More on Direct Estimates of Low-Level Radiation Risks

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In an epidemiologic study of mortality at the Portsmouth Naval Shipyard (PNS), the National Institute for Occupational Safety and Health (NIOSH) found no evidence of excess deaths due to leukemia or other cancers among workers exposed to low levels of ionizing radiation [1]. In a subsequent analysis, Bross and Driscoll [2] identified excess lung cancer mortality in PNS workers with lifetime radiation dose of 1 rem or greater and with more than 15 years' latency since first radiation exposure. Although that observation may be important and is currently being examined through case-control analyses, it must be recognized that Bross and Driscoll extracted their observation from matrices of over 4,000 data cells apparently by recombination of innumerable possible permutations of dosage and latency intervals. For that reason, their finding can be regarded as no more than a suggestion for further study. It certainly does not represent a proper scientific conclusion. Bross and Driscoll's analysis illustrates the hazard of performing multiple statistical comparisons on complex data sets in the absence of *a priori* hypotheses.

The article "Direct Estimates of Low-Level Radiation Risks . . ." by Irwin D.J. Bross and Deborah Driscoll [2] failed to provide an accurate history of the National Institute for Occupational Safety and Health's (NIOSH) study of cancer mortality in persons with radiation exposure at the Portsmouth Naval Shipyard (PNS), Kittery, Maine. This communication is intended to clarify several points which Bross and Driscoll have misconstrued.

NIOSH undertook the investigation of mortality at the Portsmouth Naval Shipyard (PNS) at the request of the Subcommittee on Health and the Environment, United States House of Representatives. The object of the investigation was either to confirm or refute a report by Najarian and Colton which found increases in proportional mortality due to leukemia and to all cancers combined among radiation workers at PNS [3]. The House Subcommittee recommended that a group of scientists outside NIOSH be established to consult with NIOSH researchers on the conduct of the study. Here it should be made clear that the function of this group was to provide NIOSH with professional review and additional expertise. It was not established to be an "oversight" committee. Dr. Bross was one of nine of these consultants. A detailed protocol establishing the hypotheses to be tested and the epidemiologic methods to be employed was drafted by NIOSH and presented to the consultants in advance of the study. Each of the consultants had the opportunity to recommend changes or additions to the protocol, and most, including Dr. Bross, took advantage of that opportunity. Part of the protocol called for calculation of

standardized mortality rates for PNS workers by specific causes of death. In accordance with the protocol, NIOSH investigators identified a cohort of over 27,000 current and former employees from records maintained by PNS. Current vital status was determined for 95 percent. Over 9,000 of the individuals in the cohort had been approved for radiation work at PNS, and annual radiation exposure records for these persons were assembled. Expected numbers of deaths adjusted for age, sex, race, and calendar time period were calculated for specific causes of death, for five-year latency periods, for five-year duration of employment periods, and, in the case of radiation workers, for specific levels of radiation exposure. All of this work was completed on time and in strict adherence to the protocol.

We did not find evidence of the previously reported fivefold excess in leukemia deaths among persons occupationally exposed to radiation [1]. We had a statistical power greater than 99 percent to observe such an increase. Furthermore, no excess in mortality due to total malignant neoplasms was observed. (It has since been determined that the major cause of the discrepancies between the conclusions of the previous researchers and those of the NIOSH study was misclassification of deaths in the previous study in regard to radiation exposure history [Colton T, Greenberg R: personal communication].)

Prior to completion and publication of the final report, we distributed a draft report to the consultants, including Dr. Bross, as well as to a number of other persons active in the field of radiation epidemiology. We received some minor comments suggesting additional or different analyses, but the reviews were overwhelmingly favorable.

Exercising his function as a consultant, Dr. Bross requested copies of all computer output generated during the analyses. Included in the material which we sent to Dr. Bross were matrices of observed and expected deaths by five-year latency and duration of employment categories, and by radiation dose categories for 83 different causes of death. With no *a priori* hypothesis ever having been presented to NIOSH or any member of the consultants' committee, Dr. Bross compared observed with expected deaths in those matrices for an indeterminate number of causes, after recombining the data by various latency periods, duration periods, and radiation exposure levels. While it was legitimate for Dr. Bross to peruse the data by stratifying in this manner, it is a fundamental principle of statistical analysis that one must resist drawing conclusions from this sort of unguided exercise [4]. It is essential to understand that in our matrices there are over 4,000 individual cells, each showing numbers of observed and expected deaths; these 4,000 cells could have been recombined into countless combinations and permutations. At a confidence level set at 95 percent (i.e., $p < 0.05$), by chance alone, 5 percent of these many permutations would appear to deviate significantly from the expected. Thus it comes as no surprise that a pattern of excess mortality emerged for deaths due to "malignant neoplasms of the respiratory system" after the data had been rearranged. Other patterns (some that would indicate excess mortality, others that would indicate deficits) could also have been developed from the data.

This is not to say that the observation of Bross and Driscoll is unimportant. It is true that excess mortality from respiratory cancer exists at PNS for persons who attained a radiation dose of 1 rem and 15 years' latency. Important questions are raised by this observation as to whether radiation is causally related, or if higher levels of radiation correlate with other occupational exposures, such as exposure to asbestos or to other respiratory carcinogens. The NIOSH protocol had anticipated

and provided for further evaluations of findings such as this, and, in fact, we are now performing nested case-control studies within the PNS cohort to look more closely at mortality from lung cancer as well as from leukemia. NIOSH is near to completion of these case-control studies, and we expect to publish results in the near future.

REFERENCES

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