



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 writ-

ten 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 McMahan 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.



In 1993, long before the recommendation by the Emergency Cardiac Care Coalition that emergency physicians treat patients with a clear diagnosis of AMI within 30 minutes,⁴ we designed a quality-improvement project to decrease door-to-needle time. We decreased the median elapsed time from admission to thrombolysis for all patients with an AMI from 62 to 40 minutes.⁵

Since then, emergency physicians across this country have achieved spectacular improvements. Centenary Health Centre in Scarborough, Ont., has reduced times to 29 minutes,⁶ and the average time at the Hamilton Civic Hospitals is 21 minutes, according to information from those hospitals. Concern is now voiced that further reductions may be achieved only with a rising cost of physician error and patient complications.

The picture of thrombolytic treatment represented in the article by Cox and colleagues no longer exists. Are Canadian physicians up to the challenge? Yes. This question has been clearly answered both in emergency medicine literature, and in practice in emergency departments across this country.

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[Three of the authors respond:]

Dr. Markel highlights some of the advances that have been made in emergency departments across Canada to achieve more rapid administration of thrombolytic drugs to patients with an AMI.

Our article addressed the issue of treatment times within the context of the GUSTO-I study. We did not state that door-to-needle times remained uniformly and unacceptably long "now," nor did we "discredit" the advances achieved by some Canadian emergency medicine practitioners. On the contrary, we specifically stated, "Since GUSTO-I was completed, many hospitals in Canada have embarked on quality improvement programs that include attention to prompt use of thrombolytic therapy."

We would like to share Markel's belief that further progress on this front is neither possible nor necessary, and we could add to his list of positive examples. But the hospitals that are measuring, improving and reporting their door-to-needle times are unlikely to be those where delays are occurring. We accordingly urge continuing surveillance by all centres to ensure that this area of practice is optimized.

We agree with Markel that it is important to administer these drugs in the emergency department, and that waiting for an internist or cardiologist to review the case contributes to delays. However, the data show that median door-to-needle times in GUSTO-I were longer than ideal for

all participating countries. We have no evidence that administration of thrombolytic agents from 1990 to 1993 was any more "under the guidance and control" of specialists in Canada than in other participating countries.

Our study reaffirmed the troubling findings of others that subgroups of patients, including elderly patients, tend to be relatively more affected. It remains incumbent on all of us who manage patients with AMI to ensure that any improvements in the process of care are applied to all eligible patients.

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Facing breast cancer far from radiation therapy centres

We read with interest the article "Patterns of initial management of node-negative breast cancer in two Canadian provinces" (*Can Med Assoc J* 1997;156:25-35), by Dr. Vivek Goel and associates, and the accompanying editorial "A surgical subculture: the use of mastectomy to treat breast cancer" (*Can Med Assoc J* 1997; 156:43-45), by Dr. Adalei Starreveld. We would like to provide a different perspective, as surgeons in a community where facilities for radiation therapy are not readily accessible to patients with breast cancer. Our point