

Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

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APPENDIX 1

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Endpoint Verification Process (EVP)

NLST's death review process, the EVP, strove to identify deaths whose underlying cause was lung cancer. For the purpose of NLST, these included deaths caused directly by lung cancer, deaths attributed indirectly to lung cancer due to diagnostic evaluation of a suspected (due either to symptoms or a positive screen) or confirmed lung cancer, and deaths associated with treatment of lung cancer. Details of the process are reported in a manuscript currently under consideration at another journal; however, a brief synopsis follows for the interested reader. A computerized algorithm identified deaths requiring review. Deaths selected for review included those with a notation of lung cancer on the death certificate and those occurring among participants ever diagnosed with lung cancer, as well as deaths within six months of a screen suspicious for lung cancer and deaths within 60 days of certain diagnostic evaluation procedures associated with a screen suspicious for lung cancer or a lung cancer diagnosis.

Information concerning deaths selected for EVP was first reviewed by the Chair of the Endpoint Verification Team (EVT). The Chair's assigned cause of death was compared with the death certificate cause of death. If the two assignments agreed with regard to lung cancer, the death was certified. If not, a second EVT reviewer examined the death certificate, the EVP's assignment, and information concerning the death. If the Chair and second reviewer agreed with regard to lung cancer, the death was certified; otherwise, the death was reviewed by a group of three EVT reviewers, including the Chair. A consensus cause of death was assigned by that group.

APPENDIX 3
Supplement Table 1

NLST Diagnostic Evaluation Procedures

Clinical Procedures:

Clinical evaluation

Radiograph – comparison with historical images

Pulmonary function tests/spirometry

Imaging Procedures:

- Radiograph
 - Bone
 - Chest
 - Other (specify)
- CT
 - Abdomen & pelvis
 - Brain
 - Other (specify)
 - Chest, limited thin section of nodule
 - Abdomen (or liver)
 - Chest, plus contrast-enhanced nodule densitometry
 - Diagnostic chest
 - Chest, low dose helical
 - Chest, limited thin section of entire lung
 - Chest and abdomen
 - Chest, abdomen and pelvis
- MRI
 - Bone
 - Brain
 - Chest
 - Other (specify)
 - Abdomen or liver
- Radionuclide scan
 - Bone
 - Brain
 - Liver
 - FDG-PET scan
 - Gallium
 - Somatostatin receptor
 - Ventilation/perfusion lung
 - Other (specify)
 - Fusion PET/CT scan
- Others
 - Fluoroscopy
 - Ultrasound (specify)
 - Echocardiography

Cytology Procedures:

Sputum
Bronchoscopic
Percutaneous transthoracic
Other (specify)

Biopsy Procedures:

Endobronchial
Percutaneous liver
Lymph node – other (specify)
Lymph node – scalene nodes
Other (specify)
Open surgical
Transbronchial
Thoracoscopic
Percutaneous adrenal
Percutaneous transthoracic yielding histology

Scope Procedures:

Mediastinoscopy/mediastinotomy
Thoracoscopy without biopsy
Thoracoscopy with biopsy
Bronchoscopy without biopsy or cytology

Surgery Procedures:

Lymphadenectomy/lymph node sampling
Resection
Thoracotomy

Other Procedures:

Other (specify)
Thoracentesis
Unknown

NLST Medical Complications

Major Complications:

- Acute respiratory failure
- Anaphylaxis
- Bronchopulmonary fistula
- Cardiac arrest
- Cerebral vascular accident (CVA)/stroke
- Congestive heart failure (CHF)
- Death
- Hemothorax requiring tube placement
- Myocardial infarction
- Respiratory arrest
- Wound dehiscence
- Bronchial stump leak requiring tube thoracostomy or other drainage for more than 4 days
- Empyema
- Injury to vital organ or vessel
- Prolonged mechanical ventilation over 48 hours post-operatively
- Thromboembolic complications requiring intervention
- Chylous fistula
- Brachial plexopathy
- Lung collapse
- Infarcted sigmoid colon

Intermediate Complications:

- Blood loss requiring a transfusion
- Cardiac arrhythmia requiring medical attention
- Fever requiring antibiotics
- Hospitalization post procedure
- Pain requiring referral to a pain specialist
- Pneumothorax requiring tube placement
- Rib fracture(s)
- Vocal cord immobility/paralysis
- Infections requiring antibiotics
- Cardiac ischemia/ST elevation
- Bronchitis
- Pneumonia
- Pleural effusion
- Sepsis
- Respiratory distress
- Splenomegaly with splenic infarcts
- Mucous plug requiring bronchoscopy
- Steroid-induced diabetes

Minor Complications:

- Allergic reaction
- Bronchospasm
- Vasovagal reaction/hypotension

Subcutaneous emphysema
Atelectasis
Pneumothorax with no chest tube
Ileus
Seroma
Paresthesias/hyperesthesias
Other (specify)

Supplemental Table 2: Lung cancer stage by screening round and trial arm.

