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REPORT OF SCIENCE PANEL

TO THE

AGENT ORANGE WORKING GROUP

There have been several meetings of the Science Panel since my last report.

Protocol Review

The Science Panel completed its review of the National Cancer Institute (NCI) "A Case-Control Study of Lymphoma and Soft-Tissue Sarcoma: Association with Herbicide Exposures." It was agreed that the individual reviews will be returned to NCI. In general, the Science Panel was supportive of the proposal, and several agencies offered to help provide specific information. We further noted that this study should be complementary to the NIOSH proposed case control study on soft tissue sarcoma. The two studies are not exclusive of one another.

Status of Fat Biopsies

The Chairman of the Fat Biopsy Subcommittee reported that the Subcommittee is developing a report to the Science Panel on fat biopsies for dioxins that will include information on (a) what is currently known and the current status, (b) when we would recommend it be done and under what circumstances, and (c) its limitations. It is anticipated that this report will be available in the near future.

Assessment of Agent Orange Health Hazards in the Population in Vietnam

Recent press reports of a group returning from Vietnam indicated that the Government of Vietnam would welcome assessment of the health risks in the Vietnam population by American scientists. There is concern about the status of the records and the availability of those records in Vietnam. Dr. T. E. Woodward, VA distinguished physician, reported that he found the records to be useful. There was general agreement that a study would be difficult to do and difficult to interpret. We believe that assessing exposure would be virtually impossible.

Public Information

A member of the Science Panel expressed concern that the public does not have information available to counter some of the claims of adverse health effects which are not yet proven. There was general discussion of this topic. Most members feel that there is insufficient data to make firm statements on these issues at the moment.

The Veterans Administration Mortality Study

The Subcommittee reviewing the proposed Veterans Administration Mortality Study has reached consensus on recommendations to be made to the Veterans Administration. These will be forthcoming to the Chair, Agent Orange Working Group within the next 2 weeks.

Review of the Veterans Administration Epidemiology Study

The Science Panel concluded its review of the Veterans Administration Epidemiology Study proposed protocol from the University of California at Los Angeles. A detailed review has been submitted to the Chair, Agent Orange Working Group for transmittal to the Veterans Administration. In summary, on the basis of the present document, the panel believes it is possible to begin the pilot phase of the study. The selection of the cohort for the Pilot Study should immediately proceed as well as the quality control and quality assurance procedures, the redesign of the questionnaire, and the determination of comparability and interpretation of some of the proposed instruments, such as nerve conduction studies, spirometry, etc., between examining centers.

Finally, we believe that major progress has been made in the past several months and that it is now possible to do the Veterans Administration Epidemiology Study, looking not only at Vietnam exposure but exposure to Agent Orange. We view as the only remaining factors that will prevent the successful completion of this study to be the degree of participation among the selected veterans and the nonavailability of necessary resources.

Vernon N. Houk, M.D.
Chair, Science Panel
Agent Orange Working Group

3/5/82

AGENT ORANGE WORKING GROUP
SCIENCE PANEL REVIEW OF PROPOSED PROTOCOL DESIGN
FOR VETERANS ADMINISTRATION EPIDEMIOLOGY STUDY

By School of Public Health
University of California at Los Angeles

The following represents a consensus of the reviewers of the proposed protocol design. All reviewers were present except one and his detailed comments were made available to the other members. The individual comments are enclosed (Tab B).

Overall Design

We agree that the historical cohort approach is the appropriate one. One member suggested more consideration be given to a case control approach but all other reviewers felt this is not possible because there is no clear cut definition of a "case." We also agree with the approach to try to make it as compatible as possible with other large studies such as the Ranch Hand and the Australian Study.

COHORT

Selection

The panel unanimously agrees that the Department of Defense (DOD) should select the cohorts in accordance with Dr. Bricker's cohort selection paper (Tab A). This will provide, we believe, for elimination of as much misclassification as is possible from the existing or potentially reconstructable records. We believe it is absolutely essential that the identification and assignment of these individuals to the different cohorts not be available to the participants or to the investigators until initial analysis of the data is completed. The Science Panel will oversee this cohort selection process. The study investigators must be aware of the method used to select the cohorts but must not be aware of the individuals placed in each group.

Criteria For Each Group

We recommend that groups be composed of high probability of exposed Vietnam veterans, high probability of nonexposed Vietnam veterans, and a non-Southeast Asia veterans group. Some felt that it would be desirable to include a Vietnam veterans group exposed midway between the first and second groups in order to make an assessment of dose response. The consensus is that though this may be desirable, the inclusion of the fourth group is not essential nor critical to the study.

