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MINUTES OF THE SCIENCE PANEL

AGENT ORANGE WORKING GROUP

The Science Panel met at 9:30 a.m. on November 12, 1981. A list of those attending is appended (Tab A).

Civilian Exposure to Toxic Chemicals in Vietnam

James S. Stockdale, Chair of the Agent Orange Working Group, referred a letter from Joan M. Maiman, Chairperson of the Veterans Leadership Conference (Tab B), expressing concern about civilians who served side-by-side with military troops in Vietnam not be denied inclusion in any testing and treatment and research programs that may be established to deal with possible effects of chemical exposure. After considerable discussion, the Science Panel concluded that it would be best not to involve them in specific studies that are presently proposed or underway. The Science Panel Chair will write Ms. Maiman stating that we will make special efforts to inform her group of the results of these studies.

Fat Biopsies

It was brought to the attention of the Panel that the State of Texas has passed an "Assistance Bill to help veterans of the Vietnam conflict who had been exposed to Agent Orange and other herbicides" (Tab C). Part of that bill is to establish a program to provide veterans with fat tissue biopsies. The Panel expressed serious reservations about this approach. A Subcommittee chaired by Major Phillip Brown to include Drs. Kimbrough, Honchar, Barnes, and Keller will examine the subject and report back to the Panel. The Panel will attempt to develop a position on the state-of-the-art and interpreting the results of fat tissue biopsies for dioxin.

Atch 2

FAT BIOPSY
SUBCOMMITTEE

Charter

The subcommittee will examine the state-of-the-art of human fat biopsies and the possible application of this technique to the assessment of body burden, exposure source identification and disease inference.

Statement of the Problem

If the technique of fat biopsy is to be useful for the identification of individuals who have been exposed to TCDD, i.e., the 2,3,7,8 isomer, what additional work must be undertaken to provide interpretable results that describe the medical meaning of low level body burdens.

Broad Approach Questions

1. Are present analytical techniques refined and documented to the point of providing reliable and consistent qualitative/quantitative analysis?

2. If there are other sources of dioxin, i.e., independent of herbicide application, can analytical techniques using pattern identification discriminate source?

3. Is there a normal background body burden of TCDD that exists in the U.S. population? The VA fat biopsy study suggests that there is may be.

4. Once analytical capability is documented and the existence of a normal background is established, is there a difference in body burden for individuals who have documented heavy exposure to TCDD via herbicide versus low or no exposure?

An ancillary question, is there a difference in body burden for individuals exposed to other isomers of dioxin as compared to the general population.

5. If heavily exposed individuals can be documented to have higher body burdens than the general population, what type of research effort is required to elicit the physiological response to those levels?

Atch 1

FAT BIOPSY SUBCOMMITTEE REPORT

STATE OF THE ART OF HUMAN FAT BIOPSIES FOR 2,3,7,8-TCDD AND THE POSSIBLE APPLICATION OF THIS TECHNIQUE TO THE ASSESSMENT OF BODY BURDEN, EXPOSURE SOURCE IDENTIFICATION AND DISEASE INFERENCE

American veterans of the Vietnam conflict have expressed a very strong concern about their exposure to the herbicides used for defoliation in South Vietnam. The central focus of concern has been the contaminant 2,3,7,8-TCDD, i.e., 2,3,7,8-tetrachlorodibenzo-p-dioxin, which is known to have been present in 2,4,5-T containing herbicides.

The actions of a number of state legislatures reflect an assumption that fat biopsies will document the presence or absence of 2,3,7-8 TCDD and the fact of exposure or nonexposure in Vietnam in any given veteran. This approach presumes that any detectable 2,3,7,8-TCDD reflects exposure in Vietnam and relegates any other exposure source to negligible importance.

In fact, these assumptions have not been verified and current information leads to a conclusion that they may be false. In particular, the presence of 2,3,7,8-TCDD in fat tissue has not been demonstrated to be a property unique to Vietnam veterans. Additionally, the presence of 2,3,7,8-TCDD in fat tissue has not been demonstrated to correlate with any particular disease state.

