Item ID Number	01724
Author	Jemison, Terry
Corporate Author	
Report/Article Title	4-Year Review Complete: Key Agent Orange Study Set to Go
Journal/Book Title	U.S. Medicine
Year	1983
Month/Day	September 1
Color	☐
Number of Images	6
Description Notes	

WASHINGTON—Many nurses and doctors in anesthesia training programs—as well as their instructors—have a problem with drug dependence, a new survey of that specialty has found.

The survey, published in the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, was prompted by problems observed in the University of California's San Diego Medical Center anesthesia training program, researchers Dr. C.F. Ward, Gretchen C. Ward, RN, and Dr. Lawrence J. Saidman related.

In general, the researchers found that there is more of a temptation for anesthesiologists to use drugs than for other specialties. One rehabilitated drug user commented that "working in the OR was like working in the candy store."

"Of the 247 programs which responded to the survey questions, 74 per cent identified at least one suspected episode of abuse, with the program incidence of at least one instance of confirmed abuse being 64 per cent," the researchers related.

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"In the western United States a significant increase in the number of heroin emergency room visits was noted in 1982 compared to 1977, but the number of emergencies is less than half the 1974-1976 peak," the NIDA work group report said.

(Continued on page 12)

pate in the decentralization program, however, but instead will receive commerical "integrated hospital systems" purchased from software firms.

(The software for the decentralized program was developed within the VA. It is in a common language and can be

(Continued on page 11)

4-Year Review Complete

Key Agent Orange Study Set To Go

By Terry Jemison

WASHINGTON—The first comprehensive series of agent orange studies involving American ground troops in Vietnam has cleared peer review.

Though one review panel's written comments are pending, which is a formality, the investigation appears ready to begin—nearly four years after Congress demanded it.

While the Veterans Administration was wrangling over the ground troops study during most of that time (it eventually was relieved of responsibility for the work), other agencies got smaller studies of Vietnam veterans off the ground.

In one, an Air Force study of 1,247 former flight crew members who sprayed the herbicide, data collection already has been completed with preliminary results clear: zero cases of several diseases of particular interest to compensation advocates.

The Centers for Disease Control, which during the four years launched a birth defects study that now is nearly complete, this year took over VA's ground troops study.

For years, some of the VA's strongest advocates in Congress, leaders of the House Veterans Affairs Committee, had stood by VA as it weathered storms of criticism. The CDC takeover occurred when some of those congressmen finally jumped ship and urged VA to give the study up. VA complied promptly.

CDC, building upon the VA's work from late 1979 through the end of 1982, was able to complete a protocol in just a few months. After several additional months of peer review, two weeks ago the CDC ground troops study was approved by a White House work group, sources said.

(Continued on page 28)

Moving To DoD

Alcohol, Drug Abuse & Mental Health Administration director, Dr. Willam E. Mayer, has reportedly been offered and has accepted the position of assistant secretary of defense for health affairs. The position is currently held by Dr. John F. Beary, who resigned his post effective mid-September.

FRANK M. BEST
Publisher

U.S. MEDICINE®

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(USPS 650-120)

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U.S. Medicine is published semi-monthly by U.S. Medicine Inc., Suite 505, 2033 M St. N.W., Washington, D.C. 20036-3362. Telephone 463-6000. Subscription price is $55 per year. Second-class postage paid: original entry, Washington, D.C.; additional entry, Baltimore, Md. Postmaster: send address changes to U.S. Medicine, 2033 M St. N.W., Washington, D.C. 20036-3362.

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800 Second Ave., New York, N.Y. 10017
Phone (212) 599-3166

9/1/83

Agent Orange Study Clears Peer Review

(Continued from page 2)

A pilot phase is scheduled first, and according to the CDC timetable developed earlier this year, selection of veterans for the pilot study will be completed two months after peer review.

CDC has "sole responsibility" for "all decisions" for interpreting the research results 4½ years from now under terms of a VA-CDC interagency agreement, according to a VA analysis of the pact. CDC will report its findings to VA.

However, even when they controlled the study, VA leaders above the level of the Department of Medicine and Surgery avoided even general commitments to any policy action based on positive—or negative—findings.

In contrast, Health and Human Services Department officials subsequently boasted that existing research and pending studies are expected to have the power to "wrap up" the agent orange issue. The House committee leaders' support for the shift of control to HHS followed their hearings where the HHS comment was made.

Peer review of the study was completed in mid-August, when a White House work group approved the work of several peer review panels.

One of the CDC investigators working on the project, Dr. Peter Layde, said before the White House meeting that no major shifts in focus had resulted from the tiers of peer review in recent months.

One of the reviews was conducted by the congressional Office of Technology Assessment (OTA).

