respect to causes of death, the soft tissue sarcomas in particular should be categorized and grouped a priori, that is before looking at the data, and something like a total of 26 overall cause-of-death categories seemed a detailed enough scheme. With respect to the multiple comparison problem, some consultants suggested a ranking of the causes of death of interest in the analysis. Other consultants were basically unconcerned about hypothesis testing, suggesting that the analysis was descriptive, and should proceed in stages.

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APPENDICES

A. INVESTIGATORS AND CONTRACTORS

B. POWER CALCULATION FORMULA

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APPENDIX A.

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APPENDIX B.

POWER CALCULATION FORMULA

The calculations for the curves shown in Figure 1 were done using the following formula for power once the observed relative risk and the proportion observed exposed after misclassification were determined via the method developed in the Appendix on Misclassification:

Power = Probnormal{-Probit(1-a)+2*sqrt(EXP)*(sqrt(r)-1)/sqrt(1+K)}.

Where

(1) a = the probability of a type I error; i.e., the probability that a difference will be asserted to be found when it is not there,

(2) EXP = the expected number of cases in the unexposed cohort,

(3) R = the assumed increased relative risk of disease in the exposed cohort,

(4) K = the factor by which the unexposed exceeds the exposed cohort in size,

(5) Probnormal(z) is the probability that a random variable with mean 0 and variance 1 will be less than z,

(6) Probit(b) is the inverse for the probnormal; i.e., the value of the normal distributed random variable with a mean of 0

and a variance of 1 for which the probability of being less than that value is b, and

(7) sqrt is the square root function.

Note that if EXP is the expected number of deaths in the unexposed cohort, then the expected number of diseased in the exposed cohort is (R*EXP)/K. The formula is derived as follows based on Beaumont and Breslow (1981): If X is normally distributed with a mean of "m" and a standard deviation of "s" then a test of the null hypothesis m = 0 against the hypothesis that m > 0 will be judged significant at the "a" level if

X/s > Probit(1-a).

The power, then, is the probability that X/s will indeed be greater than Probit(1-a) when m is in fact greater than 0. For a random variable X as described above, this is equivalent to (X-m)/s > Probit(1-a) - m/s. But (X-m)/s has a normal distribution with mean 0, variance 1, hence the probability of this happening is 1 - Probnormal(Probit(1-a) - m/s). Due to the symmetry of the normal distribution this last expression is equal to: Probnormal (-Probit(1-a) + m/s).

In the particular case at hand, two random variables, E and RE/K, are the expected number of cases in each of the two samples. The distributions of two random variables are approximately Poisson with means E, RE/K respectively. Using the square root transfomation of the Poisson, for the random variables X1 and X2, the distributions of sqrt(X1) and sqrt(X2) are normal with means sqrt(E), sqrt(RE/K) and variances 1/4, 1/(4K) respectively. The random variable sqrt(LX1/K) is then a normally distributed random

variable with mean sqrt(L*E/K) and variance L*1/(4K). The difference random variable sqrt(X2) - sqrt(L*X1/K) is again a normal random variable with mean sqrt(RE/K) - sqrt(L*E/K) and variance (1/4) + (L*1/(4K)). Since the condition (1) X2 > L*X1/K) is equivalent to (2) sqrt(X2) > sqrt(L*X1/K), hence, (1') X2 - L*X1/K > 0 is true if and only if (2') sqrt(X2) - sqrt(L*X1/K) > 0. Thus the power to detect (1) is equivalent to the power to detect (2). Since (2) represents the test of a normal random variable with mean greater than 0,

$$\text{Power} = \text{Probnormal}\{-\text{Probit}(1-a) + \frac{(\text{sqrt}(RE/K) - \text{sqrt}(L*E/K))}{\text{sqrt}(1/4 + L*1/4)}\}$$

Simplifying,

$$\text{Power} = \text{Probnormal}\{-\text{Probit}(1-a) + \frac{2*\text{sqrt}(E)(\text{sqrt}(R) - \text{sqrt}(L*1))}{\text{sqrt}(K + L)}\}.$$

Assume that the relative risk R is greater than 1. When L = 1 this produces the power of the test to detect E2 > E1/K; i.e., for a given value of the relative risk, R, the proportion in the exposed sample will exceed the proportion in the unexposed sample. In general, for a given L, the formula shows the power of the test to detect E2 > L*(E1/K); i.e., for a given value of the relative risk, R, the proportion in the exposed sample will exceed the proportion in the unexposed sample by a factor of L. If L = 1.1, for example, the power to find that proportion in the exposed sample will exceed the proportion in the unexposed sample by more than 10%. This can be viewed as the approximate lower end of the one sided (1-a) confidence interval for the relative risk R. In the case under consideration E1 is the expected number of cases in the unexposed (non Vietnam) sample and E2 is the expected number of

cases in the exposed (Vietnam) sample. The unexposed (non Vietnam) sample is "K" times as large as the exposed (Vietnam) sample. With a relative risk of R it would be expected that E2 = R*E1/K.

APPENDIX C.

EFFECTS OF MISCLASSIFICATION ON ESTIMATES OF RELATIVE RISK

The determination of the odds ratio or relative risk of an outcome between an exposed and an unexposed group depends on the collection of data which is reasonably free of misclassification [Bross (1954), Copeland, et al. (1977), Quade, et al.(1980), Lawrence and Greenwald (1977)]. While studies are designed to be as free of misclassificiation errors as possible, in some cases some amount of misclassification is unavoidable, so that it is important to assess what the effects of misclassification are.

In this appendix, we derive various mathematical expressions concerning relative risk estimates in the presence of misclassification. The first and most important section derives the result which is used in the sample size calculations in the protocol. In particular, this section shows that if misclassification is random and not excessive, then the observed relative risk will lie between the true relative risk and the value 1.0. In the last section we will explore some cases where misclassification is not random, and note the effects on the estimates of relative risk. The following table may be useful to the reader.

Table M1 Nomenclature

E exposed

U unexposed

D positive outcome (e.g., diseased, death)

N negative outcome (e.g., not diseased, alive)

C correctly classified with respect to exposure

M misclassified with respect to exposure

R rightly classified with respect to disease

W wrongly classified with respect to disease

H observed

The symbol P(R|D,C,E) is the probability of rightly classifiying (R) the disease if the person had the disease (D), had the exposure (E), and had been correctly classified (C) as exposed. RDCE is an abbreviation for P(R|D,C,E).

