

Low-Dose Computerized Tomography (LDCT) Lung Cancer Screening

INFORMATION FOR COLORADO HEALTHCARE PROVIDERS

August 2011

Purpose: This statement was developed by a diverse group of experts in Colorado to provide information for healthcare providers about lung cancer screening and to assist them in shared decision-making with their patients about the balance of benefits and harms of LDCT lung screening. It is not intended to be a clinical practice guideline. This information is based on findings from the National Lung Screening Trial (NLST) and previous observational studies. After a key study is published, it can take more than a year for national organizations to develop clinical guidelines about who should be screened, when to begin and when to stop, what methods should be used, how abnormalities should be followed up, and how to minimize adverse effects. If LDCT is to be used, benefits and harms should be carefully weighed and emphasis should be placed on preventing lung cancer through tobacco cessation efforts.

HealthTeamWorks: A nonprofit organization working to improve the quality and delivery of healthcare in Colorado coordinated the work of the expert group that developed this statement (www.healthteamworks.org). The expert committee list is included in the appendix.

NLST main findings: The NLST was a multi-center, prospective, randomized control study with over 53,000 participants. It reported that patients at high risk for developing lung cancer who received low-dose computerized tomography (LDCT) scans annually for three years to detect lung cancer experienced 20% lower lung cancer mortality than those who were screened using chest X-rays (New England Journal of Medicine, June 30, 2011). Individuals screened by LDCT also had a 7% lower risk of dying from all causes. No previous screening method had reduced lung cancer mortality.

Who was screened in the NLST?

- Men and women, ages 55-74 years
- Current or former smoker with at least 30 pack year history (1 pack-year = 20 cigarettes per day for 1 year)
- If former smoker, quit within the past 15 years
- Exclusions: previous diagnosis of lung cancer, hemoptysis, unexplained weight loss >15 lbs. in the past year

How was the LDCT screening done?

- Baseline LDCT, then two repeat exams done annually
- Screening performed in both academic and community medical centers
- Management of suspicious nodules by community providers (not NLST researchers)
- Median follow up time 6.5 years from the first LDCT screening exams

Important considerations in the NLST:

- 24% of LDCT screening tests were positive (had an abnormality), however, 96% of these were false positives (were not cancer).
- 320 patients needed to be screened to prevent one lung cancer death.
- There were 247 lung cancer deaths/100,000 person-yrs. in the LDCT group and 309 lung cancer deaths/100,000 person-yrs. in the chest X-ray group (a difference of 62 deaths/100,000 person-yrs.).
- Despite the clear decrease in lung cancer mortality associated with LDCT screening in the NLST, significant concerns remain regarding its high false positive rate and cost-effectiveness.
- Follow-up analyses of NLST data will address radiation exposure, false positive rates, overdiagnosis, cost-effectiveness from a societal perspective, and other benefits and risks of LDCT screening.

Who might benefit from LDCT screening?

- We need more research to know exactly who might benefit from screening.
- In the NLST study protocol, high risk smokers and former smokers ages 55-74 benefited from LDCT screening.
- Screening of younger, lower risk patients is expected to yield a less favorable benefit/risk ratio.

What are the potential harms from LDCT screening for lung cancer?

- Radiation burden (from repeat LDCT screens as well as from other imaging tests to assess positive screens)
 - Radiation dose from LDCT is usually 1/3 the dose of conventional chest CT and 4-5 times the effective dose of bilateral 2-view mammography.
 - See appendix for resources on assessing radiation risk.
- Risks associated with follow-up procedures (for true-positive and false-positive exams)
- Costs associated with screening, follow-up and work-up of true-positive and false-positive findings

LDCT technology and methodology

- LDCT is also known as reduced dose helical computed tomography or spiral CT.
- Scanners with 4 or greater detector rows were used in the NLST; ≥ 16 detector row scanners are preferred and are widely available.
 - In Colorado, at least 100 widely distributed radiology centers currently offer this technology.
- Acceptable LDCT protocol parameters: 3mm slices. Ideal parameters: 1 mm slices.
- Screening LDCT is done *without* injection of a contrast agent.
- The price of LDCT lung cancer screening varies widely and is currently not covered by health insurance.

