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HEALTH

New research questions key study, breast-screening guidelines

ELIZABETH PAYNE POSTMEDIA NEWS

niversity of Ottawa law professor Jennifer Quaid had just turned 50 in late 2019 when she discovered what appeared to be a lump in her breast.

It would take months for her to get a diagnosis, in part because of the impact of the COVID-19 pandemic on the health system.

When she did, her busy life came to a screeching halt.

Doctors found nine tumours in one breast and cancer in most of her lymph nodes on the same side and diagnosed her with stage 3 breast cancer. Quaid underwent a radical mastectomy of her left breast and removal of all of her lymph nodes in one arm. That was followed by aggressive treatment that would consume most of a year of her life and leave physical after-effects.

"It was very shocking. I spent 24 hours in total shell shock," she says of the diagnosis.

What is also shocking to Dr. Jean Seely, the head of breast imaging at The Ottawa Hospital, is that, like many Canadian women, Quaid had never undergone a routine mammogram before the age of 50, even though she had asked for one.

When she was in her 40s, based on an extended family history of breast cancer and nagging concerns, Quaid asked her family doctor about getting a mammogram. She was told she didn't qualify under the rules in Ontario.

Those rules are partly based on a Canadian study — the Canadian National Breast Screening Study — that has influenced breast-screening guidelines in Canada and around the world for decades. New research, co-authored by Seely and researchers from the Sunnybrook Research Institute in Toronto, the University of British Columbia, the University of Alberta and Harvard Medical School, calls that Canadian study into question.

Their commentary in the Journal of Medical Screening uses eyewitness accounts to argue that the study was Jennifer Quaid is an Ottawa law professor who was diag-nosed with Stage 3 breast cancer just after she turned 50. She had asked for a mammogram earlier, but was told she didn't qualify. POSTMEDIA News

flawed.

"What we have shown is the last straw regarding the credibility of this study," said lead author Dr. Martin Yaffe.

Yaffe, a leading breast cancer and imaging scientist from the Sunnybrook Research Institute, said 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 more than 400 women each year.

The authors are calling for women in their 40s to be offered mammograms, something being done in Nova Scotia and British Columbia.

A more recent Canadian study found that mammography screening on women in their 40s is associated with a 44 per cent reduction in breast cancer

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deaths.

"Screening saves lives," said Seely.

Still, the Canadian National Breast Screening Study — a large, randomized control study — has long been considered the gold standard and continues to influence policy.

Dr. Anthony Miller, emeritus professor at the Dalla Lana School of Public Health at the University of Toronto, recently told CBC News that extensive quality control maintained the study's integrity. He denied there was any problem with randomization in the study.

"We had a great deal of understanding of what could go wrong with randomization and we took a great deal of care to ensure it didn't apply in the National Breast Screening Study," he told CBC News. He did not immediately respond to requests for an interview from Postmedia News.

The new commentary touches on a longbrewing controversy in the world of breast cancer screening in Canada and elsewhere — whether routine mammograms are beneficial starting at age 40.

To Quaid, it is a no-brainer. She is a living example of that, she says.

"My case is an illustration of pretty much the worst outcome," said Quaid. "Thank goodness I didn't have Stage 4, but I lost a year of my life." Screening in her 40s, she said, could have caught the cancer much sooner.

In most provinces, routine mammograms are not offered to women until they turn 50. The Canadian Task Force on Preventative Healthcare, which issues guidance on screening and other preventative measures, does not recommend a routine mammogram for women between the ages of 40 to 49 except under certain circumstances, including a genetic predisposition or a direct relative who had breast cancer. Screening can lead to unnecessary harm, the task force says.

It bases its guidance, in part, on The Canadian National Breast Screening Study. Conducted in the 1980s, the initial study found that routine mammograms did not reduce deaths in women between the ages of 40 and 49. A second study came up with similar findings involving women from 50-59.

They are the only studies among eight performed in different countries that did not show a reduction in deaths resulting from mammography screening.

That research has been criticized, in part, because there was a big imbalance in the number of women with advanced cancers in the two arms of the trial, which shouldn't have been the case if the women were truly selected randomly, notes Seely. Those in one arm of the trial received yearly mammograms while the others did not.

Critics have long suspected the study was skewed, which would affect its findings, but they didn't have first-hand evidence.

New eyewitness accounts suggest women were physically examined before it was decided which arm of the trial they would be put into and that some women with signs of breast cancer were purposely placed in the arm that would get mammograms, skewing the study's results.

Seely said there are suggestions the ac-

tions at one or two of the trial sites might have been motivated by compassion — with an attempt to make sure women showing signs of breast cancer got mammograms at a time when they were not easily accessible — but the long-term impact has harmed many women since.

The research group's commentary included new evidence from whistleblowers

One of those whistleblowers, Susan Kinghorn, a medical radiation technologist, was newly graduated in 1985 when she was hired on a three-month contract to work at the St. Michael's Hospital site of the national screening study in Toronto

From the beginning, she said, she saw things that did not seem right — including patients being switched into the mammogram arm of the study after a physical exam had found an anomaly in their breasts. When she questioned why this was happening in what should have been a randomized trial, she said she was told it was decided they had to go into the mammography arm of the study after the physical exam. She said she was told not to question things, but the questions stayed with her. She said she has brought it up many times over the years.

"It has always been a peeve of mine that this study received so much recognition around the world and was flawed."

Earlier this year, she raised her concerns at a conference, saying what she saw led her to believe there were flaws in the study.

"It has always been my hope that this study would never have the recognition



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it has received and that it would be debunked," she said.

Others who have come forward saw similar things when they were involved with the study.

"There is compelling evidence of subversion of randomization in the Canadian National Breast Screening Study," wrote the authors of the Journal of Medical Screening commentary. "Misrandomization" of even a few women could markedly affect measured screening efficacy in the results.

Seely said she hopes the evidence in the paper "will empower governments to do the right thing and screen women in their 40s."