The probability of being diseased and exposed and correctly classified with respect to disease and exposure is E*CE*DCE*RDCE.

Were the probability of disease to be assessed on the basis of the observed, somewhat misclassified, data then the observed probability of disease among the observed exposed, DEH, would be:

$$\frac{E*CE*DCE*RDCE + E*CE*NCE*WNCE + U*MU*DMU*RDMU + U*MU*NMU*WNMU}{E*CE + U*MU}.$$

The first expression in the numerator is the probability of being exposed, diseased, and correctly classified; the second, the probability of being exposed, not diseased, and incorrectly classified with respect to disease; the third, unexposed, diseased, and incorrectly classified with respect to exposure; and the fourth, unexposed, nondiseased, and incorrectly classified with respect to both exposure and disease. In the denominator is the probability of an "observed" exposure: the probability of being exposed and correctly classified with respect to exposure plus the

probability of being unexposed and incorrectly classified with respect to exposure.

Similarly, the observed probability among the unexposed, DUH, would be:

$$\frac{U*CU*DCU*RDCU + U*CU*NCU*WNCU + E*ME*DME*RDME + E*ME*NME*WNME}{U*CU + E*ME}.$$

The true probability of disease among the exposed is

DE = CE*DCE + ME*DME

and among the unexposed,

DU = CU*DCU + MU*DMU.

The true relative risk of the truly exposed to the unexposed is DE/DU, whereas the observed relative risk is DEH/DUH.

Four disease probabilities are allowed for in the calculation of the observed disease probability among the exposed (DEH): DCE, the probability of disease for the correctly classified exposed; DME, the probability of disease for the misclassified exposed; DCU, the probability of disease for the correctly classified unexposed; and DMU, the probability of disease for the misclassified unexposed. If the probability of disease is independent of the exposure misclassification, i.e., disease is neither more or less prevalent among those misclassified than among those correctly classified, then DCE = DME = DE and DMU = DCU = DU, as well as, NCE = NME = NE = 1 - DE, and NCU = NMU = NU = 1 - DU ; and if the probability of misclassifying the not diseased to the diseased is zero, i.e., WNCE, WNME, WNCU, and WNMU equal zero, and if RR is the relative risk of disease among the exposed to disease among the unexposed, so that DE = RR*DU, then DEH becomes (E*CE*RR*DU*RDCE + U*MU*DU*RDMU) / (E*CE + U*MU) , and DUH becomes (U*CU*DU*RDCU +

E*ME*RR*DE*RDME) / (U*CU + E*ME). So that the observed relative risk, DUH/DEH is

$$\frac{DU*(E*CE*RR*RDCE + U*MU*RDMU)/(E*CE + U*MU)}{DU*(U*CU*RDCU + E*ME*RR*RDME)/(U*CU + E*ME))}$$

Now the "DU" is the only "disease rate" in the expression above and it "cancels" out of the numerator and denominator. In this case, then, the observed relative risk is a function of the true relative risk (RR), the proportion exposed (E,U), the misclassification probabilities of exposure (CE, ME, CU, MU), and the misclassification probabilities of the disease (RDCE, RDME, RDCU, RDMU). If it is also true that the misclassification of disease is independent of the misclassification of exposure, then RDCE = RDME and RDCU = RDMU. Then the above equation can be slightly simplified by using RDE for RDCE and RDME, and RDU for RDCU and RDMU.

Let DEHT = DCE*RDCE + NCE*WNCE and DUHT = DCU*RDCU + NCU*WNCU. Then DEH = (E*CE*DEHT + U*MU*DUHT)/(E*CE + U*MU) and DUH = (U*CU*DUHT + E*ME*DEHT)/(U*CU + E*ME). Assume that DEHT > DUHT and that CE*CU > ME*MU and that E, CE, U, CU are all greater than zero. Then,

CE*CU*(DEHT-DUHT)*E*U > ME*MU*(DEHT-DUHT)*E*U.

So that

E*CE*DEHT*U*CU - E*CE*U*CU*DUHT >

U*MU*E*ME*DEHT - U*MU*DUHT*E*ME.

Thus

E*CE*DEHT*U*CU + U*MU*DUHT*E*ME + E*CE*DEHT*E*ME + U*MU*DUHT*U*CU >

U*MU*E*ME*DEHT* + E*CE*U*CU*DUHT + E*CE*DEHT*E*ME + U*MU*DUHT*U*CU.

And

$$E*CE*DEHT*(U*CU + E*ME) + U*MU*DUHT*(E*ME + U*CU) >$$

$$U*CU*DUHT*(E*CE + U*MU) + E*ME*DEHT*(U*MU + E*CE).$$

Which is equivalent to

$$DEH = \frac{E*CE*DEHT + U*MU*DUHT}{E*CE + U*MU} > \frac{U*CU*DUHT + E*ME*DEHT}{U*CU + E*ME} =$$

$$DUH.$$

Hence DEHT > DUHT and CE*CU > ME*MU imply DEH/DUH > 1.

Also,

$$(E*CE + U*MU)*DEHT > E*CE*DEHT + U*MU*DUHT$$

Hence,

$$DEHT > (E*CE*DEHT + U*MU*DUHT) / (E*CE + U*MU) = DEH.$$

Also,

$$(U*CU + E*ME)*DUHT < U*CU*DUHT + E*ME*DEHT$$

Hence,

$$DUHT > (U*CU*DUHT + E*ME*DEHT) / (U*CU + E*ME) = DUH.$$

Then, DEHT > DUHT implies

$$DEHT/DUHT > DEH/DUH.$$

Thus, if E, U, CE, CU are greater than zero, and CE*CU > ME*MU, and DEHT > DUHT,

$$DEHT/DUHT > DEH/DUH > 1.$$

It is stated in the Sample Size section that the observed relative risk will be between the true relative risk and 1 if the misclassification is "random" and "not excessive." To see this we must first define the terms random and not excessive and show that the previously stated conditions hold in this case. The needed assumption that E, U, CE, and CU are greater than zero is trivial. The problem loses its meaning if there is not an exposed and an

unexposed group or if one never correctly classifies exposure. By "not excessive" it is meant that

$$\frac{E*CE}{E*CE + U*MU} > \frac{E*ME}{U*CU + E*ME}$$

which is the same as the condition

CE*CU > ME*MU.

