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November 2012

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Item ID Number	05683 ☐ **Not Scanned**
Author	
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Report/Article Title	Typescript: Proposed Structure of the Report on Exposure from the Ad Hoc Subcommittee of the Agent Orange Science Panel, [April 1986]
Journal/Book Title	
Year	0000
Month/Day	
Color	☐
Number of Images	0
Description Notes	Draft has handwritten editorial comments. Also included are a sheet of handwritten notes/calculations by Alvin Young, "Methodology to Avoid Exposure Misclassification," and "Estimated Amounts of TCDD Exposure From a Ranch Hand Spray Mission" (2.5 copies). Alvin L. Young filed these documents together with others under the label, "Agent Orange Exposure Project."

Proposed Structure of the Report on Exposure from the Ad Hoc Subcommittee of the Agent Orange Science Panel

The Subcommittee was directed by the Assistant Secretary of Health to evaluate information on exposure being gathered for the Agent Orange study to determine whether sufficient information is available to conduct a study. The Subcommittee met on three occasions during February and March, 1986 with representatives from CDC and ESG to hear of activities relating to exposure assessment. The evaluation by the Subcommittee is based on information obtained at these meetings and from documents supplied by the ESG.

We have approached the charge of the Assistant Secretary by asking a series of questions relating to the detail and quality of data on exposure. Answers to these questions provide a basis for evaluation of the likelihood that the proposed study can provide data to resolve the issue of health risks resulting from herbicide exposure while in Vietnam.

- these were done by ESG

Exposure Data Available

From presentations and documents provided by ESG, we believe that the military records are sufficient to locate the position of companies by geography and time rather

precisely from field reports. These positions can then be related to similar data (i.e., geography and time) of Ranchand spray missions. Duty roosters for companies are available which identify individuals available for duty each day.

A limitation of the records is the inability to determine which individuals were at the various deployment locations of a company. The records can identify the location of unit deployments, but can not determine which individuals were at which location. Displays of deployments of selected companies on various days showed a considerable variation in geographic spread. On some occasions all members of the company were in one location, on other occasions units were spread over an area of up to 20 kilometers. The latter situation presents severe problems in assessing exposure by geographic location since there appears to be no way to accurate summarize the potential for exposure for all members of the company.

In addition to Ranchand spraying, perimeters of camps were also sprayed routinely with herbicides and insecticides. The potential for exposure at the camps would appear to be considerable because of the regularity of spraying. Exposure could occur directly during spraying or indirectly from contact with contaminated surfaces. The ability to obtain information on likelihood of contact and

level of exposure for individuals while at the base, however, appears limited.

The questions specifically addressed by the Subcommittee and our answers are below.

1. Can level of exposure to herbicides over time for individuals be assessed with reasonable certainity?

Information on level of exposure would provide the strongest possible data to address the issue of health risks associated with herbicide exposure. We feel such precise information can not be assembled either for exposure from Ranchand spraying or perimeter spraying of camps. Present attempts at exposure classification employ dichotomous categories and are based on the likelihood of having contact with herbicides. They do not, however, include information on levels of exposure experienced by individuals. In such a dichotomous classification scheme the only measures of dose would be the number of exposures, latency, and duration.

Similar problems exist in attempts to assess level of exposure while in camps. The Subcommittee feels that levels of exposure are likely to higher from exposure in camps than from Ranchand spraying, but we see little opportunity for quantifying the level. Actual exposure levels would depend upon the level of contact directly from sprays and indirectly from contaminated surfaces. We see little

opportunity for individual evaluation of either method of contact.

2. Can the probability of exposure to herbicides for individuals be reasonably assessed?

To construct an index of probability of exposure, a pilot study is underway to relate location of ground forces to Ranchand spray patterns. Companies can be located rather precisely, as can deployment of squads and other units. It is not possible, however, to determine which individuals are ~~in which~~ employed units. The inability to precisely locate individuals in relation to Ranchand spray patterns would lead to exposure misclassification no matter what distance/time criteria were used. For example criteria of within 2 kilometers within 2 days of spraying has been proposed to identify companies that would be considered exposured. All persons from a company within this distance of spray tracks would be considered exposured. Two kilometers would seem to be a considerable distance and present little chance of exposure. Although the number of false positive could be reduced (at the expense of numbers of exposed) by a more restictive distance criterion, precise exposure classification would never be achieved unless companies were required to be within the spray path. An equally serious problem with this approach, however, is the inability to precisely locate ~~the whereabouts of~~ individuals. The distance factor is based on company

– not true in every case. – get a hold of those that would

location, not on individual location. The dispersion of units within a company may considerably exceed the two kilometer criterion (some units were separated by up to 20 kilometers). Thus, individuals deployed far from the spray track would be considered exposed even though they would little or no contact with herbicide residues.