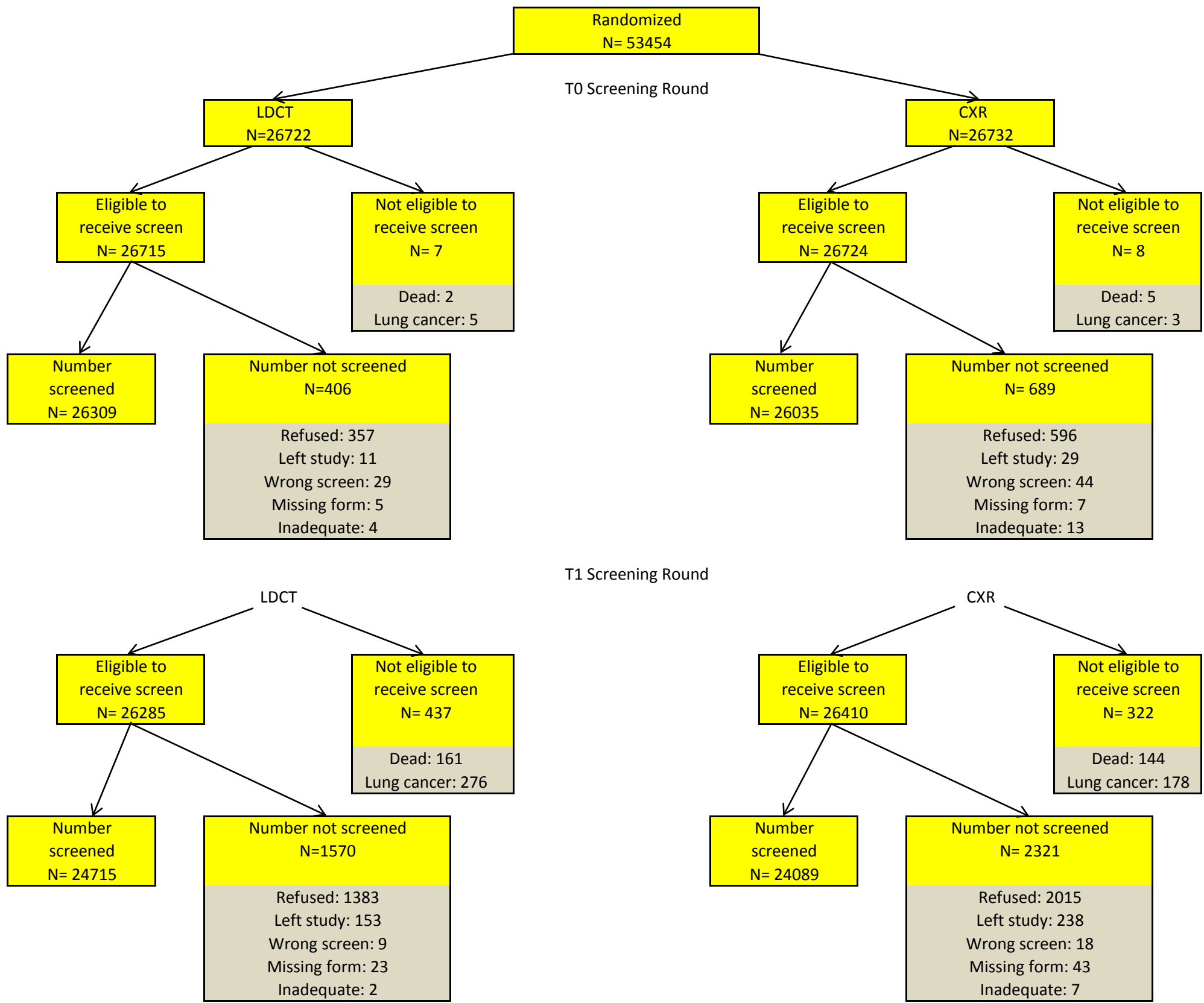
	T0				T1				T2			
	LDCT		CXR		LDCT		CXR		LDCT		CXR	
	N	%	N	%	N	%	N	%	N	%	N	%
Stage IA	133	45.4	46	24.5	87	47.5	31	23.5	116	50.4	35	24.5
Stage IB	27	9.2	24	12.8	21	11.5	11	8.3	31	13.5	13	9.1
Stage IIA	10	3.4	3	1.6	11	6.0	7	5.3	8	3.5	9	6.3
Stage IIB	12	4.1	10	5.3	7	3.8	5	3.8	5	2.2	3	2.1
Stage IIIA	34	11.6	30	16.0	14	7.7	14	10.6	15	6.5	18	12.6
Stage IIIB	30	10.2	28	14.9	19	10.4	12	9.1	20	8.7	21	14.7
Stage IV	47	16.0	47	25.0	24	13.1	52	39.4	35	15.2	44	30.8
Unknown	4	-	5	-	3	-	1	-	7	-	1	-
Total	297	100.0	193	100.0	186	100.0	133	100.0	237	100.0	144	100.0