With cognizance of these facts, the Science Panel commissioned a subcommittee to examine the state-of-the-art of human fat biopsies

and the possible application of this technique to the assessment of body burden, exposure source identification and disease inference. The above broad question was divided into four more narrowly focused questions. In the next section of this report, each question is posed and followed by the subcommittee's response and recommendation:

a. Are present analytical techniques refined and documented to the point of providing reliable and consistent qualitative/ quantitative analysis?

Subcommittee Response - The-state-of-the-art for analysis has improved dramatically over the last two years and promising preliminary work now is being reported. However, an established validated analytical method does not exist that is generally applicable for detecting and measuring 2,3,7,8-TCDD in human tissue. Fundamental work remains to be done before such analyses can be conducted in various laboratories across the United States.

Recommendation - The Government establish an interlaboratory study group to construct a research protocol with the aim of developing a statistically sufficient data base to validate various methodologies for measuring 2,3,7,8-TCDD in human adipose tissue in the low ppt range. A similar effort was jointly undertaken by U.S. and Canadian laboratories for the analysis 2,3,7, 8-TCDD in fish.

b. If there are sources of polychlorinated dibenzo dioxins (PCDD's), other than from herbicide application, can analytical techniques using pattern identification discriminate source?

Subcommittee Response - The scientific literature documents a variety of environmental sources for PCDD's. Some of the possible sources are combustion of refuse, 2,4,5-trichlorophenol, pentachlorophenol, hexachlorophene, 2,4,5-T, Silvex and the possible breakdown of other higher PCDD's. The PCDD's are a class of compounds with many different chemicals. The proportion of specific PCDD's may vary depending on the source, and it has been suggested that analyzing the "patterns" of different PCDD's might identify the source. However, exposure of individuals to multiple sources may make it impossible to determine the source of PCDD's in tissue based on pattern recognition. Pattern recognition may be further complicated by physiological factors which modify the absorption and retention of various PCDD's. Despite these uncertainties, the relative proportions of the PCDD's may be useful as pointers to possible sources of exposure.

Recommendation - That no separate examination of pattern recognition be undertaken but that the analysis for specific PCDD's, penta, hexa, hepta and octa chlorinateddioxins, be evaluated as part of the interagency validation study mentioned in (a) above.

c. Is there a background body burden of 2,3,7,8-TCDD in the U.S. population?

Subcommittee Response - The subcommittee is not aware of any large scale study which indicates a general body burden of 2,3,7,8-TCDD in the U.S. population. However, the limited study conducted by the Veterans Administration and limited data from elsewhere suggest that there may be a measurable background level in the low parts per trillion range. If an effort is made to correlate 2,3,7,8-TCDD residues in veteran tissues to Vietnam Agent Orange exposure, then a carefully designed survey of the U.S. population must be undertaken to document the existence or lack of a tissue background. This study should include analysis of the other chlorinated dioxins. After analytical procedures are ready to accept fat tissues specimens, then selective sampling should begin. The specimen size must be defined by the documentation process required in questions a and b above.

Recommendation - The subcommittee recommends that no sole purpose surgical procedures be undertaken for the collection of human adipose tissue. Should surgery be performed for other purposes, then tissue removal appropriate for research defined in this and the above questions would be in order.

d. If heavily exposed individuals can be documented to have higher body burdens than the general population, what type of research effort is required to associate a physiological response with the presence of 2,3,7,8-TCDD?

Subcommittee Response - Answers to questions a and c should be substantially completed before tissue body burdens are examined

in heavily exposed individuals. The relevance of measurable body burdens to illness would require correlation with disease observations obtained through physical examination.

Recommendation - When the analytical techniques are documented and the evaluation of a U.S. population body burden background has been completed, a selected group of individuals with documented 2,3,7,8-TCDD exposure should be examined. Perhaps the best single population of Vietnam veterans would be the Ranch Hand participants of the Ranch Hand Study. With the possible exception of long latency disease, the observation of disease in this group would have already been completed.