President Carter, who was in office when the congressional mandate for the study was passed, previously had advised federal scientists to ignore a requirement in the law that OTA review the protocol, citing it as a "legislative veto" that he opposed in principle.

The OTA review was not blocked by the Reagan administration, however, and in a report issued in July, OTA director John Gibbons praised the study design as "well constructed and strengthened by CDC's efforts to look ahead...."

The study was required by Congress in Public Law 96-151—legislation reported by committee in May 1979 which became law that December.

Since then, some of VA's delays in producing the study may be related to the disorder of Army records and litigation by veterans themselves who challenged VA's study methods. VA work on the study received considerable scrutiny from veterans groups active on agent orange, with some activists complaining VA was dragging its feet.

By comparison, when the White House, through CDC's parent agency (Health and Human Services), recently conducted a publicly announced, open meeting for a panel of scientists and outside advisors to review the protocol, no veterans groups were in attendance among the handful of observers at the outset of the meeting.

The head of that peer review committee, John A. Moore, DVM, described as a "critical question" one scientific issue that many say has been a great stumbling block to getting the study moving: quantification of exposure and selection of exposure cohorts.

He and the CDC primary investigator, David Erickson, DDS, PhD, agreed at that meeting that the question is surrounded by uncertainty, and that while "most likely exposed" and "least likely exposed" cohorts may be separated on the scale of exposure as widely as possible, scientists may never know what the top and bottom of the scale is.

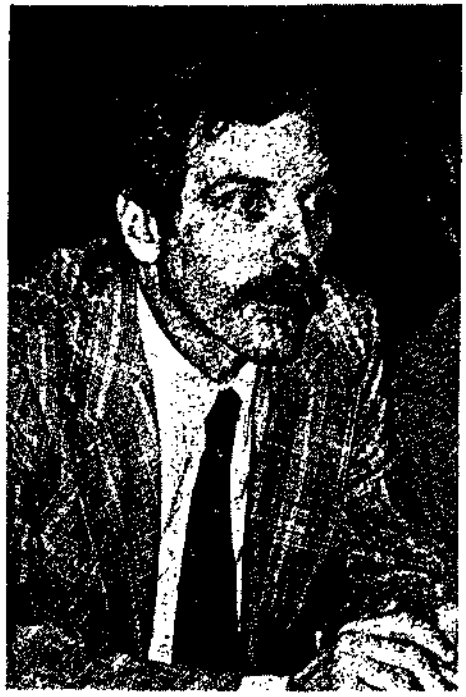
Dr. Erickson, asked by peer reviewer and Mt. Sinai medical school environmental sciences director Dr. Irving J. Selikoff about ways to verify data on herbicide spraying, said the Ranch Hand Unit defoliation missions are documented—by time, space covered and quantities used—on computer tapes. He added there is "considerable doubt about the accuracy of these records in some quarters, particularly Air Force people."

While others think the records are relatively good, Dr. Erickson said, scientists probably always will worry that some of the agent orange applications may be unknown, perhaps "buried" somewhere in records other than those of chemical units.

Dr. Selikoff suggested that in the pilot study about to begin, 100 or 200 of the enrollees could be questioned about exposure and that recalled experience could be compared with the unit location in the Ranch Hand records.

Dr. Erickson conceded such a test may be useful, but he noted that with the CDC birth-defects study already in progress he has found there is a lot of skepticism "particularly in the military" about what the veterans can tell epidemiologists.

The popular insecticide malathion intentionally was sprayed on the jungle canopy in the vicinity of ground troops, he noted, and that may be the aerial spraying a veteran recalls.



—*U.S. Medicine photo*

Dr. Peter Layde
No major shifts in peer review

Dr. Moore, director of the National Institute of Environmental Health Sciences (NIEHS) national toxicology program (and rumored to be in line for transfer to the Environmental Protection Agency), polled the peer reviewers on cohort selection and found no dissent on the concept of exposure classification.

After the meeting, Dr. Moore declined to comment on the group's consensus on the sticky scientific issue of separation of exposure cohorts.

(His secretary said he was too busy to make even 10-minute appointments for the indefinite future, and aides to both the directors of NIEHS and the National Institutes of Health indicated those program officials do not supervise his work on agent orange matters, but he reports directly to the White House group instead.)

The White House panel, the Agent Orange Work Group of the Cabinet Council on Human Resources, was the last group to consider peer reviewers' reports. It always meets in secret.

One protocol review obtained by U.S. MEDICINE—the OTA review—describes exposure cohorts that would be 6,000 Vietnam veterans each.

Sources indicated that is unchanged. There would be three such cohorts in the main study:

•Troops who served in combat areas located near an area where use of agent orange was recorded.