The proportion of the truly exposed in the observed exposed group is greater than the proportion of the truly exposed in the observed unexposed group, and the misclassified non-diseased are a smaller proportion of the non-diseased than the properly classified diseased are of the diseased. By random misclassification it is meant that : RDCE = RDE = RD and RDCU = RDU = RD and WNCE = WDE = WD and WNCU = WDU = WD. DCE = DME = DE and DCU = DMU = DU. For DEHT and DUHT as defined previously are DEHT = DCE*RDCE + WNE*WNCE and DUHT = DCU*RDCU + WNU*WNCU. When the misclassification is "random" as defined above, DEHT = DE*RD + NU*WN and DUHT = DU*RD + NE*WN. When the relative risk is greater than one, then DE > DU and DEHT > DUHT because RD > WN, (the assumption that the disease misclassification is "not excessive") so that DEHT = DE*RD + (1-DE)*WN = DE*(RD - WN) + WN > DU*(RD - WN) + WN = DU*RD + (1-DU)*WN = DUHT.

Now under the above assumptions concerning misclassification, the statement that the proportion of truly exposed in the observed exposed group is greater than in the observed unexposed group is equivalent to:

$$\frac{E*CE}{E*CE + U*MU} > \frac{E*ME}{U*CU + E*ME}$$

which is the same as the condition

CE*CU > ME*MU.

Furthermore,

DEHT = DE*(RD - WN) + WN and DUHT = DU*(RD - WN) + WN so that since DE > DU, DE*WN > DU*WN and

DE*DU*(RD-WN) + DE*WN > DU*DE*(RD - WN) + DU*WN, hence

DE*(DU*(RD - WN) + WN) > DU*(DE*(RD - WN) + WN) and

DE/DU > (DE*(RD - WN) + WN) / (DU*(RD - WN) + WN) = DEHT/DUHT

Thus the necessary conditions DEHT > DUHT and CE*CU > ME*MU hold and DEHT/DUHT > DEH/DUH > 1 and DE/DU > DEH/DUH > 1.

Thus, the conditions that the misclassification be "random" and "not excessive" are sufficient, when the relative risk is greater than one, to insure that the relative risk (DE/DU) is greater than the observed relative risk (DEH/DUH) which in turn is greater than one.

If DU > DE then the same analysis will yield the conclusion that DE/DU < DEH/DUH < 1.

Thus the effect of the random and not excessive misclassification is to bias the results towards the null hypothesis.

Under the assumptions above, the observed relative risk can be expressed in the following formula, which makes use of the following quantities: the proportion exposed and unexposed (E and U), the simple misclassification probabilities of exposure (CE,ME,CU, and MU), and the true probability of disease among the exposed and unexposed (DE,DU). This is the formula used in calculating the sample sizes in the protocol.

OBS RR= {(E*CE*DE+U*MU*DU)/(E*CE+U*MU)}/ {(U*CU*DU+E*ME*DE)/(U*CU+E*ME)}

Let us consider the case where exposure and misclassification of disease are dependent. Then,

DEHT = DE*RDE + (1-DE)*WNE and DUHT = DU*RDU + (1-DU)*WNU.

If the proportion of diseased is small relative to the chance of misclassifying non-diseased to diseased, then the misclassification of non-diseased to diseased will be the dominating factor.

Let us now look at some cases where the relative risk is greater than one and the misclassification is "not excessive" as before but misclassification of disease is dependent on the exposure status, and where there is also no possibility of classifying a non-diseased state to a diseased state. That is RDCE = RDME = RDE and RDCU = RDMU = RDU and WNE = 0 and WNU = 0. Then, DEHT = DE*RDE and DUHT = DU*RDU and DEHT/DUHT = DE*RDE/DU*RDU.

Case 1. RDE/RDU >= 1.

DEHT/DUHT = DE*RDE/DU*RDU >= DE/DU > 1. Since exposure is "not excessive" CE*CU > ME*MU. Hence, DEHT/DUHT > DEH/DUH > 1. However DEHT/DUHT >= DE/DU so that the observed relative risk, DEH/DUH, is not necessarily smaller than DE/DU, the true relative risk.

Case 2. 1 > RDE/RDU > DU/DE.

DEHT/DUHT = DE*RDE/DU*RDU > 1. Hence, as before, DEHT/DUHT > DEH/DUH > 1. In this case DE/DU > DEHT/DUHT, so that the true relative risk may be larger or smaller than the observed relative risk which itself is larger than one.

Case 3. DU/DE >= RDE/RDU.

Then DEHT/DUHT <= 1 and DEH/DUH <= 1.

It is expected that usually Case 1 will hold, where the reporting of deaths is better among the exposed than the unexposed. The expected direction of the misclassification error, then, is that the observed relative risk may be greater than the true relative risk but it will remain greater than one. In general several factors are at work here. One observation is that if the

disparity between the misclassification rates is small, the effect is small. If RDU is one and RDE is 0.8, then Case 2 would apply when the true relative risk is less than 1.25. Thus in cases where the classification is good (>= 80%) and the relative risk of interest is of reasonable size (>= 1.25), the results may be biased above the relative risk by 25% or may be biased towards the null hypothesis but will still be identifiable by a sufficiently large sample.

If the misclassification of disease is dependent only on the exposure, so that all the conditions stated above hold except that RDE is not equal to RDU, and if the condition WD = 0 is added, then if RDU/RDE < DE/DU then DEH/DUH > 1 as before. This is true because under these conditions, DEHT = DE*RDE and DUHT = DU*RDU, hence DEHT > DUHT and the proof follows as before. The condition that RDU/RDE < DE/DU means that the ratio of the percent correctly classified for disease among the unexposed to that among the exposed is less than the relative disease risk of the exposed to the unexposed. For example, if 90% are correctly classified among the unexposed, and 95% among the exposed, RDU/RDE = 0.95. Thus, the ratio of these misclassifications would have to be quite large and the relative risk in question relatively small before this would cause the observed relative risk to be less than 1 when the true relative risk was greater than one. For example, if the misclassification were 2/3 then relative risks of more that 1.5 would be entirely acceptable. That means, that 50% more of the exposed are classified correctly than the unexposed. If 100% of the exposed are classified correctly, then only 66% of the unexposed are. If 90% of the exposed are classified correctly, then 60% of the unexposed, etc. This seems like a very large

difference. DEH/DUH < (DE*RDE)/(DU*RDU) = (DE/DU)*(RDE/RDU). If RDE/RDU is sufficiently large, DEH/DUH may be bigger than DE/DU.

