Solutions for Monitoring Medical Record Abstraction Quality in a Multi-Center Study

Nancy Payte, PhD, CTR, CCRA

Society for Clinical Trials
May 16, 2011
• Westat is the coordinating center (CC) for the NLST/LSS

• Medical Record Abstraction Coordinator for the National Lung Screening Trial/Lung Screening Study (NLST/LSS)
Presentation Outline

1. Background on the National Lung Screening Trial
2. Medical Record Abstraction (MRA) Forms
3. Quality Assurance Plan
4. Lessons Learned
5. Conclusions
National Lung Screening Trial (NLST)

Randomized controlled trial designed to determine whether screening with low-dose helical computed tomography (LDCT) reduces lung cancer mortality relative to screening with conventional chest x-ray (CXR) in persons at elevated risk of lung cancer.

33 sites
53,454 participants
Age 55 – 74 years
≥ 30 pack years smoking history
Current and former smokers (quit smoking within the previous 15 years)
**NLST Endpoints**

**Primary Endpoint**
- Lung Cancer Mortality

**Secondary Endpoints**
- All-Cause Mortality
- Incidence of Lung Cancer
- Lung Cancer Survival
- Lung Cancer Stage Distribution
NLST Organization

NCI-sponsored with two collaborative administrative components

**LSS**
- Lung Screening Study
- 10 sites
- 34,614 enrolled

**ACRIN**
- American College of Radiology Imaging Network
- 23 sites
- 18,840 enrolled
NLST/LSS Sites

- Georgetown University Medical Center
  (Washington, DC)
- Henry Ford Health System
  (Detroit, MI)
- Marshfield Clinic Research Foundation
  (Marshfield, WI)
- Pacific Health Research and Education Institute
  (Honolulu, HI)
- University of Alabama at Birmingham
  (Birmingham, AL)
- University of Colorado
  (Denver, CO)
- University of Minnesota School of Public Health
  (Minneapolis, MN)
- University of Pittsburgh Medical Center
  (Pittsburgh, PA)
- University of Utah Health Science Center
  (Salt Lake City, UT/Boise, ID)
- Washington University School of Medicine
  (St. Louis, MO)
NLST/LSS MRA Forms

Diagnostic Evaluation (DE)
- Completed as follow-up to a positive screening examination or report of lung cancer
- Collected diagnostic exam information, lung cancer diagnosis and staging

Treatment Information (TI)
- Completed following diagnosis of lung cancer
- Collected treatment information for lung cancer

Cancer Progression (CP)
- Completed annually for all lung cancers
- Collected lung cancer progression information
MRA Form QA Selection

DE
- Lung Cancer
  - 100% Selected
    - Monthly

- No Lung Cancer
  - 5% Random Sample Selected
    - Monthly

TI
- 90 Randomly Selected
  - Annual

CP
- 90 Randomly Selected
  - Annual
MRA Form QA Process

- Select cases
- Request MRA form/medical records from site
- Re-abstract case at CC
- Compare (electronic) abstracts
- Generate discrepancy report
- Adjudicate if needed
- Send edit form to site
- Verify site made edits to the form and centralized data base
Components of QA Plan

- Standardized procedures
- MRA qualification and training
- Continuous monitoring
- Ongoing quality improvement
Standardized MRA Procedures

• Manual of Operating Procedures
  — Description of the study and the endpoints
  — Data definitions

• Form specifications for abstract completion
  — Extensive instructions
  — Clarified as needed

• Standardized resource materials
  — American Joint Committee on Cancer (AJCC) 6th Edition
  — Surveillance, Epidemiology and End Results (SEER) Guidelines
Components of QA Plan

- Standardized procedures
- MRA qualification and training
- Continuous monitoring
- Ongoing quality improvement
MRA NLST/LSS Certification

- Training
- Review of first 10 lung cancer cases
- Credential verification
- Review of first 10 non-lung cancer cases
# MRA Qualifications

<table>
<thead>
<tr>
<th>Medical Record Abstractor</th>
<th>ICD-9-CM Coder</th>
<th>ICD-O-3/TNM Staging Coder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge of medical record terminology, anatomy, physiology, and concepts of disease</td>
<td>Basic medical coding education</td>
<td></td>
</tr>
<tr>
<td>Minimum of two years MRA experience</td>
<td>Certified Coding Specialist (CCS)</td>
<td>Certified Tumor Registrar (CTR)</td>
</tr>
<tr>
<td>Registered Health Information Technician/Associate (RHIT/RHIA)</td>
<td></td>
<td>Tumor Registrar, CTR-eligible</td>
</tr>
<tr>
<td>Other qualifying experience</td>
<td>Other qualifying experience</td>
<td></td>
</tr>
</tbody>
</table>
MRA Training

1. Centralized training
2. Centralized refresher training at annual Steering Committee Meetings
3. Quarterly conference calls
4. Individual training as needed
Components of QA Plan

- Standardized procedures
- MRA qualification and training
- Continuous monitoring
- Ongoing quality improvement
Continuous Monitoring

Monthly QA Selection
- Provide feedback
- Identify site specific abstracting issues

Quarterly Progress Reports
- Monitor key data items
- Identify areas for re-training/clarification to all abstractors

Annual Site Visits
- Audit participant files and review source documents
- Meet with MRA staff
Components of QA Plan

- Standardized procedures
- MRA qualification and training
- Continuous monitoring
- Ongoing quality improvement
Ongoing Quality Improvement

- Communication between MRAs and CC MRA Coordinator
- Monthly and quarterly feedback
- Re-training as needed
Suggestions for Future Trials

- Web-based training modules
- Increased frequency of conference calls
- One level of abstractor
Conclusion

- Coordinated data collection and cleaning process
- Reduced data cleaning issues
- Fostered collaborative data collection effort between the sites and CC
Acknowledgements

Brenda Brewer, MMSc  Ellen Martinusen, BA

Kathy Clingan, BA  Pete Ohan, BS

This research was supported by contract number N01-CN-25476 from the Division of Cancer Prevention, National Cancer Institute, NIH, DHHS.