

Skewed research results led to lack of access to mammography for women in their 40s, say researchers

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Thousands of Canadian women may have died needlessly of breast cancer because of the fallout from two flawed studies on breast screening, according to a group of prominent researchers.

In a commentary published today in the *Journal of Medical Screening*, the researchers say they have new evidence that the Canadian National Breast Screening trials carried out in the 1980s were not randomized properly so the results were skewed. They are asking for policies made based on those results to be changed.

"It's so damaging because those results continue to influence recommendations about that age group to this day," said co-author Shushiela Appavoo, associate clinical professor in U of A's Faculty of Medicine & Dentistry.

"Evidence reviews that included the Canadian National Breast Screening results should be revised to exclude these studies and the studies should be retracted from the literature," said Appavoo, who is past chair of the Canadian Association of Radiologists' breast imaging working group, a founding member of the Canadian Society of Breast Imaging and a partner radiologist with MIC Medical Imaging in Edmonton.

The Canadian studies were the only such trials carried out around the world to find no benefit from screening for the 40-49 year old age group, Appavoo said. Though questions were raised almost immediately about the validity of the results, they continue to be referred to by policy makers in Canada and elsewhere.

In their commentary, the researchers from Sunnybrook Research Institute in Toronto, The Ottawa Hospital, the University of British Columbia, the University of Alberta and Harvard Medical School say they now have eyewitness testimonials from former study employees about errors made in randomizing participants.

"The bottom line for Canadian women is that this study suppressed screening, especially for women 40-49, for decades and likely indirectly resulted in a lot of lives lost," the authors concluded. "The study's influence on policy has had a substantial impact on [breast cancer](#) outcomes in Canada and may have contributed to the avoidable deaths of over 400 Canadian women each year."

Flawed by design

Two major flaws were built into the study when it was designed, Appavoo said. First, patients were given a physical exam by expert nurses before being placed into supposedly randomized groups for either mammography or no screening. In fact, because access to mammography outside of the trial was limited, the staff put more symptomatic women with lumps or pain into the mammography group than in the control group.

"The study design put these coordinators into a very difficult position," she said. "They would examine a patient and feel a lump on their [breast](#) or under their arm and then be forced to decide whether to put her into a screening or non-screening limb of the study."

Secondly, surgeons' offices sometimes called the study staff to ask for symptomatic women to be added to the mammography group, again because there was little access through other channels, Appavoo said.

"That's why the study results showed you had more of a risk of dying if you had been screened than if you hadn't been screened," Appavoo said.

As a result, the Canadian Task Force on Preventive Health Care recommends routine mammography starting at age 50. In Alberta, only 20 percent of women in their 40s get screened, Appavoo said, and they have to ask their doctor for a requisition to get the test.

"Because the Canadian guidelines recommend not screening until 50, a lot of women are denied that requisition," she said.

Rebuilding trust

Appavoo said a new, better-designed study is unlikely to ever be carried out in Canada, partly because of the expense and partly because it would be unethical to deny screening to half the women. Most international experts now recommend starting regular screening at age 40 or 45.

"We now know without a doubt that mammography saves lives," Appavoo said.

While there can be downsides to [screening](#), such as anxiety over false alarms, Appavoo recommends that [women](#) 40 to 49 get a mammogram every year.

"There have been a couple of studies that showed that in that age group, the risk of a missed late-stage cancer is about 25 percent higher if you screen biennially instead of annually."

Rather than shaking her faith in science, Appavoo said this is an opportunity to demonstrate that mistakes are part of developing scientific knowledge.

"My trust in the process will be renewed if this information is acted on," she said. "Science is fraught with foibles because we're human and it's natural to stumble. The important thing is to correct where we have made mistakes."

More information: Martin J Yaffe et al, The randomized trial of mammography screening that was not—A cautionary tale, *Journal of Medical Screening* (2021). [DOI: 10.1177/09691413211059461](https://doi.org/10.1177/09691413211059461)

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