To review, then, the assumptions involved are as follows: (1) the misclassified exposed are a smaller proportion of the observed unexposed than the correctly classified exposed are of the observed exposed; and (2A1) the misclassified non-diseased are a smaller proportion of the non-diseased than the properly classified diseased are of the diseased; (2A2) the disease, the exposure misclassification, and the disease misclassification are jointly independent; and (2B) the probability of misclassifying a non-disease state as a disease state is zero. In terms of almost any study, conditions 1 and 2A1 ought to be true. In fact, one will satisfy (1) by keeping both exposed and unexposed misclassification rates below 50%. Condition (2B) is satisfied in the mortality study since there is no misclassification of disease by assumption. Condition (2A2) is true for the mortality study since by assumption there is no disease misclassification and exposure misclassification is independent of disease.

ADDENDUM

Dr. Joseph Fleiss of the Columbia University School of Public Health reviewed Appendix B and suggested that although the analysis is correct, it could be simplified greatly by taking advantage of identities that exist among several of the parameters.

For example, in discussing "not excessive" misclassification (pp. 80-81), using the facts that ME=1-CE and MU=1-CU simplifies the equality at the top of page 81 to ME+MU < 1. Thus, nonexcessive classification with respect to exposure is equivalent to the more

simply stated condition that the sum of the two exposure misclassification rates is less than unity. As another example, the expression for observed relative risk on page 82 may be simplified to a function of only four parameters using the identities L=E/U and RR=DE/DU.

Dr. Fleiss also pointed out that the analysis in this appendix is similar to sections 12.3-12.5 of Epidemiological Methods: Principles and Quantitative Methods by Kleinbaum, Kupper, and Morgenstern, although the authors do not consider the problem of sample size determination in the case of misclassification.

Department of Veterans Benefits
Veterans Administration
Washington, D. C. 20420

DVB Circular 23-83-2

February 8, 1983

VIETNAM VETERANS MORTALITY STUDY

1. The Biometrics Division, Office of Reports and Statistics, is conducting a mortality study which is concerned with Vietnam veterans. The study population consists of approximately 60,000 deceased veterans who had applied for VA benefits. It is anticipated that 30,000 veterans' records will be in regional offices and the remainder will be in FARC's (Federal Archives and Records Centers). Regional offices will not be required to recall XC-folders from FARC's.

2. In February, March, May and July of this year, the Austin Data Processing Center will send batches of computer-generated cards and a computer listing of all XC-folders for which cards have been generated to regional offices via a VA Form 3230, Reference Slip. The VA Form 3230 will reference this circular. The cards will contain the veterans' names and file numbers, and they will be in terminal-digit sequence.

3. The Adjudication Officer, or Chief, Administrative activity, where applicable, will designate a control point and an individual to control processing. The computer listing will be used as the control medium. Upon receipt of the computer-generated cards, computer listing and covering VA Form 3230, regional office personnel will pull the related XC-folder, photocopy the death certificate and staple the photocopy to the computer-generated card and return the material to the regional office control point. If a death certificate is not of record, a photocopy of the DD Form 1300, Report of Casualty, will suffice. If neither a death certificate nor a DD Form 1300 is available, a VA Form 23-6547, Excerpts from Death Certificate, will be used to furnish death information, including date and place of death if shown in the folder. Only items 1 through 6 should be completed on the VA Form 23-6547. In the event that there is no evidence of death in the folder, the computer-generated card should be annotated "No evidence of death in folder."

4. If the XC-folder is "No Record" in files, normal search procedures should be undertaken. If the folder cannot be located, the computer-generated card should be annotated as "No Record." If the XC-folder is "No Record" in files and BIRLS shows the XC-folder located at another station, personnel at the control point will forward the computer-generated card to that office for processing. The computer listing will be annotated accordingly.

5. Computer-generated cards pertaining to XC-folders which have been retired to an FARC will be so marked by the control point. Be sure to specify the FARC to which the records were retired as well as the date of retirement and the retiring station.

6. The computer-generated cards and the photocopies will be dispatched by the control point to the address shown below. Those dispatches should be made monthly, beginning March 1, 1983 and ending August 15, 1983.

Moshman Associates Inc.
Suite 312
6400 Goldsboro Road
Bethesda, Maryland 20817

7. End product code 690 will be assigned for all cases reviewed under the provisions of this circular. Administrative activities are authorized to report "Other Measured Work" for work performed as a result of this project.

8. RESCISSION: This circular is rescinded January 1, 1984.

DOROTHY L. STARBUCK
Chief Benefits Director

Distribution: CO: RPC 2902
FD FLD: DVBFS, 30 each (includes 12 each to Adjudication Division and Administrative activity in ROA)
EX: ASO and AR, 1 each

Exhibit 3-2

Westat, Inc.
3-14-83
[1]

VA - Military Record Search (9510)

MILITARY RECORD ABSTRACT

Date: ___-___ - 83
M D

1. Study ID #: (1) [Rec. 01] (11) [Blank] (13) 2. Abstr. #: |__|__| (16) 3. Source: (18) S R V G 4. BR: (19) A N

[LABEL]

5. Svc. #: (20) |__|__|__|__|__|__|__|__|__|

6. SSN: (29) |__|__|__|__|__|__|__|__|__|

7. Record Location:

|__|__| BR (38) |__|__|__|__|__|__|__|__|__| Reg. # (40) |__|__| BR (49) |__|__|__|__|__|__|__|__|__| Reg. # (51) |__|__| BR (60) |__|__|__|__|__|__|__|__|__| Reg. # (62)

8. Name:

|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| (71) Last, Suffix

|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| (101) First |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| (116) Middle or M.I.

