Unacceptable mammographic image quality in the early 1980s in Canada must not influence our decision about early detection in 2014.

The attention given by the media to the "update" of the failed Canadian trials and their unjustified conclusion that early detection of breast cancer does not reduce mortality from the disease is surprising, especially after the publication of the Independent UK Panel on Breast Cancer Screening which concluded in a meta-analysis of 11 randomised trials, that "the relative risk of breast cancer mortality for women invited to screening compared with controls was 0·80 (95% CI 0·73–0·89), which is a relative risk reduction of 20%" (1). The two Canadian trials are the conspicuous outliers with no mortality decrease accomplished. It appears that Drs. Miller and Baines hope to defend the poorly designed and poorly executed CNBSS trials by any and all means available in their BMJ article and written responses. Dr. Baines' failure to remember my comments from 1984 on their serious quality assurance problems speaks for itself. Dr. Miller made no response to his co-worker Dr. Boyd's prophetic statement, "…the results of these trials should not be used to change the prevailing scientific view of the potential benefits of screening with mammography" (2).

Professor Day and colleagues pointed out in 1989 in their landmark publication on monitoring breast cancer screening programs (3) that a reduction in breast cancer mortality can occur only after a significant decrease in advanced cancers. Since the CNBSS trials are the only ones which failed to reduce the rate of advanced breast cancers, what lesson should we learn from such a colossal failure? Obviously, their screening method was not effective in finding the potentially fatal cancers, no matter how many cancers were reported. Day and colleagues wrote the following: "Table III summarises a minimum set of measures that an information system should monitor to evaluate the effectiveness of the programme in reducing severity of and mortality from the disease. A favourable value for each of these measures is necessary, however, if an acceptable effect on breast cancer mortality is to be achieved. Poor performance indicates where remedial action is required" (3).

The authors of the CNBSS, being unwilling to acknowledge and search for the reasons for the failure of their own trials, resort instead to attacking individuals who pointed out the reasons for this failure. Their attack on the Two-County Swedish Trial, using misleading allegations and outright falsehoods, is equally inappropriate and does not bring us any closer to finding out why the Canadian trials are unique among all the randomized controlled trials in their failure to reduce breast cancer mortality. Doctors Miller and Baines have been repeatedly informed both in writing and in person about the important details of the Swedish Two-County (W-E) Trial, so the ignorance they show in their published article and their responses is indeed astonishing.

To set the record straight and inform the reader:

- The Two-County Swedish Trial was designed and run by the Swedish National Board of Health and Welfare with Professor Gunnar Eklund as the Principal Investigator. It has never been my trial, contrary to Dr. Baines' allegation; Dr. Gunnar Fagerberg was the project leader for the E-county arm and I was the project leader for the W-county arm, as has been repeatedly mentioned in the publications from the trial.

- Drs. Miller and Baines insinuate that there was no informed consent in the Two-County Swedish trial, since "the controls were only contacted after screening ceased in the active study population". On the contrary, the National Board of Health and Welfare saw to it that the entire population of the two counties was extremely and repeatedly well informed by the media and by activities at all levels of the local governmental agencies. The execution of the randomization process was carried out by the local politicians according to the instructions and under the supervision of Professor Gunnar Eklund.
- It is surprising that Professor Miller, an epidemiologist, stated in this BMJ article that the randomization in the Swedish trial took place on "county level", when a Swedish county corresponds to a province in Canada or a state in the USA. It has been repeatedly published that the individual randomization units were small communities and taxation districts with equivalent socio-economic status.
- We have pointed out that the average tumor size in the control group of the Two-County Trial was not 28 mm but 22 mm. What could be the reason for all these embarrassing errors?
- Dr. Baines notes that the Canadian trials used two-view mammography at 12 months intervals whereas the Two-County trial used one-view mammography at 33 months interval. This only emphasizes the remarkable difference in the performance of early detection between the two studies, since the Swedish trial reduced both the advanced cancer rate and mortality from breast cancer, while the Canadian trials failed on both counts.
- Dr. Baines correctly mentions that "an external audit of mammography based on stratified sampling" took place in the Canadian trials, but she still cannot grasp the impact of the unacceptable quality found by these external audits, my own included. Not being radiologists, neither Miller nor Baines appear to understand that poor quality mammography means poor quality detection of the potentially fatal cancers
- Dr. Baines' comment concerning "Trial A [Canadian] has an external death review panel to determine cause of death in all cases of deaths in participants known to have breast cancer during the trial or suspected of having breast cancer after linkage with a national data base. Not so for Trial B" [Swedish]. This is an outright falsehood because so far there have been two external death review panels of the Swedish Two-County Trial, reviewing every breast cancer patient's chart combined with the linkage to the National Death Registry (4,5). The individual patient charts of all breast cancer cases are still preserved in the county archives and the data are currently under a third external review directed by Professor Richard Peto at the University of Oxford, UK. On the other hand, Dr. Miller sent me an e-mail on Aug 28, 2012, in which he declared that "it was impossible to maintain all the paper records in storage, and it would be impossible to re-conduct a death review for the CNBSS". Imagine my surprise at the publication of this "Twenty five year follow-up" without a new death review (contrary to Dr. Baines' above claim) and long after destroying the original documents from the CNBSS trials.

In summary: women, the medical profession and public health decision makers should rest assured that the successful early detection of breast cancer and treatment in an early stage significantly improve the outcome and life quality of women afflicted by this disease. There is ample evidence that the modern therapeutic regimens are most effective against non-palpable, screen detected, early stage breast

cancer. Instead of attempting to “prove” that early detection makes no difference to the outcome of breast cancer patients, our concerted efforts should use the evidence from well conducted randomized controlled trials (1) to provide even earlier diagnosis and better treatment to achieve further improvements in the outcome of breast cancer.

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