

# Informed consent: False positives not a worry in lung cancer study

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The U.S. Preventive Services Task Force recently recommended computerized tomography (CT) lung screening for people at high risk for cancer, but a potential problem with CT is that many patients will have positive results on the screening test, only to be deemed cancer-free on further testing. Many policymakers have expressed concern that this high false-positive rate will cause patients to become needlessly upset. A new study of National Lung Screening Trial participant responses to false positive diagnoses, however, finds that those who received false positive screening results did not report increased anxiety or lower quality of life compared with participants who received negative screen results.

"Most people anticipated that participants who were told that they had a positive screen result would experience increased anxiety and reduced quality of life. However, we did not find this to be the case," said Ilana Gareen, assistant professor (research) of epidemiology in the Brown University School of Public Health and lead author of the study published in the journal *Cancer*.

The NLST's central finding, announced in 2010, was that screening with helical CT scans reduced lung cancer deaths by 20 percent compared to screening with chest X-rays. The huge trial spanned more than a decade, enrolling more than 53,000 smokers at 33 sites.

In the new study, Gareen and co-authors, including Brown faculty and staff members Fenghei Duan, Constantine Gatsonis, Erin Greco, and

Bradley Snyder, followed up with a subset of participants at 16 sites to assess the psychological effects of the CT and X-ray screenings compared in the trial.

"In the context of our study, with the consent process that we used, we found no increased anxiety or decreased quality of life at one or six months after screening for participants having a false positive," Gareen said. "What we expected was that there would be increased anxiety and decreased quality of life at one month and that these symptoms would subside by six months, which is why we measured at both time points, but we didn't find any changes at either time point."

The unexpected similarity between the participants with a negative and a false positive screen result is not because getting a false positive diagnosis is at all pleasant, Gareen said, but presumably because study participants understood that there was a high likelihood of a false positive screen result.

"We think that the staff at each of the NLST sites did a very good job of providing informed consent to our participants," she said. "In advance of any 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."

## **Reassuring results**

To make its assessments, Gareen's team surveyed 2,812 NLST participants for the study. Patients responded well, with 2,317 returning the survey at one month after screening and 1,990 returning the survey at six months. The survey included two standardized questionnaires: the 36-question Short Form SF-36, which elicits self-reports of general physical and mental health quality, and the 20-question Spielberger State Trait Anxiety Inventory.

Maryann Duggan and her staff from the Outcomes and Economics Assessment Unit at Brown administered the questionnaires by mail with telephone follow-up as required.

In the study analysis, the researchers divided people into groups based on their ultimate accurate diagnoses: 1,024 participants were "false positive," 63 were "true positive," 1,381 were "true negative" and 344 had a "significant incidental finding," meaning they didn't have cancer but instead had another possible problem of medical importance.

The results were clear after statistical adjustment for factors that could have had a confounding influence. Whether participants received X-rays or the helical CT scans, the questionnaire scores of those with false positive diagnoses remained similar to those who were given true negative diagnoses.

Meanwhile, the scores of the true positive participants who were diagnosed with lung cancer markedly worsened over time as their battle with the disease took a physical and psychological toll.

Because participants received the questionnaires at one and six months, it is possible that study participants receiving a false positive screen result experienced anxiety and reduced quality of life for a short time after receiving their screen result, Gareen said. But by one month after their screening, there was no evidence of a difference between the screen result groups.

Gareen said the results should encourage physicians to recommend appropriate screenings, despite their high false positive rates, so long as patients are properly informed of the likelihood of a positive screen result and its implications. The data provide evidence that the NLST consent process provided a good model for advising those undergoing [screening](#), she said.

Provided by Brown University

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