9. DOB: |__|__|__|__|__|__|__|__| (131) M D Y 10. Sex: (139) M F U 11. Race: (140) W I S / ________ B O U

First Active Duty

12. Date: |__|__|__|__|__|__| (141) M D Y 13. Grade: (147) |__|__|__|

14. Residence: |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| (150) City |__|__| (170) St.

Latest Separation

15. Date: |__|__|__|__|__|__| (172) M D Y 16. Grade: (178) |__|__|__| 17. Disch: (181) 1 Hon 2 Died 3 UHC 4 LTH 5 UND 6 BCD 7 DHON 9 UNK Code: |__|__|__|__|

18. Educ: (186) 1 ≤ 8y 2 9-11y 3 HS 4 13-15y 5 Coll 6 Unk 19. MOSC |__|__|__|__|__| (187) 20. Total Active Duty: |__|__| YRS |__|__| MOS (192) 21. Rec. 2s: |__|__| (196)

[1] S.E. Asia Service

[Study ID #] (1) [Rec. 02] (11) [Rec. #] (13) [Blank] (15) Name: |__|__|__|__| (16)

CO Tr # From To MOSC

1. |__| (20) |__| (21) |__|__|__|__|__|__| (22) |__|__|__|__|__|__| (28) |__|__|__|__|__| (34) Prin. Duty: |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| (39)

|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| Unit: |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| (64)

|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| (113)

CO Tr # From To MOSC

2. |__| (20) |__| (21) |__|__|__|__|__|__| (22) |__|__|__|__|__|__| (28) |__|__|__|__|__| (34) Prin. Duty: |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| (39)

|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| Unit: |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| (64)

|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| (113)

Exhibit 3-2 (continued)

CO Tr # From To MOSC
3. ___ (20) ___ (21) ___ (22) ___ (28) ___ (34) Prin. Duty: ___ (39)
___ Unit: ___ (64)
___ (113)

CO Tr # From To MOSC
4. ___ (20) ___ (21) ___ (22) ___ (28) ___ (34) Prin. Duty: ___ (39)
___ Unit: ___ (64)
___ (113)

CO Tr # From To MOSC
5. ___ (20) ___ (21) ___ (22) ___ (28) ___ (34) Prin. Duty: ___ (39)
___ Unit: ___ (64)
___ (113)

CO Tr # From To MOSC
6. ___ (20) ___ (21) ___ (22) ___ (28) ___ (34) Prin. Duty: ___ (39)
___ Unit: ___ (64)
___ (113)

CO Tr # From To MOSC
7. ___ (20) ___ (21) ___ (22) ___ (28) ___ (34) Prin. Duty: ___ (39)
___ Unit: ___ (64)
___ (113)

CO Tr # From To MOSC
8. ___ (20) ___ (21) ___ (22) ___ (28) ___ (34) Prin. Duty: ___ (39)
___ Unit: ___ (64)
___ (113)

CO Tr # From To MOSC
9. ___ (20) ___ (21) ___ (22) ___ (28) ___ (34) Prin. Duty: ___ (39)
___ Unit: ___ (64)
___ (113)

CO Tr # From To MOSC
10. ___ (20) ___ (21) ___ (22) ___ (28) ___ (34) Prin. Duty: ___ (39)
___ Unit: ___ (64)
___ (113)

CO Tr # From To MOSC
11. ___ (20) ___ (21) ___ (22) ___ (28) ___ (34) Prin. Duty: ___ (39)
___ Unit: ___ (64)
___ (113)

NOTES:

3.3 Instructions for Individual Abstract Items

3.3.1 Entries for Record Type 1

Data items number 1 through 21 (that comprise Record Type 1) will be completed for all eligible persons in the study sample. Begin by entering today's date in the upper right corner of the form.

Item No. Item Name and Entry

[1 Study ID #: Do not make any entries for this item (unless the study ID label is missing). The label lists identifying information to verify that the correct military service record has been pulled. Do not use the identifiers given on this label as source data for any other abstract entries.]

2 Abstractor #: Enter the identification code number assigned to you. This should never be left blank.

3 Source: Circle the code for the type of source record(s) from which the abstract is completed, as follows:

- S - Regular military service record from NPRC
- R - Service record obtained from RCPAC (Army only)
- V - Veteran's Administration claim folder (Service record not available)
- G - Incomplete service record held by NPRC for person activated from National Guard (Branch in Item 4 coded as Army)

4 Branch: Circle the code for the veteran's most recent service branch during the Vietnam Era, as follows:

- A - Army
- M - Marine Corps

Item No.	Item Name and Entry

4 Branch (Continued)

The primary data source is the "Department" indicated on the DD-214 separation form issued after the most recent period of Vietnam Era active duty, or the DD-1300 Casulty Report for servicemen who died while on Vietnam Era active duty. Unless otherwise indicated, the specified DD-214 or DD-1300 form, issued by the branch coded in this item, will be used as the primary data source for most of the remaining Record 1 data items.

5 Service #: Enter the military service number (7-9 digits) assigned by the branch coded in Item 4. Exclude any alphabetic prefixes. If the original service number has been changed to the veteran's social security number, enter the original number here and the social security number in Item 6. If the original number is unknown, or if the veteran had no special service number, enter "*" in the first position.

6 Social Security Number: Enter the veteran's nine digit social security number, if given in the record. If unknown, enter "*" in the first position.

7 Record Location: Enter the branch code and registry number (if pertinent) for the record you used to code Item 4. Then look at the status code on the abstract label.

- If the status code is "NF" or "NC", enter branch and registry number for up to two more records, beginning with the most recent enlistment, then the next most recent enlistment.
- If the status code is "FM", ignore the remaining records (we have already recorded the registry numbers elsewhere for this case).

When entries are made on less than three records, enter "*" in the first position of all unused fields.

Complete entries as follows:

-Branch: Enter one of the following codes, as given on the record label:

AR - Army	CG - Coast Guard
MC - Marine Corps	PH - Public Health Service
AF - Air Force	NO - National Oceanic and Atmospheric Administration (NOAA)
NA - Navy	

Item No.	Item Name and Entry

7 Record Location (Continued)

-Registry #: For NPRC records enter the number given on the outside label. You must include a single prefix letter in the first position. Enter "X" if a prefix is not given. For RCPAC service records, only the letter "R" is entered in the first position.

8 -Name: Enter the veteran's name according to the guidelines below:

-Last: Enter the last name, followed by any suffix found on the DD-214 (e.g., "Johnson Jr.", "Johnson ii" for Johnson the second). The last name should never be unknown.

-First: Enter the full first name, as given. This should never be unknown.