Quality assurance

- Sites that provide LDCT lung cancer screening are encouraged to have a written quality assurance plan.
- Patients should receive information prior to screening about risks (including false-positives).
- LDCT scans must be carefully read for the presence of nodules; additional image processing may be helpful.
- Nodules should be characterized by size, attenuation, location and change from any previous imaging study.
- LDCT screening results should be communicated to both patients and providers.
- Automated reminders about follow-up LDCT screening exams or LDCT exams required for management of small nodules may be helpful.
- Consider coordinating management of larger nodules ($> 8\text{mm}$) with centers that have access to advanced diagnostic modalities, including advanced bronchoscopy, CT guided biopsy, PET-CT, and thoracic surgery.

Follow-up and management of noncalcified pulmonary nodules detected through LDCT screening

- This information is taken primarily from the Fleischner Society Guidelines: <http://healthteamworks-media.precis5.com/fleischner-statement>
- Locating prior imaging studies should be the first priority in all cases.
- Densely calcified nodules are typically benign and do not require follow-up imaging.
- Follow up should be coordinated between patients, primary care, radiology, and specialty providers as necessary.
- Management of ground glass opacities (GGO) are generally similar to those for solid nodules but may need longer than 3-year follow-up.
- This information addresses nodules identified in higher risk patients (i.e., the group studied in the NLST). Incidental findings in lower risk patients generally require less frequent surveillance (see *Fleischner Society Guidelines* - see link above).

≤ 8 mm solid nodules:

- Typically may be managed by the primary care clinician.
- Low likelihood of cancer, but still require follow-up at specified intervals.
- Managed with follow-up LDCT (frequency depends on actual size).
- Nodules stable for two years are usually benign.
- See Fleischner Society Guidelines for additional information.

> 8 mm solid nodules:

- Require specialty care.
- Moderate to high likelihood of cancer (higher if > 2 cm).
- Prompt evaluation usually indicated.
- Evaluation may include percutaneous or bronchoscopic biopsy, short term LDCT follow-up, or PET-CT (less commonly).
- Choice of follow-up depends on nodule features, lung cancer risk factors, co-morbidities, and available resources.
- See Fleischner Society Guidelines for additional information.

Ground glass nodules > 5 mm:

- Can represent adenocarcinoma in situ, a slow growing malignancy, but may be inflammatory
- If part solid, invasive adenocarcinoma more likely.
- Evaluation usually includes follow-up LDCT at three months: Nodules stable at 3 months require follow-up for > 2 years to ensure stability
- Nodules that grow or become solid should be considered for resection

Tobacco Prevention/Cessation

The trial investigators re-emphasize that the single best way to prevent lung cancer deaths and other adverse effects of tobacco use is to never start, and if already using tobacco, to quit permanently. If a person quits smoking, much of the damage is reversible over time.

- Lung cancer screening may present a teachable moment and an opportunity to promote smoking cessation.
- HealthTeamWorks Guideline for Tobacco Cessation and Second-Hand Smoke Exposure:
<http://www.healthteamworks.org/guidelines/tobacco.html>

Tobacco cessation in Colorado

- Colorado QuitLine: 1-800-QUIT-NOW (1-800-784-8669 or www.coquitline.org)
- Information about the Colorado Medicaid tobacco cessation benefit: <http://www.healthteamworks.org/guidelines/tobacco.html>

Low-Dose Computerized Tomography (LDCT) Lung Cancer Screening

APPENDIX - page 1 of 2

LDCT expert committee that drafted the information statement for Colorado healthcare providers:

