Lung Cancer Screening Registries as a Transformation Resource for Rapid Learning Across Tobacco-related Diseases

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Financial Disclosures:

- Dr. David Yankelevitz is a named inventor on a number of patents and patent applications relating to the evaluation of diseases of the chest including measurement of nodules. Some of these, which are owned by Cornell Research Foundation (CRF) are non-exclusively licensed to General Electric. As an inventor of these patents, Dr. Yankelevitz is entitled to a share of any compensation which CRF may receive from its commercialization of these patents
- Dr Yankelevitz is a consultant and shareholder for Accumetra LLC

A Foundation for Evidence-Driven Practice: A Rapid Learning System for Cancer Care - Workshop Summary

- It may seem as though new research emerges each day, promising advances in cancer treatment, and some forms of cancer already are curable. Yet despite modern advances in health IT, the way that evidence on cancer screening, early detection, and treatment is gathered and applied has not moved forward rapidly enough. Individuals and institutions working both in cancer research and treatment could take better advantage of existing resources and create new mechanisms for assessing and sharing information on the effectiveness and value of each individual treatment. Researchers already gather data on effectiveness through clinical interaction with patients, as well as from cancer registries, clinical trials, and networks of academic and community cancer centers. They could be sharing that information and aggregating it more effectively in order to accelerate advances. Health care payers, policymakers, and the public all could reap the benefits. Most importantly, patient care could be improved.

IOM: 2010

Radiology imaging facility eligibility criteria:

- Performs LDCT with volumetric CT dose index (CTDIvol) of ≤ 3.0 mGy (milligray) for standard size patients (defined to be 5’ 7” and approximately 155 pounds) with appropriate reductions in CTDIvol for smaller patients and appropriate increases in CTDIvol for larger patients;
- **Utilizes a standardized lung nodule identification, classification and reporting system**;
- Makes available smoking cessation interventions for current smokers; and
- **Collects and submits data to a CMS-approved registry for each LDCT lung cancer screening performed. The data collected and submitted to a CMS-approved registry must include, at minimum, all of the following elements:**

ACR CT Accreditation Program and the Lung Cancer Screening Program Designation

"To ensure consistent follow-up, sites must have a structured reporting system that includes management recommendations based on the findings. Lung-RADS is one such tool, but its exclusive use is not currently mandated."