-Middle: Enter the middle name(s), if any, as given. Enter the middle initial if the full middle name is not given anywhere in the record. If "NMN" (no middle name) is given on the source form, enter the word "None" on the abstract. If no middle name or initial is given on the source form, enter "*" in the first position.

9 Date of Birth: Enter the month, day, and last three digits of the year for the veteran's birthdate. Enter leading zeros in the month and day. If the month and day are unknown, enter "*" in the first position of each subfield. A "1" has been pre-printed on the form as a reminder to enter the remaining three digits for year of birth. If the year is unknown, enter "*" in only the first position of the field.

10 Sex: Circle the code that applies, as follows:

M - Male

F - Female

U - Unknown

The primary data source is DD Form 4 (Enlistment Contract). Army veterans whose military service numbers (prior to conversion to SSNs) were prefixed with "US" or "OF" are always males; those prefixed with "V" or "WA" are always females. In addition, female enlisted personnel in the Marine Corps always had a "W" service number prefix. Do not guess the sex from the individual's first name or photograph. Circle code "U" if unknown.

Item No.	Item Name and Entry

11 Race: Circle the code that applies, as follows:

W - White (including "Caucasian")

B - Black (including "Negro", and "Colored")

I - American Indian (including "Alaskian Native", and "Eskimo")

O - Oriental (including "Asian/Pacific Islander", "Malaysian", and "Mongolian")

S - Other Specified. If the veteran's race does not appear to fit the above categories, circle code "S" and enter the "other" race on the line provided.

U - Unknown

The primary data source is Form 20 for Army veterans and DD Form 4 for Marine veterans. Do not guess the race from any photographs found in the service record. If unknown, circle code "U".

[12-14 First Active Duty items. These data are to be based on the initial entry into an active duty status in the first branch of service in which the veteran enlisted (i.e., not necessarily the same branch coded in Item 4). The primary data sources for Items 12-14 are the earliest available DD-214 or DD-4.]

12 Date: Enter the date (month, day, last two digits of the year) the veteran began active duty (either "initial date of entry" or "date inducted"). If unknown, enter "*" in the first position.

13 Grade: Enter the pay grade of the veteran at the time of initial entry into active duty. Enter code "E", "W", or "O" (for enlisted, warrant officer, and officer ranks, respectively) in the first position. Then, enter the pay grade code, preceeded by a "0" in the second position. For example, a Private or Recruit is coded "E01", a 2LT is coded "o01". If unknown, enter "*" in the first position.

14 Residence: Enter the name of the city and the state code for the veteran's "Home of Record" at time of initial entry on active duty. If the name of the city is too long for the field, try to use an obvious abbreviation. If the entry residence is outside the U.S., enter "XX" in the state field and the name of the country in the city field. If the city is unknown, enter "*" in the first position of this field. If the state, or city and state, is unknown enter "*" in both fields.

Item No.	Item Name and Entry
[15-19	Latest Separation items. Items 15-19 are to be based on the veteran's latest separation from active duty with the latest branch served in (not necessarily the branch coded in Item 4.) The primary data source for Items 15-19 is the original issuance of the DD-214 form associated with the veteran's most recent period of active duty.]
15	Date: Enter the effective date (month, day, last two digits of the year) of the veteran's most recent separation from active duty, whether or not this also represents the date of final discharge from all military service obligations. If unknown, enter "*" in the first position.
16	Grade: Enter the veteran's highest active duty pay grade attained as of the latest separation from active service. Enter the "E", "W", or "O" rank code in the first position. Then, enter the pay grade code in the next two positions (e.g., E08, W02, o10). If unknown, enter "*" in the first position.
17	Type of Discharge: Circle the code that applies to the type of discharge (based on "Character of Service") as of the veteran's latest separation from active duty, regardless of whether or not it was upgraded or changed at a later date. The categories are: 1 - Hon (Honorable, including "TDRL" [Temporary Disability Retired List] and most "Permanent Retired") 2 - Died (including "Died in Combat", "Killed in Action" [KIA], "Died on Active Duty", and "Died in Service" [DIS]) 3 - UHC (Under Honorable Conditions) 4 - LTH (Less Than Honorable Conditions, including "Other Than Honorable" (OTH) and "Under Conditions Other Than Honorable") 5 - UND (Undesirable) 6 - BCD (Bad Conduct Discharge) 7 - DHON (Dishonorable) 9 - UNK (Unknown type)

Item No.	Item Name and Entry

17 Type of Discharge (Continued)

-Discharge Code: Enter the code cited as the authority for the latest separation from active duty. On Army DD-214 forms, the "SPN" or "SPD" number (usually 3 characters) is most often given near the end of te "Reason and Authority" block. On Marine forms, the regulation "section no" is most often given at the beginning of this block. The number zero must always be coded as "Ø" to distinguish it from the letter "o". If the veteran died on active duty (Type "2" circled) or the discharge code is unknown, enter "*" in the first position.

18 Education: Circle the code that applies to the veteran's highest level of formal education attained as of the time of latest separation from active duty. The categories are:

1 - Eight years or less of school ($\leq$ 8 y)

2 - Some high school, but no diploma or equivalent certificate (9-11 y)

3 - High school (HS) graduate or equivalent (e.g., G.E.D.), but no college

4 - Some college, but no degree (13-15 y)

5 - Bachelors degree and higher (Coll.)

6 - Unknown (Unk)

If the level attained is not given, or is unclear on the DD-214, alternate sources are the Form 20 for Army personnel, and the DD Form 4 for Marine Corps personnel. If unknown, circle code "6".

19 MOSC: Enter the veteran's last assigned Military Occupational Speciality code (up to five characters). The primary data source is the "Speciality Number (and Title)" block on the most recently dated DD-214. (In some Marine records it may also be given in the "Service Number" block of DD-214.) If no separation form is in the record (i.e., veteran died on active duty), alternate sources are the last "Duty MOS" entry on Form 20 (Army records) or on the Record of Service page (Marine records). When completing this entry, the number zero must always be coded as "Ø". If last MOSC is not given on the DD-214, enter "*" in the first position of this field.

