our specialty after time spent in medicine, surgery, pediatrics, family practice or other specialties.

For many students the resident-matching process begins when there are still several new rotations to be experienced. When I was interviewing potential candidates for pathology at McMaster University, students often told me they really did *not* know what choice to make, since their decisions had to be based on incomplete exposure. I know that some changes are possible at a later stage of the matching process but, as many specialists in pathology or anesthesia can attest, the need for change may become apparent much later. Any educational system should make allowances for this, yet the new system does not. It would be interesting to hear what others think.

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NBSS: opportunity to compromise the process

In 1995 I wrote to Drs. John C. Bailar III and Brian MacMahon, emphasizing to both the need to interview the individuals involved in random allocation in the National Breast Screening Study (NBSS). As the authors point out in their article "Randomization in the Canadian National Breast Screening Study: a review for evidence of subversion" (*Can Med Assoc J* 1997;156:193-9), there was opportunity to compromise the process, since the lists were open and multiple allocation numbers were frequently obtained ahead of time. As a result, lines could be skipped without any need for erasures or alterations. The most direct way to find out whether the process was compromised would be to ask those involved in the allocation and to provide them with anonymity and protection from retribution. This was not done. Consequently, the authors' review adds little to what is already known.

The reviewers confine themselves to evaluating 3 centres. Given that allocations were supposedly random and given the relatively small number of deaths due to cancer at each centre, the problems may not have occurred in the centres where the allocations appeared to be "imbalanced"; they may well have occurred in the centres where the allocations appeared "balanced."

Adding to the already large number of problems with the NBSS was the revelation by Dr. Anthony B. Miller at the recent US National Institutes of Health (NIH) Consensus Development Conference, held in Bethesda, Md., Jan. 21–23, 1997, that the control group was apparently treated differently, in community centres, than the screened group, which was treated in larger centres. The women with cancer in the control group apparently had fewer and less extensive axillary dissections. This adds another imbalance to the NBSS.

In the abstracts printed by the NIH for the conference, Miller wrote that "the number of breast cancer deaths are now 52 in each arm." At the meeting, he stated that this had been a "mistake" and that there were 82 deaths among the screened women and 67 among the controls. An independent review of the linkage and follow-up of deaths due to breast cancer in the NBSS should be undertaken to ascertain whether there are other "mistakes."

Finally, I have been identified as the major critic of the NBSS, although numerous others have written and lectured on the same problems.[1–7] I have been struck, however, by the fact that only a few researchers directly involved with the NBSS have publicly defended the trial. Had I been a radiologist involved in the NBSS, and confident in what had transpired, I would have argued strenuously in support of the methods and results of the trial. I find the absence of such support surprising.

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References

1. Moskowitz M. Author of Canadian breast cancer study retracts warnings [letter]. *J Natl Cancer Inst* 1992;84:1368-71.
2. Yaffe MJ. Correction: Canada study [letter]. *J Natl Cancer Inst* 1993;85:94.
3. Burhenne LJW, Burhenne HJ. The Canadian National Breast Screening Study: a Canadian critique. *Am J Roentgenol* 1993;161:761-3.
4. Sickles EA, Kopans DB. Deficiencies in the analysis of breast cancer screening data. *J Natl Cancer Inst* 1993;85:1621-4.
5. Kopans DB, Feig SA. The Canadian National Breast Screening Study: a critical review. *Am J Roentgenol* 1993;161:755-60.
6. Boyd NF, Jong RA, Yaffe MJ, Tritchler D, Lockwood G, Zylak CJ. A critical appraisal of the Canadian National Breast Cancer Screening Study. *Radiology* 1993;189:661-3.
7. Tarone RE. The excess of patients with advanced breast cancers in young women screened with mammography in the Canadian National Breast Screening Study. *Cancer* 1995;75:997-1003.

[Drs. Miller, Baines and To respond:]

Dr. Kopans persists in raising concerns, most of which have previously been shown to be unwarranted.[1–3]

The recent review of randomization in the NBSS was initiated after Kopans made a charge to the National Cancer Institute of Canada of scientific misconduct by one of us. This serious charge was based on hearsay from a radiographer previously employed at an NBSS centre; the radiographer had begun her employment after randomization had ceased, as Bailar and MacMahon discuss. In spite of assurances of confi-

dentiality, the employee refused to respond to Drs. Bailar and McMahon's request for confirmation of her claim. In the face of unconfirmed hearsay evidence, Bailar and MacMahon chose not to accede to Kopans' demand that they interview NBSS centre coordinators.