•Servicemen in a combat area where no such use was recorded.

•Veterans who did not serve in combat areas and who were not thought to be exposed to agent orange.

"Although it appears unlikely that the methods chosen will *not* allow some separation between exposed and non-exposed veterans, that possibility must be kept in mind," OTA said (emphasis added).

"In other words, it is still possible that studying associations between health effects and agent orange exposure may not be possible because the records will not provide information for meaningful exposure classification.

"The protocol shows that CDC is aware of the problems in deciding about exposure status and provides assurance about the ability of the CDC to make appropriate decisions as the study goes along," OTA said.

Another companion study, the "Vietnam experience study," will contrast the health status of a cohort of 6,000 Vietnam veterans with another 6,000 veterans who are not Vietnam veterans. It may test for the health effects of elements of the Vietnam environment, but is not designed to examine any specific factors.

"This study, like the agent orange study, is 'hypothesis generating,' " Gibbons of OTA said. "Currently, too little is known about possible health effects of Vietnam service to design a study to *test* hypotheses that particular diseases are associated with Vietnam service," he said.

In the formal report, OTA said that in the absence of expectations of disease based on theoretical or empirical considerations, the studies are not justified "in terms ordinarily used by scientific review bodies."

However, OTA said, if the study of the health experience of Vietnam veterans is justified "on other than only scientific basis," then the research is appropriate.

The VA's position is that no long-term health effects of exposure to dioxin have been demonstrated for diseases other than chloracne. Yet even before legally required to do so, it said its physicians' compassion for veterans compelled it to treat a veteran for a non-service-connected condition the veteran alleged was due to agent orange when hospital resources allowed it to do so.

OTA's analysis of the protocol found that the agent orange study and the Vietnam experience study will have high sensitivity to detect a two-fold increase in risk "for health outcomes that occur in the control population at a rate of about 0.5 per cent—for outcomes based on the questionnaire phase."

"For the medical, psychological and laboratory phases," OTA continued, "the studies will have high power to detect two-fold increases in outcomes that occur at the rate of 1.5 to 2 per cent in the control population.

"For outcomes occurring more frequently, and for greater increases, the studies will have correspondingly greater power.

"In comparison to most cohort studies that have been done, these studies are very powerful due to their large size. Even so, as CDC recognizes, the cohort design is not well-suited to detecting rare effects or those which occur at only slightly increased frequencies in the exposed group."

In other developments in the agent orange issue:

•A report issued by VA last month shows that nearly 6,000 veterans have

—U.S. Medicine photo

Rep. James H. Scheuer

AMA used 'loose and thoughtless' language

filed disability compensation claims for skin conditions they relate to agent orange.

Earlier, it was incorrectly reported that a third of skin condition claims had been granted (though not due to agent orange specifically). A VA newsletter on which the calculation was based did not qualify its statement that "3,200 claims (have been) filed by Vietnam veterans" as being only a partial total of claims, a sampling used to check the claims for chloracne cases.

(In fact, only one case among the 6,000 now is considered possibly chloracne, an agent orange office researcher recently said.)

The 1,300 claims that had been allowed are among 6,000 claims, not 3,200.

•According to a later issue of the same newsletter, "Agent Orange Review," chief medical director Dr. Donald L. Custis has reported that about 9,400 Vietnam veterans received care in approximately the first year of an agent orange medical care law raising their eligibility above most non-service-connected veterans.

The VA's monitoring covered the period February 1982 to February 1983. The law, signed in November 1981, gives VA broad authority to treat veterans when the origin of their illness is uncertain and the possibility of a temporal relationship to Vietnam service cannot be ruled out.

During the same period, there were 369,000 outpatient visits.

•The House Veterans Affairs subcommittee on compensation and pensions reportedly advanced legislation that would provide compensation to Vietnam veterans suffering from chloracne, porphyria cutanea tarda and soft-tissue sarcoma if the disease appears within 20 years of discharge.

Sponsor Rep. Thomas Daschle (D., S.D.) has maintained that scientific literature supports an association between the diseases and exposure to agent orange or its components.

The Veterans Administration, which disagrees, opposed the bill, and according to press reports, the subcommittee split on party lines, with seven Democrats favoring it and four Republicans opposing the measure.

•The American Medical Association, offering testimony at recent congressional hearings, is stressing the inadequacy of the science base to blame agent orange for long-term health effects other than chloracne, and it said legislation providing compensation should go no further than chloracne.

AMA representative Dr. John R. Beljan, who chaired an association

advisory panel on toxic substances, has been kept busy explaining the association's action at a June meeting.

The group accepted a resolution that AMA begin "an active public information campaign to get accurate information on dioxin before the public to prevent irrational reaction and unjustified public fright."