Although companies are apparently sometimes deployed as a single unit and exposure assessment could be restricted to such situations. Ignoring exposure when deployed in units would not, however, eliminate the misclassification associated with the situation. The assumption for such a situation would be that the average exposure for all multi-location deployments of companies are equivalent. An assumption that surely is not correct.

Exposure while in camps presents a different set of problems in developing a scale of probability of exposure. Although we can reasonably conclude that exposures occur in camps, except for cases where applicators can be identified, we see little opportunity for distinquishing the probability of exposure among individuals while in camp. A cohort of persons spending time in camps where spraying occurred could, however, be compared with persons not in such camps, if such a referent cohort can be identified.

In summary, plans to construct a probability of exposure index based on distance and time from Ranchand spray patterns based on company locations would introduce

without regard to deployed

misclassification. This misclassification arises from two sources: 1) Inclusion of companies without actual exposure would occur no matter how small the distance and time criteria, and 2) Members of companies would be assigned identical exposure probabilities even though deployment of some units would place them in locations where exposure was not possible. The combined effect of these two sources of misclassifiction is unclear, but undoubtedly they would seriously bias measures of effect toward the null and greatly reduce study power. Evaluation of probability of exposure while in base camps seems more promising (because of our assumption that all persons while in camp would be exposed). To effectively capitalize on the camp exposures requires the identification of a combat cohort that did not spend time in the camps or in other situations where exposure to herbicides occurred.

3. If either level or probability of exposure for individuals can be estimated with reasonable confidence, can a dose gradient be created?

The Subcommitte feels that it will not be possible to estimate level of exposure. Although probability of exposure can be assigned, we fear that misclassification may seriously compromise the study. However, if the misclassification problem can be resolved, a dose gradient could be developed based on number of contacts, latency, and total duration of contact. In camps, a gradient could be

based on duration of time spent in camps, latency, and possibly number of perimeter spraying operations for the camp.

4. Are levels of exposure likely to be meaningful biologically?

5. Can a non-exposed population be identified?

This question is especially important if base camp exposure are to be considered. Since both camp and Ranchand exposures occur primarly among combat troops, a comparison population would also need to be composed of combat units.

6. For the study to be feasible and creditable, what quality of exposure assessment is required?

The Subcommitte recognized the social importance the Agent Orange - health risk issue and the need to provide data that can address concerns raised by veterans. Completion of a study with poor definition of exposure, however, may not resolve the issue. In a strict scientific sense, the misclassification issue must be clearly addressed. The pilot study should provide information regarding estimates of misclassification likely given whatever criteria are used to assess exposure. These misclassification estimates can then be used to evaluate affects on study power.

Dispersion

None	17	Company-days (includes 2 comp-days in which inhabs. moved)
< 2km	1	
3-5km	5	
6-10km	4	
11-20km	5	
20+km	4	
Total	36	Company days (6 BT in a pilot test)

↓ (1 CO/BT)

= 18 on wash

plus

18 additional

↓

6 CO

↓

6 days/CO

3/month/year

Max distance 29 km

Methodology to Avoid Exposure Misclassification

1. Define grid locations (UTM Coord) of all perimeter and ground spraying from Services Herbs and Helicopter sprays in HERBS.

2. Compare Firebase and Base camp grid coordinate to perimeter and ground spray in time window. (1 Oct 66 - 30 Mar 69).

3. Select fire bases and base camps having highest numbers of perimeter and ground spray. List in decending order of frequency.

4. Find units assigned to fire bases and base camps.
Select those units having highest permanent stay time on each fire base such as artillery batteries that were stable and served as one whole unit at base camp or fire base.

5. Figure out how many times these stable units were in the fire base or base camp when a perimeter or ground spraying took place.

6. Check personnel present for duty in battery at base camp or fire base when spraying took place. List their basic exposure date and continuing presence for secondary exposure.

7. Figure initial exposure concentrations and graded residual exposure concentration as long as troops continued to be on that fire base or base camp.

8. Establish cumulative total exposures for personnel assigned to these more or less stationary companies and/or batteries at the fire base. List personnel by name in decending order of exposures.

9. To find non-exposed comparable cohort on non-sprayed fire base or base camps.

A. Compare list of all fire bases and base camp grid coordinates to master list of ground and perimeter spray coordinates.

B. Select base camps which have not received any perimeter sprays by Orange or unknown agents.

C. Determine units which were assigned to these non-sprayed fire bases and select comparable assigned personnel who served whole tour in these units at non-exposed locations. Probably mostly artillery personnel.

ESTIMATED AMOUNTS OF TCDD EXPOSURE FROM A RANCH HAND SPRAY MISSION

We have summarized various estimates made for amounts of TCDD exposure of a serviceperson from the Ranch Hand spray mission. As we will briefly describe for each estimate many assumptions were made and entered into the calculation.