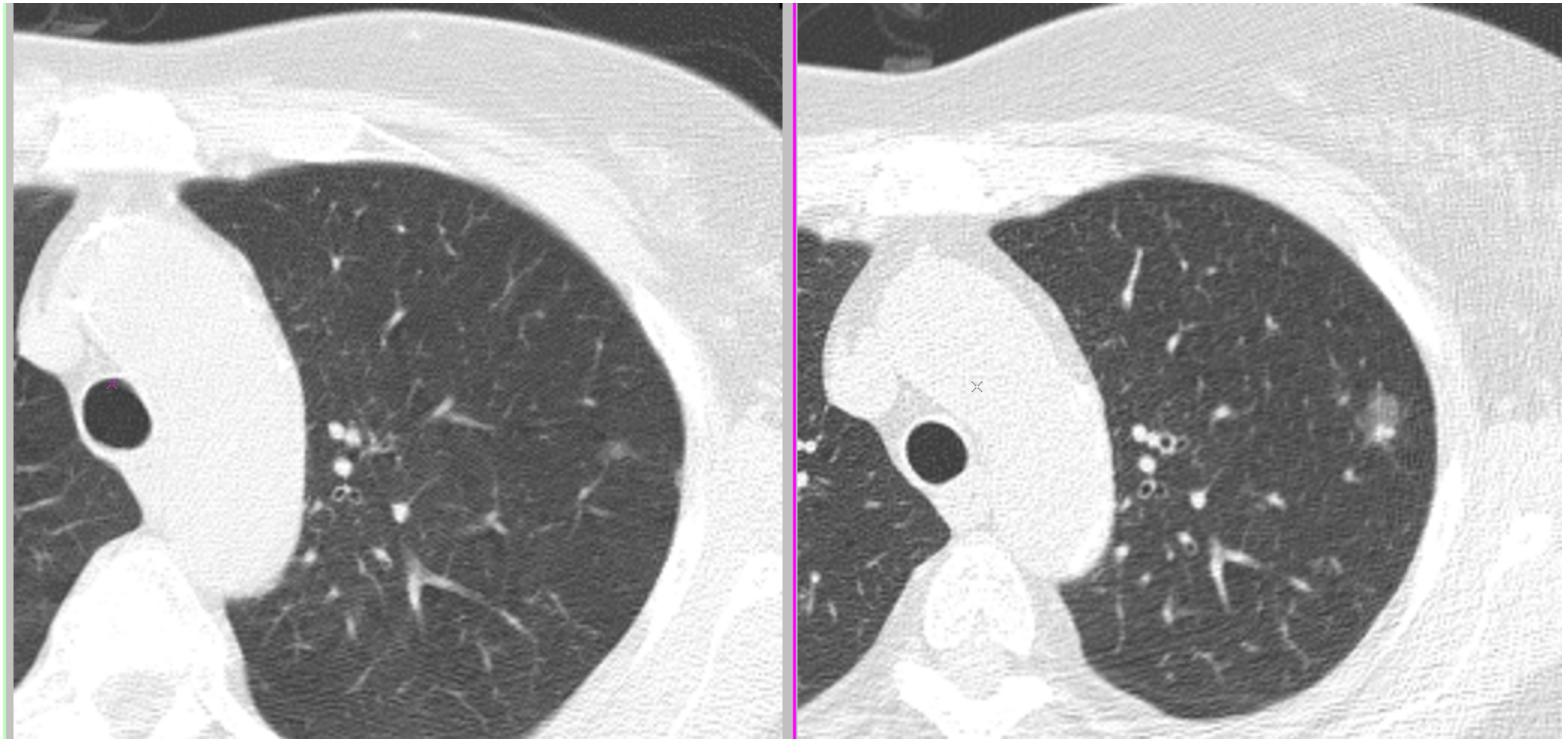
Kazerooni et al. J Am Coll Radiol 2015

Registry for Lung Screening Excellence (RLSE)

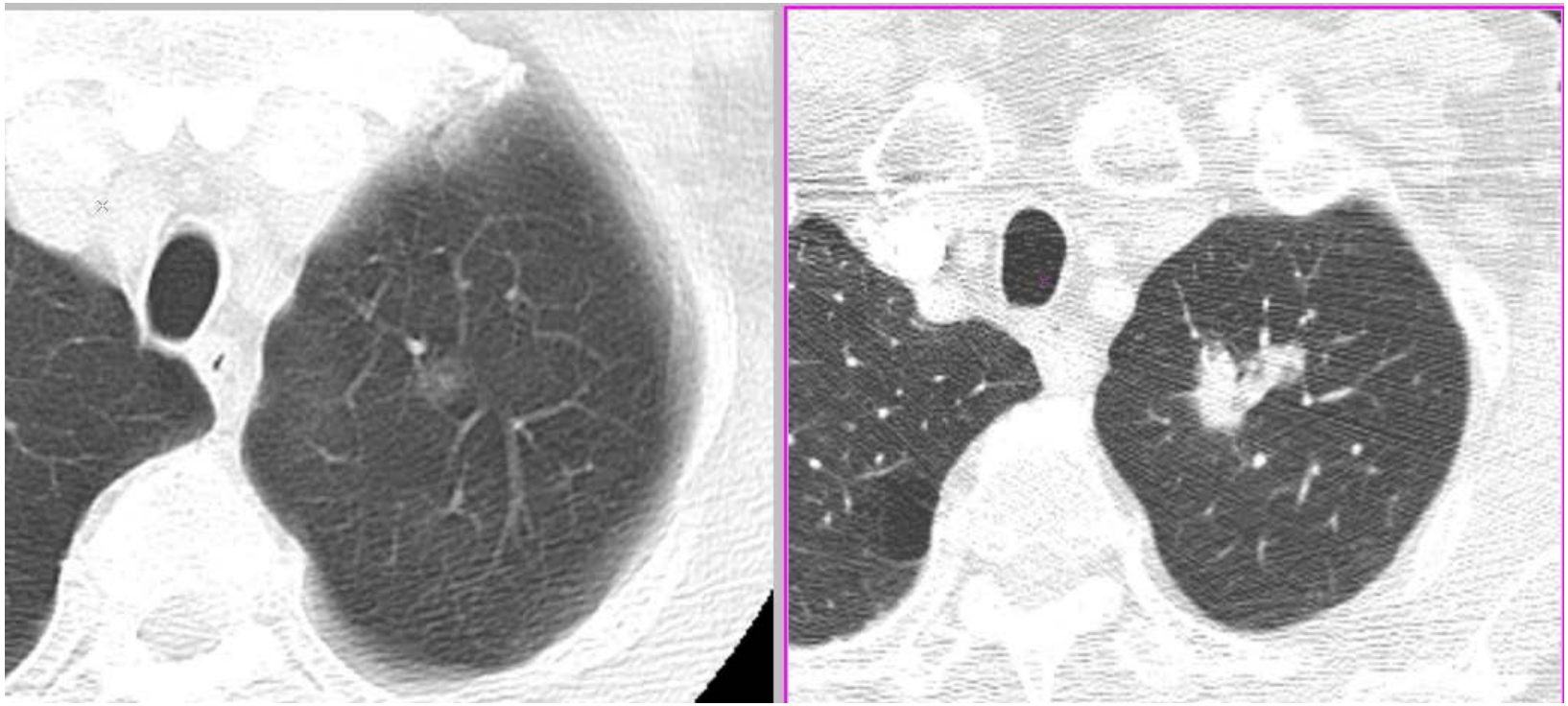
- Enhanced clinical data collection
- Image collection
  - Image quality assurance
  - Analysis of ancillary findings