OVERALL RECOMMENDATIONS FOR THE CONSIDERATION OF THE SCIENCE PANEL:

1) Fat biopsy procedures should not be performed until such time as analytical procedures are documented and appropriate segments of the U.S. population are evaluated for background body burdens.

2) The sequential studies recommended by the subcommittee should be referred to an appropriate group for an assessment of research requirements and funding projections.

3) The Agent Orange Working Group, through the Science Panel, be tasked to oversee the development of detailed research protocols for each of the recommendations.

FOR: DR. KELLER
FROM: SANDY LANGE

Executive Committee
Committee to Coordinate Environmental and Related Programs
Minutes of July 16, 1982 Meeting

The seventh meeting of the Executive Committee of the Committee to Coordinate Environmental and Related Programs was convened by Dr. William H. Foege, Chairman, on Friday, July 16, 1982 at 1:00 p.m. The following Executive Committee members or their representatives were in attendance: Dr. James Dickson, Senior Adviser for Environmental Affairs; Dr. William Foege, Director, CDC; Dr. Robert Gordon, Special Assistant to the Director, NIH (for Dr. James Wyngaarden, Director, NIH); Dr. David Rall, Director, NIEHS and NTP; and Ms. Helen Trilling, Special Assistant to the General Counsel (for Mr. Juan del Real, General Counsel). In addition, the following guests were present: Dr. Vernon Houk, Acting Director, Center for Environmental Health, CDC; Dr. Donald Millar, Director, National Institute for Occupational Safety and Health (NIOSH) CDC; Ms. Sandra Lange, Administrative Officer, NIEHS/NIH, and Ms. Maureen Corcoran, Special Assistant to the General Counsel, HHS. Ms. Francie de Peyster, CDC, was also present as Executive Committee staff.

I. NEW BUSINESS

A. Agent Orange Working Group/Science Panel-Consideration of Fat Biopsy Subcommittee Report

Dr. Foege advised the Committee that Mr. James Stockdale, in his capacity as Chairman of the White House Agent Orange Working Group, had requested the Executive Committee's review of the Science Panel's Fat Biopsy Subcommittee Report. Since Dr. Vernon Houk chairs the Science Panel whose subcommittee developed the Fat Biopsy Report, Dr. Foege asked him to present the report to the Committee. Dr. Houk began with a brief overview of the Agent Orange Working Group. (Copies of the Working Group's charter and membership were distributed and a set is attached at Tab A.) Dr. Houk then described the key factors which led to the development of the Fat Biopsy Report. He mentioned that one major impetus for the fat biopsy study has been the profusion of State agent orange laws which reflect an assumption that fat biopsies will document the presence or absence of the contaminant 2,3,7,8 tetrachlorodibenzo-p-dioxin (TCDD) and thus, the fact of exposure or nonexposure to agent orange in Vietnam for any given veteran. In view of the many uncertainties surrounding this topic, the Science Panel commissioned a subcommittee to examine the state of the art of human fat biopsies. The panel addressed four major questions:

1) Are present analytical techniques adequate to provide reliable analysis?

2) If there are sources of polychlorinated dibenzo dioxins (PCDD's), other than from herbicide application, can analytical techniques using pattern identification discriminate among the sources?

3) Is there a background body burden of 2,3,7,8-TCDD in the U.S. population?

4) If heavily exposed individuals can be documented to have higher body burdens than the general population, what type of research effort is required to associate a physiological response with the presence of 2,3,7,8 TCDD?

A copy of the Fat Biopsy Subcommittee's report and recommendations is attached at Tab B. The three overall recommendations were:

1) Fat biopsy procedures should not be performed until such time as analytical procedures are documented and appropriate segments of the U.S. population are evaluated for background body burdens.

2) The sequential studies recommended by the subcommittee should be referred to an appropriate group for an assessment of research requirements and funding projections.

3) The Agent Orange Working Group, through the Science Panel, be tasked to oversee the development of detailed research protocols for each of the recommendations.