1. FLANDERS (CDC)

Dr. Flanders in his estimate of TCDD exposure from a single Ranch Hand spray assumed an extreme case scenario. He assumed that Agent Orange sprayed in Vietnam contained 47ppm of TCDD, that 5 gallons of Agent Orange were applied per acre of land, and that each gallon of Agent Orange weighed 10.7 pounds. Using these figures he calculated that the amount of TCDD/M^2 of land was 282ug. He further assumed that all Agent Orange sprayed on the jungle reached ground level, and that the whole body surface (not just head, shoulders, arms) was equally exposed to Agent Orange whether that part of the body was clothed or not. Using a body surface area of 1.85m^2/servicemen, he was able to estimate the ug TCDD/serviceperson to be 522. Taking a 3% dermal absorption rate for TCDD he estimated that 16ug of TCDD would be absorbed into the serviceperson from a single direct exposure to a Ranch Hand spray mission. This is equivalent to 0.22ug per kg body wieght for a 70kg serviceperson.

2. GOUGH (FORMERLY WITH OTA)

In his recent book, Gough presnts as an appendix calulation of the amount of dioxin exposure of a person standing under a Ranch Hand spray mission. His extreme scenario, that is, a serviceperson standing in the open area while being sprayed on with Agent Orange containing 50ppm TCDD with the application rate of 3 gallons per acre resulted in 32.4ug of TCDD falling on a serviceperson's head and shoulders. Another extreme case was a serviceperson standing under jungle conopy while being sprayed on with Agent Orange containing 0.5ppm TCDD with the same application rate resulting in exposure to 0.02ug TCDD on the head and shoulders.

He had assumed that 6% of Agent Orange sprayed on the jungle would reach ground level. Assuming that 0.05% of TCDD contacted by the serviceperson would be absorbed by the body, the amounts of TCDD absorbed per kg body weight under these two senarios were 2.3×10^{-4} and 1.4×10^{-7}, respectively.

3. STEVENS

Dr. Stevens in his calculation of TCDD exposure from a single Ranch Hand mission made many assumptions which were similar to Gough. For a 70kg serviceperson the amount of TCDD absorbed per kg body weight was estimated to be 7×10^{-6} ug.

ESTIMATED AMOUNTS OF TCDD EXPOSURE FROM A RANCH HAND SPRAY MISSION

	FLANDERS	GOUGH		STEVENS
		OPEN	JUNGLE	
TCDD/AO (ppm)	47	50	0.5	2
JUNGLE CANOPY	No	No	Yes	Yes
PROTECTIVE CLOTHING	No	Yes	Yes	Yes
DERMAL ABSORPTION	3% .05	Yes	Yes	Yes
ug TCDD/M^2 ground	282	180	$1x10^{-1}$	$5x10^{-1}$
ug TCDD/serviceman	522	32.4	$2x10^{-2}$	<1
ug TCDD absorbed/ serviceman	16 .016	$1.6x10^{-2}$	.00001 $1x10^{-5}$	$5x10^{-4}$
ug TCDD absorbed/kg BW	$2.2x10^{-1}$	$2.3x10^{-4}$	$1.4x10^{-7}$	$7x10^{-6}$
Fraction of FDA's VSD of $13x10^{-6}$ ug (daily for 70 years) total $3.3x10^{-1}$ ug	48	$4.8x10^{-2}$	$3x10^{-5}$	$1.5x10^{-3}$
Fraction of MTD of $1x10^{-1}$ ug/kg	2.2	$2.3x10^{-3}$ 100 pg/kg	$1.4x10^{-6}$ .1 pg/kg	$7x10^{-5}$ 7 pg/kg

VSD = Virtually Safe Dose
MTD = Minimum Toxic Dose

ESTIMATED AMOUNTS OF TCDD EXPOSURE FROM A RANCH HAND SPRAY MISSION

	FLANDERS	GOUGH		KINGSLEY & STEVENS
		OPEN	JUNGLE	
TCDD/AO (ppm)	47	50	0.5	2
JUNGLE CANOPY	No	No	Yes	Yes
PROTECTIVE CLOTHING	No	Yes	Yes	Yes
DERMAL ABSORPTION	3%	Yes	Yes	Yes
ug TCDD/M^2 land	282	---	---	8(6% reached the forest floor)
ug TCDD/serviceman	522	32.4	$2x10^{-2}$	1(transfer factor of 1:2050)
ug TCDD absorbed/ serviceman	16	$1.6x10^{-2}$	$2x10^{-8}$	$5x10^{-4}$
ug TCDD absorbed/kg BW	$2.2x10^{-1}$	$2.3x10^{-4}$	$2.8x10^{-10}$	$7x10^{-6}$
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Fraction of MTD of $1x10^{-1}$ ug/kg	2.2 x [redacted]	$2.3x10^{-3}$	$2.8x10^{-9}$	$7x10^{-5}$

VSD = Virtually Safe Dose
MTD = Minimum Toxic Dose estimated by [redacted] Stevens

Judgment & assumptions

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