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 What Kopans fails to acknowledge is that at the conference other investigators presented revised figures that superseded the data in their abstract submitted months before.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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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-

stances of name alterations (the majority explicable), his statement, if true, would reflect poorly on NBSS investigators. In fact, Boyd appears to have misunderstood information from the references and, in the process, undermined the credibility of NBSS investigators.

NBSS investigators have never reported that name alterations did not occur among the entries for the 90 000 NBSS participants; alterations clearly did occur. We have reported that no suspicious changes in the random allocation sheets had been identified in the participants who died of breast cancer.

The external review found that, of 97 unexplained alterations on lines allocating women to mammography, only 1 was associated with a woman who died of breast cancer, and breast cancer had not been diagnosed at the first screen in this case. This alteration was either overlooked by us or detectable only by forensic experts.

Since most readers have neither the interest nor the time to check the references cited, I offer citations from the articles for comparison with Boyd's interpretation of what we reported.

"The original randomization sheets were carefully rechecked, specifically in relation to women who died; no evidence of any falsification, erasure or other changes was found."[1]

"The original randomization sheets were re-examined to look for changes in script or pens used, crossing out of names, erasures, or problems with date sequences with special attention given to the records of those who had died of breast cancer. No suspicious entries were found."[2]

It is important to note the use of the words "rechecked" and "re-examined." All NBSS randomization sheets were routinely and carefully examined each month at the national coordinating centre during the recruitment period.[1,2]

It is unrealistic to expect that written entries could be made for 90 000 participants without errors requiring correction. The issue is not whether changes were made but whether suspicious changes were made. Suspicion, like beauty, is in the eye of the beholder. Those who are suspicious should demand equal scrutiny of random allocation procedures in all screening trials.

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[The author responds:]

To my eye and, I suspect, to anyone else's, the first quotation cited by Dr. Baines clearly states that no erasures were found. The article she cites concerns women 40 to 49 years of age; it is in this group that Bailar and McMahon found erasures. Whether the absence of "suspicious erasures" claimed in the article concerning women 50 to 59 years of age would be confirmed by a similar examination, we do not know.

The need for any erasures in the randomization lists is far from clear. Although, as Baines states, the NBSS did enrol a large number of women, names were entered on randomization lists only after the completion of several procedures. Why, after a woman has completed 2 questionnaires, undergone a breast examination and signed a consent form, there should be any remaining doubt about her name, is something that I do not understand.

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Thrombolytic therapy: time to treatment

To conclude that the time to thrombolytic therapy for patients with an acute myocardial infarction (AMI) was slower in Canada than in other countries was correct at the time of the GUSTO-I trial; but to state that door-to-needle time is unacceptably long in Canadian hospitals now is untrue and discredits the advances achieved by those in emergency medicine in this country ("Time to treatment with thrombolytic therapy: determinants and effect on short-term nonfatal outcomes of acute myocardial infarction" *Can Med Assoc J* 1997;156:497-505, by Dr. Jafna L. Cox and colleagues).

The GUSTO-I trial compared the effects of 4 thrombolytic strategies on mortality.[1] After subsequent analysis of this data, the researchers claimed, in 1994, that the choice of thrombolytic therapy was less important to survival than time to treatment.[2,3] The GUSTO-I data are old (1990 to 1993), and the study is representative of a different era when the administration of thrombolytics was under the guidance and control of internists or cardiologists.

Since then, the responsibility for the immediate assessment and treatment of patients with an AMI in the emergency department has essentially been assumed by emergency physicians; across Canada, they have achieved great reductions in the time to thrombolysis.