

Control Selection at Certain Hospitals

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The selection of controls at each hospital is the responsibility of the Clinical Coordinator at the hospital. The Clinical Coordinators were given a copy of the following instruction:

Instruction for selecting controls in the AML/NHL case-control study

English	中文
Selection of controls (1 case – 2 controls)	对照组的选择 (1 个病例 – 2 例对照)
1. Same gender	1. 性别相同
2. Age $\pm$ 5 years	2. 年龄 $\pm$ 5 岁
3. No disease of the lymph or blood system	3. 无淋巴或血液系统疾病
4. <u>Closest</u> admission date	4. 入院日期 <u>最</u> 相近
5. Same hospital	5. 同一医院
6. If the case is an inpatient, controls will be inpatients as well. If the case is an outpatient, controls will be outpatients as well.	6. 如果病例是住院病人, 对照也是住院病人. 如果病例是门诊病人, 对照也是门诊病人.

If a control cannot be found, relax age to $\pm$ 10 years.

如果找不到对照,放松年龄 $\pm$ 10 岁.

If only one control can be found, we will keep both the case and the one control.

如果只找到一个对照,我们就保留这个病例及这个对照.

In February 2004, a review of the questionnaire data of the cases and controls was carried out. Two irregularities were noted:

1. Quite a few controls at the Tumor Hospital lived in the same neighborhood (neighbors or relatives).
2. Several controls at No. 6 Hospital were health care workers (nurses or doctors).

The numbers of neighbors or relatives (21, 52%) and health care workers (6, 50%) appeared to be higher than one might have expected if the selection of controls was random. All these "suspect" controls were outpatients with some very minor complaints, such as flu or upset stomach. An investigation of the selection procedures at these two hospitals was made in February and March, 2004.

At the Tumor Hospital it was found that the Clinical Coordinator relied on one certain nurse for control selection. For some outpatient cases, the nurse "recruited" controls among her relatives or neighbors who fulfilled the gender and age matching criteria. Once an appropriate candidate had been identified, she asked the latter to register as an outpatient at the hospital (for a fee of ¥6), thus becoming eligible as a potential control who would be entitled to receive the ¥240 participation fee (equivalent to approximately a department store salesperson's salary for one week).

At No. 6 Hospital, for some cases the Clinical Coordinator simply "recruited" co-workers (nurses and doctors) who met the matching criteria for gender and age. The same economic gain applied.

The selection of controls from non-patients (relatives, neighbors and coworkers) will likely introduce selection bias. For co-workers, this procedure may possibly result in an under-representation of exposure among the controls. For relatives or neighbors, it is difficult to predict whether this selection procedure could bias study results. The primary motivation for this "unorthodox" approach appeared to be the ¥240 participation fee. In addition to the financial incentive, another motivation might be convenience.

Two separate meetings with the Clinical Coordinators at the Tumor Hospital and No. 6 Hospital were held to discuss corrective measures. Given the different setups at each hospital and the number of individuals involved, the only "fool-proof" method is to require all controls to be selected from inpatients. It is highly unlikely that a non-patient will be willing or able to register as an inpatient, if he or she is not actually sick.

Of the 284 total cases in the study as of 20 April 2004, 26 (9%) are outpatients from the Tumor Hospital or No. 6 Hospital. Of these, we believe inappropriate controls were selected for 19 (73%) outpatient cases. Overall, inappropriate controls were selected for 7% of the cases (19/284). Our review did not detect any other irregularities in control selection, although we cannot guarantee that other inappropriate controls (possibly friends or relatives) were not selected for other cases. We do feel confident that this problem will be circumvented through the use of inpatient controls.

While there may be some slight social class differences in outpatients and inpatients, we don't believe that these slight differences will cause a significant bias in the likelihood of occupational exposure. If such a bias is present, we believe it will be much smaller than the potential bias in selecting neighbors, co-workers, friends, or relatives. There is no ground to suspect that outpatients and inpatients differ substantially in any occupational or lifestyle factor. Dr. Ye Xibiao, the Project Coordinator at Fudan University, provided the following comparison between outpatients and inpatients. There are some minor differences in terms of smoking and age. Age is one of the matching variables, and, therefore, will not be an issue. Smoking will be treated as a confounding variable, and all analyses will be adjusted for smoking.

Variables		Types of patients		Total
		Outpatients	Inpatients	
SEX	Male	78 (60.5)	401 (55.6)	479 (56.4)
	Female	51 (39.5)	320 (44.4)	371 (43.6)
MARTIAL STATUS	DNK	0	5 (0.7)	5 (0.6)
	DIVORCED	0	7 (1.0)	7 (0.8)
	MARRIED	111 (86.0)	604 (83.8)	715 (84.1)
	NEVER MARRIED	12 (9.3)	76 (10.5)	88 (10.4)
	WIDOWED	6 (4.7)	29 (4.0)	35 (4.1)
EDUCATION	DNK	1 (0.8)	3 (0.4)	4 (0.5)
	HIGH	37 (28.7)	196 (27.2)	233 (27.4)
	MIDDLE	35 (27.1)	228 (31.6)	263 (30.9)
	NONE	5 (3.9)	53 (7.4)	58 (6.8)
	POSTGRADUATE	3 (2.3)	4 (0.6)	7 (0.8)
	PRIMARY	21 (16.3)	111 (15.4)	132 (15.5)
	UNIVERSITY	27 (20.9)	126 (17.5)	153 (18.0)
SMOKE*	No	72 (55.8)	447 (62.0)	519 (61.1)
	Yes, but not now	16 (12.4)	120 (16.6)	136 (16.0)
	Yes, still smoke	41 (31.8)	154 (21.4)	195 (22.9)
DRINK	DNK	0	5 (0.7)	5 (0.6)
	No	96 (74.4)	544 (75.5)	640 (75.3)
	Yes	33 (25.6)	172 (23.9)	205 (24.1)
CITY	Shanghai	99 (76.7)	586 (81.3)	685 (80.6)
	Out of Shanghai	30 (23.3)	135 (18.7)	165 (19.4)
AGE(yrs)*	18-	24 (18.6)	131 (18.2)	155 (18.2)
	35-	25 (19.4)	88 (12.2)	113 (13.3)
	45-	32 (24.8)	173 (24.0)	205 (24.1)
	55-	28 (21.7)	121 (16.8)	149 (17.5)

65-	20 (15.5)	208 (28.8)	228 (26.8)
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* p<0.05