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### **About the National Lung Screening Trial**

The National Lung Screening Trial (NLST) is the largest trial of lung computed tomography (CT) screening to date. The central finding of the NLST, which was published in the New England Journal of Medicine (2011), was that screening with low-dose CT reduced lung cancer deaths by 20 percent compared to screening with chest x-ray (CXR). This huge trial spanned more than a decade, randomly assigning more than 53,000 men and women at high risk of developing lung cancer to receive either three annual low-dose CT scans or CXRs at 1 of 33 medical centers in the United States. Eligible participants were between 55 and 74 years of age at the time of randomization, had a history of cigarette smoking of at least 30 pack-years, and, if former smokers, had quit within the previous 15 years. Study participants were followed for up to five years. The study was conducted by the American College of Radiology Imaging Network (ACRIN), now part of the ECOG-ACRIN Cancer Research Group, and the Lung Screening Study Group of the National Cancer Institute, part of the National Institutes of Health.

### **About the Health-Related Quality of Life and State Anxiety Survey Method**

The study, Impact of Lung Cancer Screening Results on Participant Health-Related Quality of Life and State Anxiety in the National Lung Screening Trial, was part of the original NLST protocol. To make their assessments, researchers surveyed 2,812 NLST participants for the study. In the study analysis, the researchers divided people into groups based on their ultimate accurate diagnosis: 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 medical problem. The patient response rate was uniformly high, with 2,317 returning the questionnaire 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.

### **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 significance of using a comprehensive consent process is bolstered by comparison with the consent process used in the Pittsburgh Lung Screening Study (PLuSS), which advised participants of a potential false positive rate of only 25 percent rather than as much as 50 percent as described to patients in the NLST. Conversely, PLuSS *did* find an increase in anxiety among participants with a false positive result compared to those who received negative results. Additionally, in a separate qualitative study of lung-cancer perceived risk, the NLST participants reported that they understood that they had a high likelihood of false positive findings because they had been told this during the consent process.

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.

### **Excerpt from the NLST Consent Form that Explains Risks**

While on the study, you are at risk of the following side effects. You should discuss these with the study investigator and/or your regular doctor. Risks and side effects related to screening for lung cancer include the following:

#### Very Likely

- Radiation dose from a screening spiral CT (100-300 mrem), which is less than or equal to the average annual dose from natural sources of radiation (300 mrem).
- Radiation dose from screening chest x-ray (8-12 mrem), which is much less than the average annual dose from natural sources of radiation (300 mrem).
- False positive screening spiral CT requiring a limited CT scan test in 3 months (20-50%). The term “false positive” refers to a screening test in which findings initially of concern for cancer are later found *not* to be cancer.
- False positive screening CXR requiring a non-contrast CT scan (5-10%).
- Anxiety about evaluation of false positive screening spiral CT or CXR results.
- Detection of abnormalities unrelated to lung cancer that could lead to unnecessary testing or treatment from screening with either spiral CT (10-15%) or CXR (1%).

#### Less Likely, but Serious

- False positive screening spiral CT requiring a full CT scan with intravenous contrast or other potentially invasive procedures (2-7%).
- False positive screening CXR requiring a full CT scan with intravenous contrast or other potentially invasive procedures (1-5%).
- Earlier diagnosis and treatment of lung cancer that is ineffective or unnecessary (< 2%) from screening with either spiral CT or CXR.
- Failure to detect a lung cancer that is present, and possibly miss an opportunity for cure.
- Death from biopsy (less than 1% of all biopsies); death from surgery (2-4% of all having surgery).

- Death from reaction to contrast material used in diagnostic CT scans (less than 1 in 40,000 of all receiving intravenous contrast).

There also may be other side effects that we cannot predict. Most side effects go away shortly after the screening is completed, but in some cases side effects can be serious or long lasting or permanent. You should also be aware that these screening tests are not a replacement for a physical examination or a substitute for a visit to your doctor.

**Facilities (16) that Participated in the Anxiety/Health-Related Quality of Life Study**

Beth Israel Deaconess Medical Center	Boston, MA
Brigham and Women’s Hospital	Boston, MA
Brown University, Rhode Island Hospital	Providence, RI
Rutgers Cancer Institute of New Jersey	New Brunswick, NJ
Dartmouth-Hitchcock Medical Center	Lebanon, NH
Jewish Hospital Rudd Heart and Lung Center	Louisville, KY
Johns Hopkins University and the Sidney Kimmel Comprehensive Cancer Center	Baltimore, MD
Mayo Clinic, Jacksonville	Jacksonville, FL
Mayo Clinic, Rochester	Rochester, MN
Moffitt Cancer Center	Tampa, FL
St. Elizabeth Health Center	Youngstown, OH
University of California, Los Angeles	Los Angeles, CA
University of California, San Diego	San Diego, CA
University of Michigan Medical Center	Ann Arbor, MI
University of Texas MD Anderson Cancer Center	Houston, TX
Comprehensive Cancer Center of Wake Forest University	Winston-Salem, NC