

Contact:

Diane M Dragaud, MA
Director of Communications
ddragaud@ecog-acrin.org
215.789.3631

Full Explanation Reduces Seniors' Worries about Lung Cancer Screening

Researchers at the ECOG-ACRIN Cancer Research Group say comprehensive informed consent is likely the key to preventing undue anxiety over lung screenings.

Philadelphia, Pa., July 25, 2014 — A new study of participants in the National Lung Screening Trial (NLST), the results of which are published today in *Cancer*, found evidence that men and women between the ages of 55 and 74 who had an abnormal finding on a lung cancer screening test did not experience more anxiety or reduced quality of life than did those who were screened and found to be cancer-free.



This result came as a surprise to the researchers. “We expected that participants with an abnormal finding would be more worried and uneasy about that finding,” said lead study author [Ilana F. Gareen, Ph.D.](#), assistant professor of epidemiology research at the Brown University Center for Statistical Sciences, Providence, R.I. “Instead we found that people had anxiety levels and quality of life that were similar, whether their screening test found something suspicious or nothing at all.”

Gareen and her colleagues hypothesize that the thorough consent process used in the NLST helped mitigate potential increases in anxiety and/or declines in health-related quality of life. The consent form for the NLST was vetted by patients and clinicians and aimed to fully inform trial participants ahead of time that the screening test they were about to undergo frequently shows abnormal findings (called positive results) that may later be deemed negative/not cancer, after further testing. “In advance of the screening, participants were advised that 20 to 50 percent of those screened would receive false positive results, and that the participants might require additional work-up to confirm that they were cancer free,” said Gareen.

The study, *Impact of Lung Cancer Screening Results on Participant Health-Related Quality of Life and State Anxiety in the National Lung Screening Trial*, is available online at <http://onlinelibrary.wiley.com/doi/10.1002/cncr.28833/pdf>. It was conducted through the American College of Radiology Imaging Network (ACRIN), now part of the ECOG-ACRIN Cancer Research Group, with funding from the National Cancer Institute (NCI).

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"At the introduction of agreeing to participate in the NLST, I was fully aware of the potential ramifications of whatever potential medical results that might be given to me as an outcome of the screening, knowing full well that tests do come back with false-positives at times," said participant Kit Spikings. "This truly did not play a factor or have any negative connotation for me to second-guess if I truly wanted to partake in the NLST. I believe I was more concerned with the final results of the NLST, and the chance to take part in a study so important and so vital to every human being who smokes."

The [U.S. Preventative Services Task Force recently recommended low-dose CT screening every year](#) for people between 55 and 80 years old who are at high risk for lung cancer because they are currently heavy smokers or have quit within the past 15 years. The recommendation is based, in large part, on the central finding of the NLST, [published in the New England Journal of Medicine \(2011\)](#), that low-dose computerized tomography (CT) is associated with a 20 percent reduction in lung cancer mortality compared to chest x-ray (CXR).

However, a major barrier to the adoption of low-dose CT screening is the concern that the high rate of false positive findings may cause undue worry, dread and fear among people. "False positive" is a term used by physicians to describe a screening test in which findings initially indicating concern for cancer are later found not to be cancer.



"These results are very gratifying, given that one of the concerns with CT screening is patient anxiety. It also reinforces that fact that communication between the health care provider and patient is critical for both informed decision-making and understanding the implications of test results," said NLST lead investigator [Denise R. Aberle, MD](#), professor of radiology and bioengineering vice chair, research, at the University of California, Los Angeles, as well as deputy chair of ECOG-ACRIN's Imaging Sciences.

Green and co-authors mailed questionnaires to a subset of NLST participants at 16 facilities that perform lung screening. Psychological effects of screening were assessed at the Brown University's Center for Statistical Sciences through the use of two measurement tools, one evaluating anxiety and the other assessing health related quality of life, sent in the mail one month after screening and again at six months.

About the NLST Consent Form

Currently, there is no standard consent form used in lung cancer screening. Facilities that perform lung screening may explain the procedure to patients using whatever consent form they choose. There is no standard information provided to patients regarding false positive results. The consent form used in the NLST is part of an accompanying [fact sheet](#) that is available online at ecog-acrin.org.

Other Findings

The study also found that there were no changes in the levels of anxiety or quality of life at one month or six months after screening for participants having an abnormal finding. "We

measured at one month and six months because we expected that there would be greater anxiety and reduced quality of life initially, and that these feelings would subside over time,” said Gareen. Additionally, the results were no different whether participants received low-dose CT or CXR.

About ECOG-ACRIN

The ECOG-ACRIN Cancer Research Group is a multidisciplinary, membership-based scientific organization that designs and conducts biomarker-driven cancer research involving adults who have or are at risk of developing cancer. The Group was formed in May 2012 by a merger that combined the complementary strengths of the Eastern Cooperative Oncology Group (ECOG) in cancer therapy and the American College of Radiology Imaging Network (ACRIN) in cancer imaging. ECOG and ACRIN were two highly respected NCI-sponsored cancer cooperative groups. ECOG-ACRIN comprises nearly 650 member institutions in the United States and around the world. Approximately 6,000 physicians, translational scientists and associated research professionals from the member institutions are involved in Group research, which is organized into three scientific programs: [Cancer Control and Outcomes](#), [Therapeutic Studies](#) and [Biomarker Sciences](#). ECOG-ACRIN is supported primarily through NCI research grant funding, but also receives funding from private sector organizations through philanthropy and collaborations. It is headquartered in Philadelphia, Pa., as is PrECOG LLC, a not-for-profit company that partners with ECOG-ACRIN and industry to develop and conduct clinical trials in all areas of oncology. For more information, visit www.ecog-acrin.org or call 215.789.3631.

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