Supplemental Table 3: First-line treatment¹ by stage and trial arm.

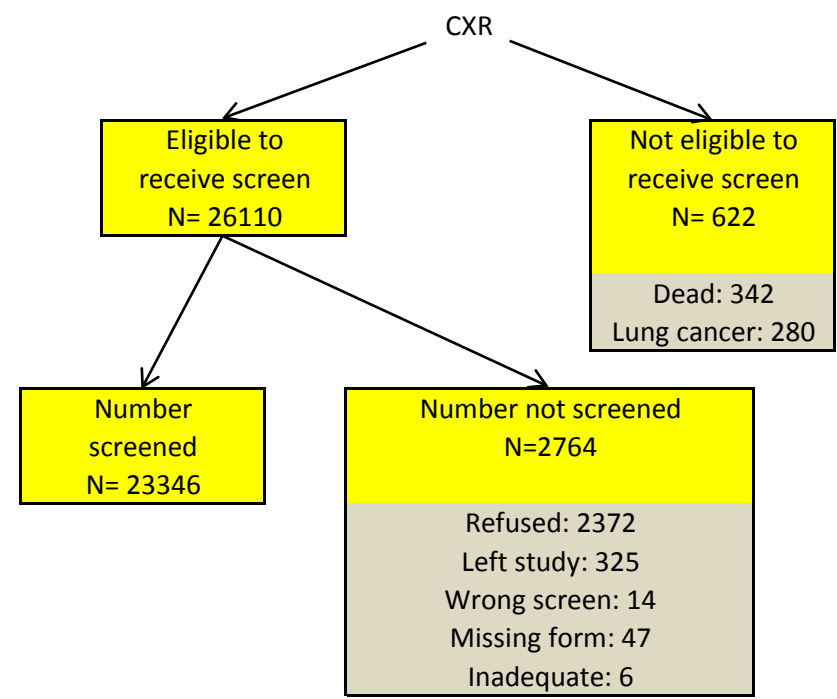
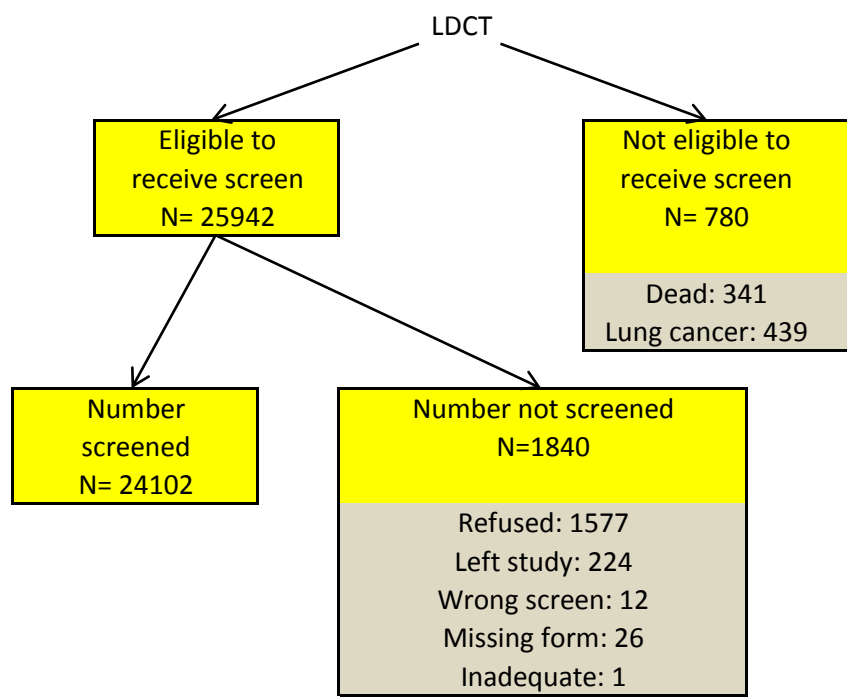
First-line treatment		Stage																Total	
		IA		IB		IIA		IIB		IIIA		IIIB		IV		Unknown			
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
LDCT	Surgery only	358	86.1	63	60.6	10	28.6	9	23.7	8	8.1	11	9.0	8	3.5	6	30.0	473	44.6
	Surgery and chemotherapy	20	4.8	28	26.9	14	40.0	12	31.6	10	10.1	16	13.1	9	4.0	0	0.0	109	10.3
	Surgery and radiotherapy	4	1.0	0	0.0	2	5.7	2	5.3	3	3.0	3	2.5	3	1.3	0	0.0	17	1.6
	Surgery, chemotherapy, and radiotherapy	6	1.4	2	1.9	5	14.3	5	13.2	16	16.2	6	4.9	3	1.3	0	0.0	43	4.1
	Chemotherapy only	0	0.0	3	2.9	2	5.7	0	0.0	6	6.1	19	15.6	87	38.5	1	5.0	118	11.1
	Chemotherapy and radiotherapy	2	0.5	1	1.0	2	5.7	6	15.8	45	45.5	50	41.0	50	22.1	4	20.0	160	15.1
	Radiotherapy only	14	3.4	4	3.8	0	0.0	1	2.6	7	7.1	4	3.3	16	7.1	1	5.0	47	4.4
	Other treatment	3	0.7	0	0.0	0	0.0	1	2.6	0	0.0	2	1.6	4	1.8	1	5.0	11	1.0
	No treatment	8	1.9	3	2.9	0	0.0	1	2.6	3	3.0	10	8.2	40	17.7	3	15.0	68	6.4
	Treatment data incomplete	1	0.2	0	0.0	0	0.0	1	2.6	1	1.0	1	0.8	6	2.7	4	20.0	14	1.3
Total	416	100.0	104	100.0	35	100.0	38	100.0	99	100.0	122	100.0	226	100.0	20	100.0	1060	100.0	
CXR	Surgery only	150	76.5	57	61.3	9	28.1	8	19.0	5	4.6	10	8.2	11	3.3	2	16.7	252	26.8
