



## From the NLST Principal Investigator

The NLST Newsletter has served as a tool for communicating with the participants of the National Lung Screening Trial (NLST). In 2002, over 50,000 men and women at high risk for lung cancer answered the call when researchers at the American College of Radiology Imaging Network (ACRIN) and the National Cancer Institute (NCI) announced plans to study the role of lung cancer screening in reducing lung cancer deaths. This massive collective undertaking got off the ground and was successfully completed largely because of the interest and dedication of those who enrolled as participants. Although the simple words, "thank you", don't seem sufficient, they do represent the gratitude felt by all of us who serve NLST in a professional capacity.

In joining this special group of clinical trial enrollees, you made a several-year commitment of time and energy. You have undergone screening tests, completed innumerable questionnaires, and provided us with ongoing health information that is critical to the trial endpoints. Many of you have shared in print your personal experiences as a participant or contacted us directly to express your enthusiasm for completion of the screening stage of the trial and transition to the follow-up phase.

Please know that the impact of your participation in NLST goes beyond helping to meet the trial's primary goal. Ongoing research using the NLST database has the potential for dramatically improving the lives of people affected by lung cancer and other related diseases. As we continue this final phase of follow-up by contacting you for updates on your health, we thank you and wish you and your family the best in your endeavors.



*Denise Aberle, MD, ACRIN-NLST Principal investigator acknowledges the NLST participants' role in learning about lung cancer screening.*

## NLST Data Analysis: Keeping track of the numbers

"A rich and extensive body of information has been generated by NLST," states Amanda Adams, a biostatistician at the American College of Radiology Imaging Network (ACRIN) Biostatistics and Data Management Center at Brown University. Adams ought to know; she works on a daily basis, almost exclusively, with the data that are collected on the follow-up forms submitted by the over 18,000 ACRIN-NLST trial participants.

### The Data Review Process

She and five other statisticians perform several important data analysis functions that help ensure reliable study data. First, they regularly run reports of the NLST data that are collected by electronic Web forms

and stored in the ACRIN database. If data submitted on a follow-up form appears to be in error, Adams flags it for follow-up. An ACRIN data manager then contacts the research facility that enrolled the participant to request the data in question be reviewed and corrected. Ensuring the accuracy and completeness of NLST data has been an enormous task given the millions of data elements collected during the past 7 years.

### Developing NLST Scientific Papers

After all the trial data have been collected, the biostatisticians support the writing teams that prepare the scientific papers about the trial results. The team, typically

consisting of a trial principal investigator, lead statistician, epidemiologist, biostatisticians, data managers, and others with specialized knowledge, determines the data to review and how it should be organized for analysis. Adams and her colleagues prepare the data and identify any discrepancies that may, again, require follow-up with the trial sites.

Through conference calls, in-person meetings, and e-mails, the writing team develops and refines the draft paper, ensuring the data accuracy at each step of the process. In addition, several scientific committees scrutinize the draft paper before it is approved for final publication.

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**R**esearchers from a variety of disciplines have been involved in the design and conduct of the National Lung Screening Trial. In addition to the paper that will report the primary results, researchers have already begun work on developing scientific papers using the extensive NLST data to explore other important scientific aims, including those below:

- To assess the impact of lung cancer screening on smoking behaviors
- To summarize the characteristics of NLST participants with regard to age, race, location, smoking history, etc.
- To compare differences in the stage of lung cancer detected between the CT and chest x-ray study arms in persons who had lung cancer diagnosed on a screening examination
- To compare issues of quality of life and psychological effects associated with annual lung cancer screening between the CT and chest x-ray study arms
- To compare the amount of lung cancer-related medical resources used between the two arms of the study
- To assess the economic consequences of lung cancer screening with CT versus chest x-rays
- To evaluate the correlations between smoking history and screening results
- To investigate the extent and significance of incidental findings (something discovered not related to lung cancer) reported as a result of lung cancer screening
- To explore the estimated radiation dose to participants in both the CT and chest x-ray study arms

*NLST Data Analysis continued from page 1*

### NLST Data Support Publications on Wide-Ranging Research

The extensive resource of NLST data supports researchers in developing three types of publications. The primary paper reports the trial results regarding the NLST's major goal: to determine whether lung cancer screening using low-dose spiral CT reduces cancer-specific mortality relative to screening with chest x-rays for people at high risk for lung cancer. Its development requires extensive data review and writing team coordination. Due to the volume of data to be analyzed and the importance of the results for public health policy, a specific time frame for publication of the primary paper has not been established. However, the publication is expected to create significant national media attention, including TV, radio, Internet, and newspaper reports. (Please see the sidebar for how you can learn about the NLST primary results.)

Other scientific papers report on the results of important secondary aims described in

the research protocol. Examples include the trial's design, various characteristics of the NLST participants (eg, age, sex, smoking behavior), and the prevalence of cancers discovered.

"Ancillary" scientific papers use the data collected for the trial to investigate topics unrelated to the trial's primary or secondary aims. For example, NLST investigators are evaluating the presence of incidental findings reported, such as the prevalence of thoracic aneurysms identified during the scanning phase of the trial.

"Working directly with the data collected for NLST," concludes Adams, "I appreciate how much time and effort have been given by the participants, study coordinators, and ACRIN leadership and staff. It is rewarding to know that my role in analyzing the data and preparing manuscripts will help this groundbreaking study realize its goals."

## NLST Results Resources

The NLST is sponsored by the National Cancer Institute (NCI). Information will be available on the NCI's Web site at [www.cancer.gov](http://www.cancer.gov) when the primary results are published. In addition, participants will be able to contact the NCI's Cancer Information Service to request results information at 1-800-4-CANCER (1-800-422-6237).