Sample Size

We agree that 6,000 in each cohort group is a reasonable figure. As the study progresses and as more information becomes available from other studies, this issue may need to be reexamined. DOD anticipates being able to provide 12,000 in each of the study groups for selection.

Proposed Exclusions from the Cohort Group

We believe it is unreasonable to exclude officers and multi-tour Vietnam veterans. These may be separately identified so that appropriate analysis can take place but they should not be excluded from the study.

QUESTIONNAIRE

Questionnaire to Personal Health Providers of the Individual Veterans

Some of the selected veterans may have had multiple health care providers since returning from Vietnam. The panel doubts that many private physicians will fill out detailed questionnaires on their patients and thus wonder about the usefulness of this part of the study. The needed information may have to be obtained in other ways.

Individual Veteran Questionnaire

The questionnaire as it now exists is unacceptable. It is overly long and uses highly technical terminology which many people including many physicians will not understand. We recommend that careful thought be given to the information that is needed to be gathered, who will administer and where the questionnaire will be administered (telephone, home visits, etc.), and that the questionnaire be redesigned to meet those criteria. The questionnaire should be limited to information that is critical to the study and that will be used in the analysis of the results.

Other Instruments

The psychological and neuropsychological instruments, all of which were not available for review, should be evaluated and should include only information that will be used in the analysis of the results and presented in a way that would not be offensive to the participants.

Physical Examination

Data collected from the physical examination should be limited to those items that will be used in the analysis of the study. This does not mean that the physcial examination should not be comprehensive as determined by the examining physician for the particular individual, although items to be used for analysis of results must be collected according to a standard protocol.

Laboratory

The final decision for the inclusion of laboratory tests for this study should be made after consultation with laboratory scientists to ensure that the best tests for that particular purpose are being used. There are other tests such as chest x-ray, spirometry, nerve conduction tests, etc., that probably have limited usefulness because of the inability to standardize and to intrepret between multiple examining centers.

It is critical that the standardization of laboratory procedures proceed with quality control and quality assurance for collection, transportation, handling, and analysis and that this process be begun immediately in the participating laboratories.

Other Areas of Concern

For all participants, the panel believes that information should be collected only on those items that are critical to the study, can be standardized, and are such to appropriately interpret between multiple examining centers and laboratories. If the practising physician feels that additional information is necessary for a particular patient to evaluate the health status, it obviously should be done but should not be part of the overall data collection and analysis for the purposes of this study.

It is not clear from the proposed protocol the duration of the overall study or time estimates for each individual participant. These should be determined. A possibility that should be considered in regard to future duration is that after completion of the initial examination and analysis, the cohorts names be matched against the National Center for Health Statistics (NCHS) Annual Mortality Index. This would provide nearly all of the necessary followup information and would be more efficient than a mail survey or a hands-on followup of each individual.

It should be explicitly stated in the final design that when an abnormality for an individual is found, how that abnormality will be followed, who will follow and treat it, and what system will be set in place to ensure that each individual will receive the necessary medical care.

After the initial analysis has been completed and depending upon the results, additional well focused, smaller studies, such as specific case control studies, may be necessary to further define the extent of possible uncovered problems.

After the initial analysis has been completed, the method of cohort selection should be made public. While still ensuring individual confidentiality, each participating veteran should be informed of his or her status in the cohort selection process.

The panel assumes that the final protocol will address the usual concerns of patient confidentiality, freedom to withdraw from the study, and methods of providing the individual veteran specific medical information of which he or she or his or her physician should be aware for the proper care of the individual veteran.

Pilot Study

We believe the Pilot Study should include 5 percent of the anticipated study population. We recognize it may not be possible that this be a random sample of the population but that it be clearly stated and understood what that 5 percent represents. The panel unanimously disagrees that the Pilot Study should take place in only one study site but recommends strongly that it be conducted in all examination centers and study sites that will

be used in the overall study. The Pilot Study should be used to determine participation rates and to further refine the instruments to be used in this study. An analysis of the results of the pilot study can be used to make a determination of the possibility of success of the larger study. The results should in no way be interpreted as to effects but only whether it is possible to conduct a scientifically valid overall study.

Summary

On the basis of the present document, the panel believes it is possible to begin the pilot phase of the study. The selection of the cohort for the Pilot Study should immediately proceed as well as the quality control and quality assurance procedures, the redesign of the questionnaire, and the determination of comparability and interpretation of some of the proposed instruments, such as nerve conduction studies, spirometry, etc., between examining centers. Finally, we believe that major progress has been made in the past several months and that it is now possible to do the Veterans Administration Epidemiology Study, looking not only at Vietnam exposure but exposure to Agent Orange. We view as the only remaining factors that will prevent the successful completion of this study to be the degree of participation among the selected veterans and the nonavailability of necessary resources.