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The National Research Council was organized by the National Academy of Sciences in 1916 in order to provide for a broader participation by American scientists and engineers in the work of the Academy. The Academy was chartered by the U.S. Congress in 1863 as a private organization with a responsibility for examining questions of science and technology at the request of the Federal Government. The National Academy of Engineering was organized in 1964 under the original NAS charter. The National Research Council now serves as the agent of both Academies in the conduct of studies and investigations in the public interest.

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Date: Nov. 9, 1982

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Recommends delay until
Air Force study completed

file: Agent Orange
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PLAN FOR AGENT ORANGE STUDY OF VETERANS NEEDS "CONSIDERABLE REVISION," RESEARCH COUNCIL COMMITTEE SAYS

FOR IMMEDIATE RELEASE

WASHINGTON - Citing several design flaws in a research plan to identify possible health effects of the herbicide Agent Orange, a National Research Council committee advised* the Veterans Administration (VA) today to revise the plan and to delay the pilot study of Vietnam ground troops exposed to the chemical until results from a similar Air Force study are available.

The Air Force's "Ranch Hand" study is examining veterans assigned to air crews that sprayed Agent Orange and other defoliants in Vietnam. Guidance from the results of this study "should have a significant impact on the directions, methods, and procedures" of the proposed VA study, the committee said.

The committee recommended "considerable revision" of both a questionnaire to be administered to selected Vietnam veterans through personal interviews and of proposed procedures to be used in follow-up physical examinations. It also told the VA that neither of the two methods currently proposed for selecting veterans to be included in the study was satisfactory. The selection method, it added, "requires much further investigation" before a final choice should be made.

(OVER)

*Copies of the committee's report are available from the Medical Follow-up Agency at the letterhead address. Reporters may obtain copies from the Office of Information, also at the letterhead address.

The VA asked the committee to review a study plan prepared for the agency by the University of California, Los Angeles (UCLA), and to recommend improvements. Noting that the UCLA protocols have already been reviewed in detail by two other scientific panels, the committee chose to address broad issues "which the VA and other planners of this study must face in the next few months."

SELECTION OF PARTICIPANTS

The committee pointed out that the selection method proposed by the UCLA researchers may be unnecessarily costly because it would require calculation of exposure levels to the herbicide for all Vietnam ground troops. An alternative method proposed by the Department of Defense (DOD), said the committee, would first estimate the exposure of military units and then select individual veterans with high and low exposures. The DOD method would be much less expensive, but also less valid, according to the committee. "It may be that an intermediate procedure can be identified which combines the advantages of the UCLA proposal with the (relative) economy of the DOD procedure."

Enlisted men with multiple tours of duty, officers, and Air Force personnel should not be included in the study, the committee said, because differences between these groups and the majority of Army ground troops would "unnecessarily complicate the analysis."

However, marines should be included, it continued, if enough participants are available to allow a separate analysis. Air and maintenance crews assigned to Army-based helicopters used in spraying operations should also be studied, if possible, the committee said.

QUESTIONNAIRE AND CLINICAL PROTOCOLS

Calling the proposed questionnaire "formidable," the committee recommended that it be focused more on known human and animal effects from exposure to Agent Orange and similar herbicides. Questions asked in the VA study, it emphasized, should be coordinated with those asked in the Air Force study so that data from the two projects will be compatible. Any attempt to study a broader array of possible health effects stemming from the "Vietnam experience," the committee commented, should be independent of the Agent Orange study.

(MORE)

Although the questionnaire has been kept confidential, the committee advised that it be provided to veterans groups and other interested parties. The possibility that public release of the survey might influence veterans' responses, said the committee, should not pose problems as long as participants do not know whether they are assigned to the high- or low-exposure groups.

The committee also called for removal of ambiguous and esoteric terms from the questionnaire, greater emphasis on symptoms rather than on diagnoses, more detailed attention to quality control and standardization of clinical and laboratory examinations, and additional mortality or cause-of-death analyses to distinguish differences between veterans with high and low exposures.

WHO SHOULD CONDUCT THE STUDY

The committee concluded that "a stronger central scientific team to coordinate the whole effort can be assembled outside the VA than within it." Consequently, it recommended that the study be conducted by an academic coordinating center strong in biostatistics and epidemiology and with experience in multi-center collaborative studies.

A subcommittee of the Committee on Epidemiology and Veterans Follow-up Studies of the Research Council's Commission on Life Sciences reviewed the VA Agent Orange study proposals.

The subcommittee was chaired by Brian MacMahon, department of epidemiology, Harvard University School of Public Health, who also chairs the parent committee.

Other subcommittee members were George C. Becking, health protection branch, Department of National Health and Welfare, Ottawa, Canada; Gary Friedman, medical methods research department, Kaiser-Permanente Medical Care Program, Oakland, Calif.; Allyn W. Kimball, department of biostatistics, School of Hygiene and Public Health, The Johns Hopkins University; and Leonard Kurland, department of epidemiology and medical statistics, Mayo Clinic, Rochester, Minn.

C. Dennis Robinette of the Research Council's Medical Follow-up Agency served as the staff officer for the subcommittee.

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