ACRIN will also post announcements on its Web site at [www.acrin.org](http://www.acrin.org) and, depending upon individual site resources, research staff at participating NLST sites may directly contact the NLST participants with results information.

The National Lung Screening Trial was carried out at more than 50 sites across the country with coordination provided by both the NCI and the American College of Radiology Imaging Network (ACRIN).

Send questions or comments to:

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**ACRIN**<sup>™</sup>  
AMERICAN COLLEGE OF  
RADIOLOGY  
IMAGING NETWORK

NATIONAL  
CANCER  
INSTITUTE



“  
**If I can contribute  
in some way to curing  
cancer, why not do it?**  
”

— *NLST participant Wesley Snow*

**T**he pastimes and occupations of the 18,000 people who are participating in the ACRIN-NLST are far ranging. For trial participant Wesley Snow, pastime and occupation blend on his family's 40-acre dairy farm in the rolling hills of Vermont. As Snow reflects, "We're in a beautiful spot. I can see Killington Mountain from one side of my barn and Camel Hump Mountain from the other." However, starting most days with milking at 4:30 AM doesn't give him time to stand back and appreciate the landscape surrounding the farm that he works with his wife Brenda and 9-year-old son, Jarrett.

Snow enrolled in the NLST at the Dartmouth-Hitchcock Medical Center, about a 40-mile drive from his home, near the 600-person town of Brookfield,

Vermont. When asked about his interest in NLST participation, Snow mentions several motivations. "My doctor suggested I participate, and I thought it would be interesting. Plus, if I can contribute in some way to curing cancer, why not do it?" Also, milking 45 Jersey cows daily and caring for a total herd of 70 head make it difficult for Snow to enjoy a change of scenery. As he comments, "Participating in the trial was a nice opportunity for me to take a break from the farm. I enjoy people watching; and, during my clinic visits, I saw more people in one day than I typically see all the rest of the year here on the farm."

Living on the dairy farm involves maintaining the family's post and beam home that dates back to the 1830s, which they've lived in for the past 35 years. Although both Snow and his wife enjoy antiques, they emphasize that they are practical people and their possessions must also be functional. A collection of butter churns is particularly cherished; they hope to have time to put them to use once they retire. For now, Brenda Snow takes time to make the family's yogurt, but the rest of the farm's milk goes into the production of cheese.

When asked if he'd recommend clinical trial participation to others, Snow concludes, "It was a positive experience for me. It didn't hurt or cost me anything; and, while it took a little time, it wasn't anything serious. Best of all, I met some very nice people."

So, the next time you bite into a creamy chunk of Vermont cheddar, think of NLST participant Wesley Snow, whose hard work contributes to a healthy table and the future health of cancer patients.

*Please see the dessert recipe with cheese on the back cover.*



*A Jersey cow and her calf*

### Heartfelt Thanks

The quality of the relationships developed among the individuals and groups involved in any large-scale undertaking is a crucial element in its ultimate success. This is certainly evident in the sharing taking place between the staff and research subjects participating in the National Lung Screening Trial.

We have been together for a long time! Collecting the information needed on the health questionnaires that are required by the research protocol every 6 months gives the staff an opportunity to say "Hi," ask about the family, sympathize with your losses, cheer you up when you are feeling a little low, or just listen. In return, the information that you provide to us regarding your health and smoking status is collected, added to the massive database, and will ultimately be used to determine whether lung cancer screening reduces lung cancer-specific mortality for those at a higher risk of developing lung cancer.

So, from the NLST staff community to you, once again, please accept our heartfelt thanks for the time, effort, and dedication you have invested in this study. Without your participation, new knowledge about lung cancer screening would not be possible.

*D. Lynn Werner, RN, CCRP, on behalf of the staff at all participating NLST sites*

### Please Keep In Mind

As the study enters its 8th year, the tissue sample collection process is getting underway. As reported in the previous newsletter, most NLST participants signed a study consent form at the beginning of the trial to allow a tissue sample from any biopsy that might be performed during the trial to be sent to a tissue bank for future research. However, because the consent process varies from institution to institution, some participants may also be contacted by their NLST site representative to seek this permission. Please accept our apologies should you be contacted for the extra consent step, and keep in mind the safeguards that are established at various institutions are for the protection of your personal health information.



### Ricotta-Honey Mousse with Summer Berries

*The ricotta mixture and berry mixture may both be prepared hours in advance and layered just before serving. Use a mild-flavored honey, such as orange blossom, for the best flavor.*

#### Yield:

6 servings

#### Ingredients:

- 1/3 cup honey
- 1 1/2 teaspoons grated orange rind
- 12 ounces whole-milk ricotta cheese
- 1 1/2 cups halved small strawberries
- 1 1/2 cups raspberries
- 1 1/2 cups blackberries
- 1/4 cup fresh orange juice
- 3 tablespoons sugar
- 1 1/2 tablespoons thinly sliced fresh mint
- Mint sprigs (optional)



#### Preparation:

Place honey, rind, and ricotta in a medium bowl; stir well with a whisk to combine. Cover and chill. Don't be tempted to use a blender or food processor for the ricotta mixture; doing so will liquefy the ricotta.

Combine berries, juice, sugar, and sliced mint, tossing gently to coat. Let stand at room temperature 5 minutes; cover and chill. Spoon 1/3 cup berry mixture into each of 6 parfait glasses or small bowls; top each serving with about 1/4 cup ricotta mixture. Divide remaining fruit mixture evenly among servings. Garnish with mint sprigs, if desired.

*From Cooking Light, May 2004*