There was general discussion about the state of the art of fat biopsy, the cost per specimen, and the extent to which the concentration of dioxins in Veterans' body tissues might have diminished because, in most cases, soldiers' body fat was at its leanest in Vietnam. Dr. Rall distributed copies of minutes of a 1979 Dioxin Analytical Meeting (Tab C), pointing out that CCERP had convened a panel once before on this topic and since many questions still remain it would be appropriate to establish a similar panel now. The Executive Committee members agreed that the questions raised by the Fat Biopsy report required an in-depth technical analysis and concurred with the suggestion that CCERP set up an appropriate technical panel. Dr. Rall, as Chairman of the CCERP, agreed to include representatives from the Veterans Administration, Department of Defense, and the Environmental Protection Agency, and said he expected to set up the group within about a month.

UPDATE: Attached at Tab D is a copy of Dr. Foege's August 2 memo to Mr. Stockdale notifying him of the Executive Committee's action on this matter.

SUBCOMMITTEE TO ASSESS THE STATE-OF-THE-ART FOR
ANALYSIS OF 2,3,7,8-TCDD IN HUMAN FAT BIOPSIES
AND TO MAKE RESEARCH RECOMMENDATIONS OF THE DHHS-
COMMITTEE TO COORDINATE ENVIRONMENTAL AND RELATED PROGRAMS

Purpose

Several States have passed legislation offering to pay for taking fat biopsies from Vietnam veterans and analyzing them for 2,3,7,8-TCDD. The successful execution of their intent, the subsequent use and interpretation of the data obtained, and their potentials for predictiveness, is the assumption that the analytical methodology for 2,3,7,8-TCDD has the validation (confirmation), precision and accuracy needed to accomplish this task. The report of the Fat Biopsy Subcommittee of the Science Panel, Agent Orange Working Group, subsequently transmitted to the Chairman, Agent Orange Working Group, recognized possible analytical problems as one among many needing consideration and evaluation. The Executive Committee of the DHHS-CCERP in reviewing the report of the Fat Biopsy Subcommittee and their recommendations concluded that they all required an in-depth technical analysis.

This Subcommittee of the DHHS-CCERP is being established specifically to look at the analytic issues, evaluate their state-of-the-art, make appropriate research recommendations, if required, and estimate the time and effort needed to develop adequate analytical tools for this type of study. Technical analysis of the other recommendations of the Fat Biopsy Subcommittee is dependent on the conclusions of this Subcommittee. These other recommendations will be addressed immediately by appropriate subcommittees, when and if needed.

Structure

Members of the Subcommittee will include representation from the following agencies other than DHHS:

Environmental Protection Agency
Veterans Administration
Department of Defense

The Chairperson of the Subcommittee is chosen by the Chairman, DHHS-CCERP, and its membership is chosen by the Subcommittee Chairperson. Other members may be appointed from other agencies by the Chairperson of this Subcommittee as needed. Outside experts will be brought in as consultants as needed in order to better meet their objectives.

Management and Control Function

The Subcommittee shall be accountable to the Chairman of the DHHS-CCERP.

Reporting

The Subcommittee shall report to the Chairman, DHHS-CCERP, upon completion. This report will then be forwarded to the Chairman, Executive Committee, CCERP.

Duration of the Subcommittee

This Subcommittee shall be chartered for an initial period of 90 days and may be renewed for an additional 90 days if deemed necessary by the Subcommittee Chairperson.

Approved:

30 Oct 82
Date

Chairman, Department of Health and Human Services--Committee to Coordinate Environmental and Related Programs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control

Memorandum

Date March 31, 1983

From Chairman, Executive Committee
Committee to Coordinate Environmental and Related Programs (CCERP)

Subject CCERP Executive Committee Action on Agent Orange Working Group Science Panel's Report on Fat Biopsy

To Chairman
Agent Orange Working Group

This is in followup to my August 2, 1982, memorandum to James S. Stockdale to advise you of the Executive Committee's action concerning our technical review of the Fat Biopsy Subcommittee Report.

