According to the American College of Radiology and Society of Breast Imaging, the recent breast cancer screening article (Miller et al) published in the *British Medical Journal (BMJ)* (1) is an incredibly misleading analysis based on the deeply flawed and widely discredited Canadian National Breast Screening Study (CNBSS). The results of this *BMJ* study, and others resulting from the CNBSS trial, should not be used to create breast cancer screening policy as this would place a great many women at increased risk of dying unnecessarily from breast cancer.

Experts called on to review the CNBSS confirmed that the mammography quality was poor (2). The trial used second hand mammography machines, which were not state of the art at the time of the trial. The images were compromised by “scatter,” which makes the images cloudy and cancers harder to see since they did not employ grids for much of the trial. Grids remove the scatter and make it easier to see cancers. Also, technologists were not taught proper positioning. As such, many women were not properly positioned in the machines, resulting in missed cancers. And the CNBSS radiologists had no specific training in mammographic interpretation. The CNBSS own reference physicist stated that “...in my work as reference physicist to the NBSS, [I] identified many concerns regarding the quality of mammography carried out in some of the NBSS screening centers. That quality [in the NBSS] was far below state of the art, even for that time (early 1980s).”(3)

In this latest *BMJ* paper, only 32 percent of cancers were detected by mammography alone. This extremely low number is consistent with poor quality mammography. At least two-thirds of the cancers should be detected by mammography alone (4). In an accompanying *BMJ* editorial, Kalager and Adami admit that “The lack of mortality benefit is also biologically plausible because the mean tumour size was 19mm in the screening group and 21mm in the control group... a 2mm difference.” The documented poor quality of the NBSS mammography screening alone explains these results and should disqualify the CNBSS as a valid scientific study of modern mammography screening. Yet, the CNBSS trial was even more troubled (5).

To be valid, randomized, controlled trials (RCT) must employ a system to ensure that the assignment of women to the screening group or the unscreened control group is random. Nothing can should be known about participants until they have been assigned to one of these groups. The CNBSS violated these fundamental rules (6). Every woman first had a clinical breast examination by a trained nurse so that they knew which women had breast lumps, many of which were cancers, and which women had large lymph nodes in their armpits many of which indicated advanced cancer. Before assigning the women to be in the group offered screening or the control women, investigators knew who had large incurable cancers. This was a major violation of RCT protocol. It most likely resulted in the statistically significant excess of women with advanced breast cancers assigned to the screening arm compared to those assigned to the control arm (7). This guaranteed more deaths among the screened women than the control women.

The five year survival from breast cancer among women ages 40–49 in Canada in the 1980s was only 75 percent, yet the control women in the CNBSS, who were supposed to reflect the Canadian population at the time, had a greater than 90 percent five year survival (8). This indicates that cancers may have been shifted from the control arm to the screening arm. Coupling the fundamentally corrupted allocation process with the documented poor quality of the mammography should have long ago disqualified the CNBSS as a legitimate trial of modern screening mammography.

References:

5. Kalager M, Adami HA. *BMJ* 2014;348:g1403 doi: 10.1136/bmj.g1403