Item No.	Item Name and Entry
20	Total Active Duty: Enter the total time (in completed years and months) the veteran has served on active duty. If the person served in multiple branches, the entries will pertain only to the branch coded in Item 4. Exclude periods of active duty with other branches, periods of reserve duty, or time not in any branch. Include any "non-pay periods--time lost" (e.g., for disciplinary reasons). The primary data source is the "Total Active Service" block on the DD-214 separation form used to abstract the branch in Item 4. Enter the "years" and "months" as given, disregarding the "days". Active duty of less than 60 days would be entered as "00 01". If any "time lost" is indicated on the DD-214 form, it must be added to the given "Total Active Service" time before it is entered on Item 20. If the "Statement of Service" is not given (e.g., no DD-214 in record), compute the total active duty time between first entry and latest active duty dates (Items 12 and 15), deducting periods of reserve duty or time not in active service with the specified branch. Item 20 should never be blank or unknown.
21	Number of Record 2's: This item is completed after entries have been made, if applicable, under Southeast Asia Service. Enter the total number of individual Southeast Asia assignments recorded on the main abstract (i.e., the last entry number used), plus those on a continuation form (e.g., "05", "14"). If no Southeast Asia service is recorded, enter "00".

3.3.2 Entries for Records Type 2

The data items for Records Type 2 will be completed for each unit to which the veteran was assigned in Cambodia, Laos, Thailand, or Vietnam during the period July 4, 1965 through March 28, 1973, while serving with the branch coded in Item 4. If the veteran did not serve with the specified branch in these countries during this period, enter "00" in Item 21 and leave this section of the abstract blank.

The steps below describe how to determine whether or not Record 2 entries are required, and if so, how they are to be completed.

Step 1 - Determine the fact of Southeast Asia service during defined Vietnam Era from one of the following sources:

Army
- DD-214 - "Decorations ..." block (Awarded "Vietnam Service Medal" (VSM) or "Vietnam Campaign Medal" (VCM).

Marines
- DD-214 MC - "Decorations ..." block (Awarded VSM or VCM); or
- NAVMC-118(9) Combat History page - (Engagements in Southeast Asia countries and/or awarded VSM or VCM).

Step 2 - Determine country name(s) and approximate period(s) of Southeast Asia service from one of the following sources:

Army
- Form 20 - "Foreign Service" block (e.g., "USARPAC [Vietnam]").

Marines
- NAVMC-118(17) Sea and Air Travel form - (From date "arrived and disembarked" in Southeast Asian country, to date "embarked and departed therefrom".

Step 3 - Determine Record 2 entries for the period(s) defined in Step 2, from one of the following sources:

Army • Form 20 "Record of Assignments" block.

Marines • NAVMC-118(3) "Record of Service" page; or

• NAVMC-123(2) "Chronological Record of Duty Assignments" page (for officers).

Step 4 - Complete Record 2 abstract entries:

For the initial Record 2 (positions 20-113) enter the designated information on the veteran's first applicable Southeast Asia assignment that concluded July 4, 1965 or later. Any of the following changes would then be entered as a separate Record 2:

- Change in unit (transfer to another unit within a country)
- Change in unit designation (unit formally "redesignated ..."; occurs frequently in Marine records. Ignore minor differences in assignment entries if the major unit designations [i.e., Co, Bn, Div] remain the same).
- Change in location (reassigned to another one of the four specified countries); or
- Change in "Principal Duty" (new duty assignment with no change in unit or location)

Ignore service record entries for "Promotions", "Reductions", "Reenlistments", or "Semi-Ann(ual)" proficiency ratings, unless a change in assignment is also indicated.

Continue in chronological order through the last applicable Southeast Asia assignment that began on March 28, 1973 or earlier.

The main abstract form has fields for entering a history of up to 11 assignments (Record 2's). If there are more than 11 Southeast Asia assignments, continue on another abstract form. Enter the study ID number above "Name" on the Record 2 section, and the first four letters of the last name. Draw a line through the record number on the left (the "1", "2", etc.) and renumber the records, beginning with "12" and continuing. Staple this form to the main abstract form (staple in upper left corner).

Entries for each Record 2 should be made as follows:

Item Name and Entry

Name — Last Name: Enter the first four (4) letters of the person's last name. This need only be entered once.

Co — Country: Enter the code that applies to the specific Southeast Asia country where the person was stationed on each Southeast Asia assignment as follows:

- C - Cambodia
- L - Laos
- T - Thailand
- V - Vietnam
- * - Unknown country (Marine Corps only)

Tr # — Tour Number: This sequential code number is entered in order to identify a group of continuous assignments in one country, which we have called a "tour". The same tour number is used to link all unit assignments in one country during a continuous period of time. Begin with "1" for the first group of continuous assignments within the same country; number the next group "2" and continue with sequential numbers.

If the veteran is transferred to one of the other Southeast Asia countries, or leaves and returns to the same Southeast Asia country, this is considered a different tour.

From — Date Assignment Began: Enter the date (month, day, last two digits of the year) that the person joined the unit, or first arrived with the unit, in the Southeast Asia country. If the person goes directly from one assignment in this country to another (i.e., the same tour, but with a new unit, unit designation or principal duty), this date should be the same as the "To" date of the prior assignment. If a "From" date cannot be determined for a particular assignment, enter "*" in the first position of the missing field.

To — Date Assignment Ended: Enter the date (month, day, last two digits of the year) that the person left this assignment for another, or departed with the unit out of the Southeast Asia country. "In Transit" time is included in this assignment only if the next assignment is in the same Southeast Asia country (i.e., same tour number). Otherwise ignore "In Transit" (or "Casual") time. If a "To" date cannot be determined for a particular assignment, enter a "*" in the first position of the missing field.

MOSC — Military Occupational Speciality Code: Enter the MOS code (up to five characters) given for this assignment as the "Duty MOS" in Army records or the "Primary Duty" entry in Marine records. When the code includes the number zero, it must be entered as "Ø". If there is no MOSC for this assignment or if it is unknown, enter "*" in the first position of this field.

Principal Duty — Assigned Principal Duty: Enter the first principal duty, associated with the MOSC, exactly as it is given in the service record for this assignment. Use "Ø" for zeros. If the entry given is too long to fit in the number of spaces provided on the abstract, consult the Field Supervisor. If unknown, enter "*" in the first position of this field.

Unit — Service Unit and Location: Enter the Corps area (in Vietnam, if given), the unit to which the person was assigned, and the location (if given), during this specific period of time, as shown in the record.

Enter the unit designation exactly as it is given on the Army "Record of Assignments" or Marine "Record of Service" pages.

Use "Ø for zeros.