On July 16, 1982, the Executive Committee, CCERP, in response to Mr. Stockdale's request, considered the Fat Biopsy Subcommittee Report and asked Dr. David Rall, Chairman, CCERP, to set up an appropriate scientific group to conduct a technical review of the report. On March 30, 1983, the Executive Committee considered and approved the attached report of the CCERP subcommittee's technical review. The Executive Committee agreed with the report that although fat biopsy is technically and analytically possible, it is not practical to use this technique on large populations at this time.

The Executive Committee, through CCERP, will monitor the progress of this issue and report future findings to you.

William H. Foege, M.D.
Assistant Surgeon General
Director

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Institute of
Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, N.C. 27709

Memorandum

Date February 8, 1983

From Chairman, CCERP

Subject Fat Biopsy Analysis for TCDD

To CCERP Executive Committee

At the July 16, 1982, meeting of the Executive Committee of the CCERP, the members agreed that questions raised by a Fat Biopsy report from the White House Agent Orange Working Group required an indepth technical analysis. A Subcommittee of CCERP, chaired by Dr. Henry Fales, Chief, Laboratory of Chemistry, National Heart, Lung, and Blood Institute, was established specifically to look at the analytical issues, evaluate their state-of-the-art, make appropriate research recommendations if required, and estimate the time and effort needed to develop adequate analytical tools for this type of study. Technical analysis of other recommendations of the Fat Biopsy report were dependent on the conclusions of this Subcommittee and were to be addressed when and if needed.

Following submission of the CCERP Subcommittee report (attached), a meeting was held on January 27, 1983, with representatives of the Veterans Administration (V.A.), the Environmental Protection Agency (EPA), the Department of Defense, the Agent Orange Working Group, Dr. Fales and me. At this meeting the Subcommittee report was discussed along with a planned project involving an interagency agreement between the V.A. and the EPA to study levels of 2,3,7,8-TCDD in adipose tissue collected by EPA from a selected group of U.S. males as part of the National Human Adipose Tissue Survey. This study will include the specification and testing of analytical methods for the determination of selected dioxins and furans in human adipose tissue.

Other aspects of the study include the identification of military service status of approximately 500 males of appropriate age who were included in the National Human Adipose Tissue Survey. The analysis of tissue and preparation of a final report are anticipated to be completed by early 1985.

It was agreed at the meeting that the group would reconvene in 6-12 months and progress of this study would be reported at a regular CCERP meeting. The issue of funding remains unresolved.

Dave Rall

David P. Rall, M.D, Ph.D.

Attachment

The Analysis of 2,3,7,8-Tetrachlorodibenzodioxin in Fat Biopsy Specimens

On the basis of conversations with the analysts named on the appended list, a conclusion has been reached concerning the feasibility of analysis of 2,3,7,8-tetrachlorodibenzodioxin (TCDD) in fat biopsy samples. Using existing methods, analysis of 5-10 g samples at the low (10) part per trillion level with an accuracy of 20-40% is feasible. Several respondents consider that this same sample size can yield results of the same reliability even at the 1 part per trillion level. Cost per sample estimates ranged from $600-1200 per sample, based on a project involving 100 samples.

It is important to note that these estimates do not imply that everyone queried was either willing or able to carry out these analyses. In fact, some respondents consider that only 2-4 laboratories in the United States are currently capable of performing such analyses reliably. All analytical schemes now in use involve time-consuming and tedious procedures that require inordinate attention to the most minute detail. All respondents agree that a large number of blanks must be distributed among the unknowns to provide assurance that contamination by TCDD or other substances has not occurred. These blanks are partly responsible for the above cost estimates although it seems reasonable that their number might be reduced as a given laboratory gains experience with a large number of samples. On the other hand, the use of several independent laboratories provides cross-checking that is considered essential at the present stage of development of this analysis.