| Name | Institution(s) | Title(s) |
|--------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| Tim Byers MD, MPH | University of CO School of Public Health | Associate Dean for Public Health Practice |
| | University of CO Cancer Center | Associate Director, Cancer Prevention and Control |
| Paul Bunn MD | Dept of Medicine, University of CO, Denver | James Dudley Endowed Professor of Lung Cancer Research |
| | International Association for the Study of Lung Cancer | Executive Director |
| Kevin Fitzgerald MD | Rocky Mountain Health Plan | Medical Director |
| | HealthTeamWorks Board of Directors | Member |
| Kavita Garg MD | University of CO, Denver | Professor of Radiology |
| | | Site Principal Investigator, National Lung Screening Trial |
| Edward Hendrick PhD | University of CO, Denver | Clinical Professor, Department of Radiology |
| James Jett MD | National Jewish Health | Professor of Medicine |
| Martha Johns MD, MPH | HealthTeamWorks | Medical Director, Guidelines and Evaluation |
| | Denver Health and Hospital Authority | Family Physician, La Casa/Quigg Newton Family Health Center |
| David Jones, MD | Department of Preventive Medicine | Resident in Preventive Medicine |
| | University of CO School of Public Health | Public Health Student |
| Timothy Kennedy MD | Thoracic Oncology, Presbyterian-St. Lukes Medical Center | Medical Director |
| | Division of Pulmonary Sciences and Critical Care Medicine, University of CO, Denver | Clinical Professor |
| Jeffrey Kern MD | National Jewish Health | Chief, Division of Oncology |
| | | Vice-Chair, Department of Medicine |
| | | Director, Lung Cancer Center |
| Elizabeth Kraft MD | HealthTeamWorks Board of Directors | Chair |
| Fred Larke MS | University of CO, Denver | Medical Physicist |
| David Lynch MD | National Jewish Health | Professor of Radiology |
| | | Co-Director, Division of Radiology |
| Stephen Malkoski MD, PhD | University of CO, Denver, Lung Nodule Clinic | Assistant Professor of Medicine |
| York Miller MD | Division of Pulmonary Sciences and Critical Care Medicine, University of CO, Denver | Thomas L. Petty Chair of Lung Research |
| | University of CO Cancer Center | Co-Leader, Lung, Head and Neck Cancer Program |
| | Denver Veterans Affairs Medical Center | Staff Physician |
| Timothy Moore MD | Advanced Medical Imaging | Former President |
| Kavita Nair PhD | University of CO, Denver | Associate Professor (Center for Pharmaceutical Outcomes Research) |
| | | Director of Graduate Studies in the Pharmaceutical Outcomes Track |
| Yvonne Nelson MD | United Health Care | Medical Director |
| Peter Sachs MD | University of CO, Denver | Associate Professor, Section Chief, Chest Imaging- Department of Radiology |
| Tim Tsai MD | University of CO School of Public Health | Public Health Student |
| Holly Wolf PhD, MSPH | University of CO, Denver | Professor |
| Judy Zerzan MD, MPH | CO Department of Health Care Policy and Financing | Chief Medical Officer/Deputy Medicaid Director |
| Thelissa Zollinger | | Patient Advocate SPORE Committee |

Committee Coordinator: Carolyn Swenson, MSPH, MSN, Senior Project Manager, HealthTeamWorks

The National Lung Screening Trial:

- Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening (NEJM, June 2011): <http://healthteamworks-media.precis5.com/nejm-june-2011>
- National Lung Screening Trial – Primary Results: Questions and Answers: <http://healthteamworks-media.precis5.com/nlst-qa>
- National Lung Screening Trial (NLST) Primary Results: Fast Facts: <http://healthteamworks-media.precis5.com/nlst-fast-facts>
- American College of Radiology Imaging Network: <http://www.acrin.org>

Resources to about assessment of radiation risk:

- Radiation Exposure in X-ray and CT Examinations - RadiologyInfo.org (the radiology information resource for patients): <http://healthteamworks-media.precis5.com/radiation-exposure>

Follow-up and management of lung nodules:

- Guidelines for Management of Small Pulmonary Nodules Detected on CT Scans: A Statement from the Fleischner Society: <http://healthteamworks-media.precis5.com/fleischner-statement> (note the timeline for updating these guidelines)
- Subsolid Pulmonary Nodules and the Spectrum of Peripheral Adenocarcinomas of the Lung: Recommended Interim Guidelines for Assessment and Management: <http://healthteamworks-media.precis5.com/nodule-management-naidich-godoy>

HealthTeamWorks coordinated the work of the expert group that developed this statement:
www.healthteamworks.org