Though not now part of AMA policy, a series of "whereas" clauses that precede the resolve drew sharp reaction. They said in part, "The news media have made dioxin the focus of a 'witch hunt' by disseminating rumors, hearsay and unconfirmed, unscientific reports, including quotes attributed to scientists whose quote should have been, 'I don't know.' "

Rep. James H. Scheuer (D., N.Y.), for example, in hearings of his House Science and Technology subcommittee, told Dr. Beljan that the AMA staff technically may dissociate itself from the colorful "whereas" clauses of the sponsoring (Missouri) delegation, but the language remains part of the AMA's "public posture."

"I am really astonished that a professional organization as highly respected as the AMA...should have represented itself in such—well, to put it charitably—loose and thoughtless language," Rep. Scheuer said. He heads the subcommittee handling environmental matters.

The controversial preamble to the resolution in the AMA house of delegates alleged the lives of people in areas of dioxin-contaminated sites have been ignorantly damaged "by this hysterical mal-reporting."

"If one of my kids wrote such an irresponsible editorial in a high-school newspaper...I would whack their fannies," Rep. Scheuer said.

Dr. Beljan said, "I regret the unfortunate continuing use of the words 'witch hunt.' That is not AMA policy." Another AMA witness explaining the AMA policy process—delegation proposals, reference committee review, and house of delegates action—told Rep. Scheuer that the clarification of just what part of the resolves were adopted by AMA was pursued in 75 media contacts in just the first week after the meeting.

Explaining that the AMA recognizes chloracne as a possible long-term effect of dioxin exposure, Dr. Beljan added, "With respect to other alleged human health effects attributed to dioxin, the (AMA) Council on Scientific Affairs and its advisory panel concluded there was insufficient published data subject to peer review to establish a relationship between dioxin exposure and the adverse health effect."

Two days before that hearing, Health and Human Services assistant secretary for health Edward N. Brandt Jr., MD, PhD, said in a letter to AMA president Frank J. Jirka that while he agreed with the policy to provide dioxin information to the public and the practicing physician, "we do not agree with some of the preparatory statements in that resolution."

•Though the absence of any major unusual mortality patterns in the members of the Ranch Hand Unit that sprayed agent orange had been suggested earlier in raw data, the Air Force has released its detailed statistical comparison of study subjects and controls that formally affirms it.

Morbidity analyses are continuing and only raw data have leaked out.

"The mortality analyses described in the report have not revealed any statistical excess in the deaths recorded in the herbicide/dioxin-exposed group," the Defense Department said in a statement.

"At this time, there is no indication that Operation Ranch Hand personnel have experienced any increased mortality or any unusual patterns of death in time or by cause. They are not dying in increased numbers, at earlier ages or by unexpected causes."

—U.S. Medicine photo

Dr. John R. Beljan
'Whereases' are not AMA policy

Statistically insignificant were findings of an increase in liver disorder deaths and a decrease in cancer deaths in the 1,247 defoliation pilots and flight crew members, compared to controls.

"Highly significant" was lower mortality among Air Force members, both Ranch Hands and controls, compared to the average U.S. male, the Defense Department said.

The statistical power of the study was criticized by some veterans. An attorney representing 20,000 Vietnam veterans or their families was quoted as calling the study "a patent fraud.... It has no power to detect anything short of a catastrophe."

The 1,247 Ranch Hand unit members were compared to 6,171 controls who flew only cargo missions to, from or in Vietnam during the same period.

"By a computerized 'nearest neighbor' selection process, up to 10 comparison individuals were matched to each Ranch Hander by job category, race, and age to the closest month of birth," the study summary reported.

Five individuals were randomly chosen from each comparison set for a 1:5 design.

"This baseline mortality report can in no way be regarded as conclusively negative because this small, young, and relatively healthy cohort may not have yet reached the latency period wherein attributable fatal disease might be expected and detected within limited power boundaries of this study," the report cautioned.

Principal investigators for the study, conducted at the School of Aerospace Medicine at Brooks AFB, Texas, are Col. George D. Lathrop, USAF, MC; Col. Patricia M. Moynahan, USAF, NC; Dr. Richard A. Albanese of the Data Sciences Division; and Lt. Col. William H. Wolfe, USAF, MC.

•A conference at the Centers for Disease Control in Atlanta has produced a consensus that a safe level of dioxin contamination in the soil of residential areas is 1 ppb.

But Dr. Vernon N. Houk, director of the CDC Center for Environmental Health, cautioned, "There can't be a single national standard of any magic number."

While the 1 ppb level can be used as an "action level," local demographics as well as the nature, pathways and lengths of exposure also must be considered, he said.

"There may be levels of concern in each kind of situation," he said at a hearing following the conference.