Regarding analytical methods, there is general agreement that gas chromatography-mass spectrometry has sufficient selectivity and sensitivity to do the job. Commercially available capillary columns have demonstrated resolution of 2,3,7,8-TCDD from all other isomers but access to isomers eluting near 2,3,7,8-TCDD is still needed in checking g.c. resolution. Several respondents consider that electron capture gas chromatography is itself sufficiently sensitive to provide reliable quantitation provided the sample has undergone a careful cleanup procedure. However, confirmation that the eluted peaks are actually TCDD is best done by mass spectrometry and any laboratory heavily involved in this work should have access to both high and low resolution spectrometers. Internal standards of 2,3,7,8-TCDD (^{13}C and ^{37}Cl) are available.

One respondant, in a preliminary investigation, has shown that needle biopsy samples (0.25-1 g) may be practicable, at least at the 20 ppt level. Further evaluation of this technique is desirable since the usual 5-10 g biopsy involves considerable trauma. Such a study might be carried out in parallel with the limited project recommended below.

Most respondants feel that it would be very unwise (perhaps even impossible) at this time to initiate a large scale project involving thousands of samples using one rigid analytical protocol. There has been insufficient experience on this particular type of sample (human fat biopsy) and, as mentioned, the surgery

involved is not trivial. More appropriate is a second series of analyses involving a limited number of samples, perhaps 100-200, from the population at risk which would be compared to a like number from the general population. If values from individuals in the two populations are found to be grossly different, certain economies might be effected in larger scale efforts. If the two populations turn out to be statistically similar, even more rigid protocols will be necessary. It is even possible that new methods will have to be developed to provide the necessary accuracy. The precise number of samples and overall design of the experiment should be conducted with advice from experienced epidemiologists so that this necessarily expensive and laborious experiment will yield statistically significant results.

DIOXIN FAT BIOPSY

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December 15, 1982
Corrected copy December 20, 1982

RETROSPECTIVE STUDY OF DIOXINS AND FURANS IN ADIPOSE TISSUE

In a limited study conducted in 1979-1980 the Veterans Administration (VA) found that 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD) could be detected and quantified in adipose tissue removed from Vietnam-era veterans. Although there was no clear relationship between levels of 2,3,7,8-TCDD and either Vietnam service, exposure to Agent Orange, or current health status, the study indicated the need for further investigation. The VA, in cooperation with the Environmental Protection Agency (EPA) is now finalizing an interagency agreement to study levels of 2,3,7,8-TCDD in adipose tissue from a selected group of U.S. males.

The Environmental Protection Agency has been collecting adipose tissue for its National Human Adipose Tissue Survey. This survey has been conducted annually since FY 1970. Adipose tissue is collected from a statistically representative segment of the general population and analyzed for residues of selected organochlorine pesticide-related chemicals and PCBs. Approximately 12,000 specimens have been collected and analyzed, and of these approximately 4,000 have excess tissue left over from the original analysis which can be used for further chemical analyses. These excess tissues are stored in a tissue bank at EPAs Toxicant Analysis Center, Bay St. Louis, Mississippi. Represented within this bank is adipose tissue from approximately 500 males born between 1937 and 1952. Many of these individuals will have served in the military during the Vietnam-era and some will have served in Vietnam during the period of Agent Orange use. A retrospective study of selected chlorinated dioxins and furans (chemicals similar in structure to the dioxins) may establish data on background levels of 2,3,7,8-TCDD in the U.S. male population as well as whether service in the military and especially in Vietnam has had an effect on the levels of TCDD in adipose tissue.

The study will be conducted in three phases. Phase I will be to obtain the name and social security number for the approximately 500 males noted above. This information will be used to determine military service status. Phase II will be the development of analytic methods for the determination of selected dioxins (especially the 2,3,7,8-TCDD) and furans in human adipose tissue. The method will be subjected to rigorous interlaboratory validation by an independent Analytic Referee, e.g., the Association of Official Analytical Chemists. Phase III will be the analysis of the adipose tissue and the preparation of a final report. Phases I and II should be completed within fiscal year 1983, and the report from Phase III should be available in early 1985.