	Surgery and chemotherapy	14	7.1	24	25.8	13	40.6	14	33.3	17	15.6	15	12.3	8	2.4	0	0.0	105	11.2
	Surgery and radiotherapy	3	1.5	0	0.0	3	9.4	1	2.4	2	1.8	1	0.8	3	0.9	1	8.3	14	1.5
	Surgery, chemotherapy, and radiotherapy	3	1.5	2	2.2	2	6.3	3	7.1	15	13.8	12	9.8	7	2.1	0	0.0	44	4.7
	Chemotherapy only	0	0.0	1	1.1	0	0.0	1	2.4	3	2.8	18	14.8	132	39.4	3	25.0	158	16.8
	Chemotherapy and radiotherapy	3	1.5	6	6.5	4	12.5	13	31.0	54	49.5	46	37.7	86	25.7	1	8.3	213	22.6
	Radiotherapy only	14	7.1	0	0.0	0	0.0	0	0.0	6	5.5	4	3.3	37	11.0	1	8.3	62	6.6
	Other treatment	0	0.0	0	0.0	0	0.0	0	0.0	2	1.8	2	1.6	9	2.7	0	0.0	13	1.4
	No treatment	8	4.1	3	3.2	1	3.1	1	2.4	5	4.6	13	10.7	38	11.3	3	25.0	72	7.7
	Treatment data incomplete	1	0.5	0	0.0	0	0.0	1	2.4	0	0.0	1	0.8	4	1.2	1	8.3	8	0.9
Total	196	100.0	93	100.0	32	100.0	42	100.0	109	100.0	122	100.0	335	100.0	12	100.0	941	100.0	

¹Table includes first-line treatments that occurred within 6 months of diagnosis. “No treatment” includes participants who received no treatment at all or who received first-line treatment after the 6 months following diagnosis.

APPENDIX 4 Consort Diagram



T2 Screening Round



T3-T8
Follow-up

Lung cancer mortality
Deaths through January 15, 2009

Analyzed: N= 53454
Excluded: N= 0

All-cause mortality
Deaths through December 31, 2009

Analyzed: N= 53454
Excluded: N= 0