Randomization in the NBSS was not "open."[3] Individualized randomization was achieved by a process in general use before distributed computing and electronic mail were available. Instead of telephone operators consulting prearranged lists, we had specially trained administrative staff handle our randomization process. Only they had access to the lists. The screen-examiners did not conduct the process, nor did they have access to the lists.

The NBSS is the only screening study in the world that can completely document balanced randomization in the 2 allocation arms.[4] Three other screening studies have used cluster randomization, which often yields imbalanced distribution of variables between arms. Such imbalance has been reported in the Edinburgh trial.[5]

Two external evaluations of randomization in the NBSS have failed to find evidence of falsification.[6] No other screening study has been subjected to equivalent scrutiny, although questions should have been raised not only by the Edinburgh trial but also by the recently published Gothenburg trial, in which screening did not detect a higher rate of breast cancer than in the control group.[7]

It is not a "revelation" or an "imbalance," as Kopans claims, that women in a usual-care group, in whom breast cancer is mainly detected on clinical grounds, are treated at different institutions than those receiving screening mammography. What may have been a revelation to Kopans was that women with breast cancer in the usual-care group fared no worse than those who had been screened with mammography, although they had lesser degrees of axillary dissection and less extensive histologic examination of resected tissue.

Kopans refers to "mistakes" in the data we submitted for the NIH consensus conference.[8] At the conference, we reported 82 deaths due to breast cancer in the mammography arm and 72 in the usual-care group, not 82 and 67, as Kopans states. What Kopans fails to acknowledge is that at the conference other investigators presented revised figures that superseded the data in their abstract submitted months before. The purpose of all presentations at the conference was to give the most recent data.

The NBSS has revealed clearly what other studies have only hinted at: namely, mammography's failure to demonstrate a prompt and substantial reduction in the mortality rate among younger women who volunteer to be screened.[9] Mammography is an inadequate technology; tumours for which the prognosis is good are detected early, but those for which the prognosis is poor are not detected early enough to benefit the women affected.[10] Radiologists such as Kopans, who rely on good survival from screen-detected case series to establish that a benefit exists,[11] are unhappy because women 40 to 49 years of age with mammographically detected breast cancer in the NBSS achieved a 90% 10-year survival rate, and yet these good survival data do not translate into a reduced rate of death due to breast cancer. Kopans' zeal may be excessive.[12]

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References

1. Miller AB, Baines CJ, Sickles EA. Canadian National Breast Screening Study. *Am J Radiol* 1990;155:1133-4.
2. Miller AB. The breast cancer screening controversy continues [letter]. *Ann Intern Med* 1993;118:748-9.
3. Baines CJ. The Canadian National Breast Screening Study: a perspective on criticisms. *Ann Intern Med* 1994;120:326-34.
4. Miller AB, Baines CJ, To T, Wall C. Canadian National Breast Screening Study: 1. Breast cancer detection and death rates among women age 40 to 49 years [published erratum appears in *Can Med Assoc J* 1993;148:718]. *Can Med Assoc J* 1992;147:1459-76.
5. Alexander FA, Roberts MM, Lotz W, Hepburn W. Randomization by cluster and the problem of social class bias. *J Epidemiol Community Health* 1989;43:2-36.
6. Cohen MA, Kaufert PA, MacWilliam L, Tate RB. Using an alternative data source to examine randomization in the Canadian National Breast Screening Study. *J Clin Epidemiol* 196;49:1039-44.
7. Bjurstam N, Björnheld L, Duffy SW. The Gothenburg Breast Screening Trial: results from 11 years' follow up. *Monogr Natl Cancer Inst*. In press.
8. Miller AB, To T, Baines CJ, Wall C. The Canadian National Breast Screening Study — update on breast cancer mortality. *Monogr Natl Cancer Inst*. In press.
9. Kerlikowske K. Efficacy of screening mammography among women aged 40 to 49 years and 50 to 69 years. *Monogr Natl Cancer Inst*. In press.
10. Miller AB. Screening for cancer: Is it time for a paradigm shift? *Ann R Coll Physicians Surg Can* 1994;27:353-5.
11. Stacey-Clear A, McCarthy KA, Hall DA, Pile-Spellman E, White G, Hulka C, et al. Breast cancer survival among women under age 50: Is mammography detrimental? *Lancet* 1992;340:991-4.
12. Taubes G. How one radiologist turns up the heat. *Science* 1997;2275:1057.

NBSS: changes were made, suspicious changes were not

In the editorial "The review of randomization in the Canadian National Breast Screening Study: Is the debate over?" (*Can Med Assoc J* 1997;156:207-9), Dr. Norman F. Boyd writes, "The absence of name alterations had previously been cited by the NBSS investigators as evidence that randomization had not been subverted." He cites 2 articles from the National Breast Screening Study (NBSS). In the context of a review that has documented several in-