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Author Kang, Han K.

Corporate Author

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Description Notes

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Retrospective Study of 2,3,7,8-TCDD
in Human Adipose Tissue

Objectives

1. To develop a reliable, precise and sensitive analytical method for the determination of 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD) and other dioxins and furans in human adipose tissue.
2. To estimate background levels of 2,3,7,8-TCDD in the fat-of the American adult male population.
3. To determine whether the dioxin body burden of Vietnam veterans is different from that of other Vietnam era veterans and the general population.

Source of Adipose Tissue

Under the National Human Adipose Tissue Survey (NHATS) the Environmental Protection Agency (EPA) has been monitoring the concentrations of various pesticides in the adipose tissue collected from a broad segment of the U.S. general population. The Veterans Administration (VA) has identified the archived adipose tissue specimens from the NHATS as a source of adipose tissue. Represented within the archived tissues are approximately 550 males born between 1937 and 1952, i.e., the birth date window of men who potentially served in Vietnam.

Status of Study

Under an interagency agreement (IAG V101 (91) P-82016, EPA No. AR 36 F3A 439) EPA is to collaborate with VA in the following phases:

1. Assess the status of archived adipose tissue and develop a survey design. Obtain Social Security number and autopsy or surgical report for each of the 550 males.
2. Develop a collaborative validated method to analyze for 2,3,7,8-TCDD in humans. The method is to be subjected to rigorous laboratory validation by an independent analytical referee, e.g., the Association of Official Analytical Chemists (AOAC).

3. Develop a rigorous quality assurance program to assure the quality of the analytical procedures and results.

To date:

1. The 550 adipose tissue specimens slated to be used for the study have been identified and moved from the EPA Toxicant Analyses Center, Bay St. Louis, Mississippi to the Midwest Research Institute, Kansas City, Kansas.

2. A total of 397 pathology reports and 268 Social Security numbers have been obtained for these 550 deceased individuals.

3. The published literature on dioxin analyses for biological matrices has been critically reviewed and a consensus has been reached by experts on an analytical method to be validated by intra and inter-laboratory tests.

Problems

1. EPA could not come up with the necessary matching funds and personnel to continue the study.

2. VA has only enough funds to complete the development of analytical method for TCDD in adipose tissue.

3. No funds are currently available for interlaboratory validation of the analytical method and actual analysis of TCDD in 550 archived adipose tissues.

Options

1. We can use an existing analytical method with a minimum attempt for interlaboratory validation and complete the analysis of the 550 adipose tissue specimens.

Pro: We may be able to obtain data on 2,3,7,8-TCDD levels in the adipose tissue specimens without a substantial increase in funds.

Con: There is room for criticism for not using an analytical method which is validated by an independent analytical referee.

2. We can present Option 1 to the Science Panel, AOWG and proceed only when the panel approves the approach.

Pro: The study results will be less likely to be questioned.

Con: If we cannot obtain a blessing from the panel the entire project is stalled.

3. We can present the problems to the Chief Medical Director (CMD) and request resources to complete the study as originally conceived.

NOTE: I believe in light of the CDC's independent effort to develop an analytical method for dioxin in blood and EPA's reluctance to support the study it is not realistic to anticipate financial support from other agencies via AOWG.

Recommendation

I recommend you seriously consider Option 1. We requested a total of \$300,000 (200k, FY 1985; 100k, FY 1986) for a prospective study of dioxin in human adipose tissue. If all or some of this amount is approved we can use the funds to support a limited inter and intralaboratory validation for the present project.



HAN K. KANG, Dr.P.H.
Chief, Research Section
Agent Orange Projects Office