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Sent: Monday, October 16, 2006 10:58 AM
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Cc: Bruce Jarnot; Russell White
Subject: Update on the Shanghai Health Study

Attachments: CC Progress report rev 08-09-2006.pdf

Dear Colleagues,

I am writing to provide you with important updates on the current status of the Shanghai Health Study. I regret that the minutes of the Houston meeting have not yet been completed, but I hope to distribute those to you in the very near future. Meanwhile, a problem with the lymphoid neoplasm ("NHL") arm of the case-control study has come to light, about which both Panels need to be informed.

You will recall that at the Houston meeting, there was an extended discussion about case accrual for the NHL study, and there was some controversy about when case accrual could be considered complete. Richard Irons had reported that 336 "NHL" cases were in the JCML database as of 1 May 2006, and that 433 NHL cases (520 lymphoid neoplasm cases) were projected by the end of 2006. An implicit assumption in this debate was that essentially all AML and lymphoid neoplasm cases diagnosed by the JCML were potentially available for inclusion in the case-control study, pending completion of the questionnaires and proper exposure assessments for each case and its controls.

At the Houston meeting Otto Wong presented his preliminary review and analysis of a sample data set from the NHL study. He had noted that questionnaires were only available for about half the cases and controls in this sample. After the meeting, Otto revised his progress report (attached) to include his preliminary findings. I draw your attention especially to pages 7 - 9 of the attached report, specifically the section entitled "Test Data Sets." In that section, it is reported that while 95% of AML diagnoses and matched controls were accompanied by questionnaires, that was true for only 41% of the NHL cases and controls. Locating the missing questionnaires has become a matter of highest priority.

Otto's revised (August 9) progress report has been followed during September by intense efforts in Shanghai on the part of Richard, Otto, and Fu Hua to clarify this situation and to initiate corrective action. It turns out that for some time there has been a problem with case registration at the Shanghai Tumor Hospital, at which most of the NHL cases are initially seen. In fact, questionnaires have been obtained for fewer than two-thirds of these patients ever since 2003, and the proportion of cases with completed questionnaires has been dropping ever since. Currently (2006) the fraction of recently presenting NHL cases with questionnaires on file is below 10 per cent. The investigators are making an intense effort to correct this situation so that essentially all lymphoid tumor cases which present in the future are processed correctly. The investigators are also attempting to locate previous cases in an effort to obtain the missing questionnaire information. However, it is unlikely that questionnaires will eventually be obtained for all, or even most, of the lymphoid tumor cases in the JCML tumor bank.

The numbers of such cases presented in the successive case accrual tables we have seen in progress reports during the last few years therefore do not accurately reflect the number of lymphoid tumor cases actually available for analysis in the case-control study. Furthermore, as not all the lymphoid tumor cases that have presented in Shanghai since the JCML began operations are captured in the case-control database, the question arises whether some kind of selection bias might affect conclusions that are based on that partial database.