

It is important to note that this "exposure" rate is only a rough estimate of aerial herbicide spraying within 2 miles of a residence, and not a measure of actual exposure to herbicides. It appears to be impracticable, if not impossible, to determine retrospectively what the true exposure of pregnant women was. We can only evaluate if aerial spraying occurred in the general proximity of infants with CNS defects more often than in a group of normal infants. The misclassification of women into exposed and not exposed categories would have the effect of lowering the power of the study to detect possible teratogenicity.

Sample Size Estimate

The sample size needed to detect an exposure effect depends on the rate of "exposure", the increase in risk among these exposed, and the statistical power desired. Using the estimate of 4.6% overall "exposure" from the pilot, if we want to have at least an 80% chance of finding a 2-fold increase in risk, we would need 435 cases and 435 controls. If the attack rate is 1-1/2 times greater in exposed than in unexposed, we would need 1,533 each of cases and controls.

A statistical power of 80% was the minimum figure we had hoped for. Unfortunately, we can't find enough cases in western Oregon with documented exposure status to achieve this power. Table 1 presents an estimate of the number of cases that could be located, interviewed, and the herbicide exposure documented. This number of cases (264) and an equal number of controls would produce a study with a 62% chance of detecting a 2-fold difference in attack rates, using a 1-tailed test at the 0.05 level of significance. If the attack rate is 1-1/2 times greater in cases than controls, then we have a 27% chance of finding a difference.

Proposed Epidemiologic Study

Hypothesis: The hypothesis to be tested is whether maternal exposure to aerial spraying of herbicide is associated with the birth of infants with central nervous systems (CNS) defects.

Study Design: A retrospective matched case-control study in western Oregon. Indepth personal interviews would be conducted of 264 CNS cases and 264 normal controls to evaluate various maternal and paternal risk factors.

Cost: To conduct this proposed study would cost approximately \$192,000 (See attached budget).

Required Time: With adequate staff the study could be completed in 9 to 18 months after approval to conduct the study has been given.

Summary: With completion of the pilot, some judgements can be made about the merits of the proposed epidemiologic study of "herbicide exposure" and birth defects. The measurement of exposure is troublesome. Lacking some better way to identify exposed mothers, we can only investigate the relationship between proximate aerial herbicide spraying and CNS birth defects. Such a study would compare these exposure rates in infants with CNS defects and normal infants.

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