

Bioethics Meeting in Salt Lake City, 10/26/2000

Comments from the Bioethics Panelists on the case-control study of AML and NHL

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Comment 1

Are AML and NHL the only diseases of concern?

Yes, based on current epidemiologic studies, only AML (acute myeloid leukemia) and NHL (non-Hodgkin's lymphoma) have been linked to benzene exposure. In fact, other than the Chinese Academy of Preventive Medicine-US National Cancer Institute (CAPM-USNCI) study, no other studies of workers exposed to benzene have reported an increased risk of NHL.

Comment 2

The CAPM-USNCI study reported results in terms of ANLL, whereas the protocol uses the term AML. What is the difference between ANLL and AML?

ANLL stands for acute non-lymphocytic leukemia, which includes in addition to AML other variants such as acute monocytic leukemia, myelomonocytic leukemia and promyelocytic leukemia. However, the other variants are very rare in comparison to AML, and the terms ANLL and AML are used interchangeably. To be consistent, we will use the same term that CAPM-USNCI used, ANLL. This change will be made in the revised protocol.

Comment 3

What is the statistical power of the study?

Based on a previous estimate, we should have approximately 400-500 cases of AML and NHL for the duration of the study. This sample size would allow us to detect a risk as small as three-fold. (In the CAPM-USNCI study, the relative risks of AML and NHL were both approximately 3-fold.)

We will add a statistical power discussion in revising our protocol.

Comment 4

Is there a formal procedure for choosing controls?

It was pointed out at the meeting that a procedure for choosing controls has already been included in the current protocol. We briefly went over the procedure at the meeting, and it appeared that the bioethics panelists were satisfied.

Comment 5

Will the questions in the questionnaire on employment history and disease history be sensitive to Chinese study participants?

The questions on employment history should not be sensitive to study participants at all. We will ask participants to list the names of their employers only, but will go through the Shanghai Municipal Center for Disease Prevention and Control to retrieve the actual employment records.

At this point, we have identified a few "sensitive" diseases (such as STD and reproductive impairments). We will revise the list after we have talked to Dr. Fu. We will not be able to finalize the list of "sensitive" diseases until after we have tested the draft questionnaire in a small pilot study of patients in Shanghai. (These patients will not be eligible for the case-control study.)

Comment 6

How many databases will there be in all three studies?

The answer is limited to the case-control study and the disease progression study only, since these two studies will share some patients in common (i.e., AML and NHL patients). In addition to its own research questions on disease progression of AML cases, the disease progression study will also be responsible for providing detailed diagnostic information on AML and NHL cases to the case-control study. However, some of the AML patients may not wish to participate in the disease progression study and none of the NHL patients will be part of the disease progression study. Dr. Brody suggested the following three databases:

- Database of AML and NHL cases and their controls in the case-control study.
- Database of detailed clinical information on disease progression of AML, MDS, and BP cases in the disease progression study.
- Database of diagnostic information on AML and NHL cases (for both studies).

Comment 7

There should be two consent forms in the case-control study: one for AML or NHL patients and one for controls. The content of the consent form should reflect the fact that the AML or NHL patients have already been diagnosed with diseases that might be linked to occupational exposures.

We will follow this suggestion in revising the current draft consent form.

Comment 8

A plan for communicating study results should be developed.

A number of suggestions for a communication plan were discussed at the meeting. It appeared that the biggest problem is that we as scientific researchers from the US lack both the authority and resource in Shanghai to carry out an effective communication program. Our best resource will most likely be the Shanghai Municipal Center for Disease Prevention and Control. We will explore this option further with our colleagues in Shanghai.