If a veteran's primary duty or location changes, another Record 2 entry is always required. If there is no change in unit assignment, it is not necessary to repeat the unit entry. Simply enter the word "SAME" for the new record.

An "unknown" entry is never allowed for service unit. Always attempt to determine the unit assignments from other record documents (e.g., transfer orders, combat history, etc.) if primary source forms are missing.

[Item 21 When all Southeast Asia service assignments are recorded, enter the total number of completed Record 2's in Item 21. Be sure to check your count. If no Southeast Asia assignments were recorded, enter "00" in Item 21.]

Correcting Record 2 Abstracting Errors

If you (or the verification editor) determine that a service record assignment was not included on a completed abstract, do not erase Record 2 entries in order to insert the overlooked assignment in the proper chronological sequence. Simply enter the additional assignment(s) at the end of the service history. Be sure to revise all prior tour numbers and/or dates, as required. Correct Item 21 as well.

3.3.3 Alternate Procedures for Marine Corps Record 2 Entries

The instructions given in the previous section apply to the great majority of service records that you will be abstracting. A limited number of Marine records, however, may lack one or more of the designated source forms. The following "alternate procedures" have been developed to properly abstract Record 2 entries in these cases.

Sea and Air Travel Slips and Combat History Dates are Both Missing

The fact of Southeast Asia service for a Marine may be verified (DD-214 shows award of VSM/VCM), but the inclusive dates and/or specific country of service are not given on the DD-214, Sea and Air Travel, or Combat History pages. For these

cases, complete a Record 2 on all assignments designated on the Record of Service page as:

"FMF ....."
that occurred during Vietnam Era.

This entry usually (but not always) concludes with "...FPO, San Francisco" (SERAN). Exclude "FMF" entries that specify a country other than Vietnam, Laos, Cambodia or Thailand. But include FMF entries that do not specify any country. To indicate "unknown" country, always enter "*" as the "CO" code for each of these "FMF" assignments.

Southeast Asia Service Sea and Air Travel Slips Missing, but Combat History Dates Available

The DD-214 may show award of VSM/VCM, and the specific dates of Southeast Asia service may be given on the Combat History page or DD-214 (generally in "Remarks" block), but no Sea and Air Travel slips indicate the Marine disembarked in one of the Southeast Asia countries. (He may have served on board ship in "contiguous waters of RVN".) For these cases, complete a Record 2 for each specified period of service in the Southeast Asian country that occurred during the Vietnam Era. (Abstract "country" and "From/To" dates from DD-214 or Combat History page, and all other entries from Record of Service page.)

In addition, complete a Record 2 on all assignments designated on the Record of Service as:

"FMF ..."
that occurred during Vietnam Era.

Exclude "FMF" entries that specify a country other than Vietnam, Laos, Cambodia or Thailand, but include all "unknown" country FMF entries ("CO" code = "*").

"Marine Security Battalion, Quantico" Entry on Record of Service

A group of Marine Corps veterans served as U.S. Embassy Security personnel in Southeast Asia, but will not show "FMF ..." as an assignment. If the Record of Service shows:

"Marine Security Battalion, Quantico"

check both the Combat History page and DD-214 for award of VSM/VCM. If Vietnam service is identified, record assignment to the security battalion as a Record 2. If no mention of Vietnam service, do not include the security battalion assignment.

Entering Tour Numbers for the Above Procedures

If a Marine's assignment changes from "FMF ..." (e.g., transfer to Camp Pendelton) it is the end of a tour. If the veteran is later assigned again to any "FMF ..." location, it begins another tour. Assignments to non-Southeast Asia countries, or to locations other than "FMF ...", or Marine Security Battalion during the Vietnam Era are not recorded.

APPENDIX E.

QUALITY OF DEATH CERTIFICATE INFORMATION

Studies have been done on the quality of the medical certification on the death certificate. These studies have generally found that reporting is good for many causes of death. However, for a number of causes of death they have also found differences between the reported information on the death certificate and that from other records such as clinical records and pathology reports. Systematic differences have been shown to exist between cause of death reported on medical records and those reported on the death certificate. Variations in death certificate medical recording have been observed between:

(1) different geographic areas,

(2) different time periods,

(3) urban and rural areas,

(4) different types of certifiers; i.e., medical examiners, coroners, and physicians,

(5) different age-at-death groups,

(6) males and females,

(7) different socioeconomic status groups, and

(8) different causes of death.

Different diseases pose different problems to the medical certifier in specifying the cause of death. Diseases may be difficult to diagnose because their signs and symptoms may be difficult to observe, or because some diseases closely resemble each other. For example, pancreatic cancer is a more difficult disease to find than colorectal cancer, although, in general, cancer appears to be easier to correctly identify than cardiovascular diseases. Cases of pulmonary embolism are sometimes misdiagnosed as myocardial infarction. Rare diseases are often more difficult to diagnose. Another difficulty is the lack of specificity in the recorded cause of death. Myeloid and lymphocytic leukemia are often reported as leukemia with no further detail given. Where the difficulty is in diagnostic detail, accuracy can be improved by aggregating diseases into broader categories.

The classification of underlying cause of death also poses problems. The rules used by the World Health Organization (WHO) for coding deaths due to surgical misadventures, for example, attribute the death to the disease for which the operation was performed. Under the Eighth Revision of the International Classification of Diseases, deaths can be attributed to diseases such as cataracts, varicose veins, and hemorrhoids. Since the death certificate asks for the immediate cause of death and up to two conditions which gave rise to the immediate cause, and allows for the entry of other significant medical conditions present at death, additional information is available to supplement the analysis of underlying cause of death.

While the information on the death certificate is not necessarily as complete and detailed as it would be from a

combination of clinical records and pathological findings, it is still considered adequate and useful for many epidemiological studies. In fact, death certificates represent the only consistent source of mortality status available for the entire population of veterans.

Although the profile of cause of death does have shortcomings, the reasons for these shortcomings, as outlined above, should be roughly equal in the two groups of interest in this study: veterans who served in Vietnam and those who did not. Thus, on the whole, the comparison of causes of death should be valid. Of course this type of study will not answer all questions. It will not address the question of rare or difficult to diagnose diseases very well, nor will it answer questions about diseases which are not usually fatal. It will provide information about the general pattern of deaths among Vietnam era veterans.

APPENDIX F.

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