Examples of the power of large registries

- Change in management of lung cancer
- Risk prediction for vascular events in specific populations



3.3 years



8.9 years

NCCN: Lung Cancer Screening Guidelines

Part 4: The screening process

Non-solid nodule

Second screening test

Baseline LDCT results	Testing recommendation
Lung nodule ≤5 mm in width	Get follow-up LDCT in 12 months
Lung nodule 5.1–10 mm in width	Get follow-up LDCT in 6 months
Lung nodule >10 mm in width	Get follow-up LDCT in 3–6 months

Non-solid nodules may be cancer, but they may also be small areas of infection or inflammation that will resolve. Nodules that are large are more likely to be cancer than smaller nodules. The more likely there's cancer, the sooner the second test will be suggested. Lung nodules that are 5 mm or smaller in width should be assessed again in 12 months with LDCT. Another LDCT in 6 months is recommended for nodules wider than 5 mm but no wider than 10 mm. Nodules that are wider than 10 mm should be assessed again in 3 to 6 months.

NCCN: Lung Cancer Screening Guidelines

Part 4: The screening process

Care after second test

Baseline LDCT	Second LDCT	Recommended care
Lung nodule ≤5 mm	No increase	Start yearly LDCT screening
	Increase	Get another follow-up LDCT in 3–6 months, or Consider surgery
Lung nodule 5.1–10 mm	No increase	Start yearly LDCT screening
	Increase	Surgery
Lung nodule >10 mm	No increase	Get another follow-up LDCT in 6–12 months, Biopsy, or Consider surgery
	Increase	Surgery

The chart above shows the recommended care based on comparing the second screening test to the baseline test. If the non-solid nodule has disappeared or gotten smaller, there is a good chance that it was just a small infection that resolved and not cancer. If a nodule has grown or become more solid, it may be cancer and surgery probably should be considered. A nodule about the same size and density at follow-up suggests that it may be cancer, but it also may be t benign. Since some of these lung cancers grow very slowly, more follow-up testing may be recommended.

For a 10 mm or smaller nodule that didn't increase, yearly screening is suggested. Screening should occur every year for at least 2 years. After 2 years, your doctors may want you to continue yearly screening. Screening isn't recommended for people with poor health, who if diagnosed with cancer would not be able to receive curative treatment.

There are three options if there were no increases in a nodule that was 10 mm or larger at baseline. Three options are given because a nodule of this size is more likely to be cancer than smaller nodules. First, another follow-up LDCT could be done. If cancer is present,

Recommendations for the Management of Subsolid Pulmonary Nodules Detected at CT: A Statement from the Fleischner Society

- "Although previous reports have suggested that pure GGNs larger than 10 mm should be resected when persistent, this decision should reflect the clinical context in which these lesions appear. This would include, for example, the patient's age, given documented prolonged doubling times. For lesions that enlarge and/or increase in attenuation, consideration should be given to surgical resection, including video-assisted thoracic surgical wedge, segmental, or subsegmental resections."

Radiology: 2013

The nonsolid nodule

- ELCAP database
- NLST database
- Comprehensive review of world literature

Current guidelines: nonsolid nodule

- Nonsolid cancers 100% curable
- Among those nonsolid nodules that ultimately do progress to become part-solid, the one year interval remained short enough so as to not allow them to progress beyond curability

Category 2 (Benign appearance or behavior)
< 1% probability of malignancy

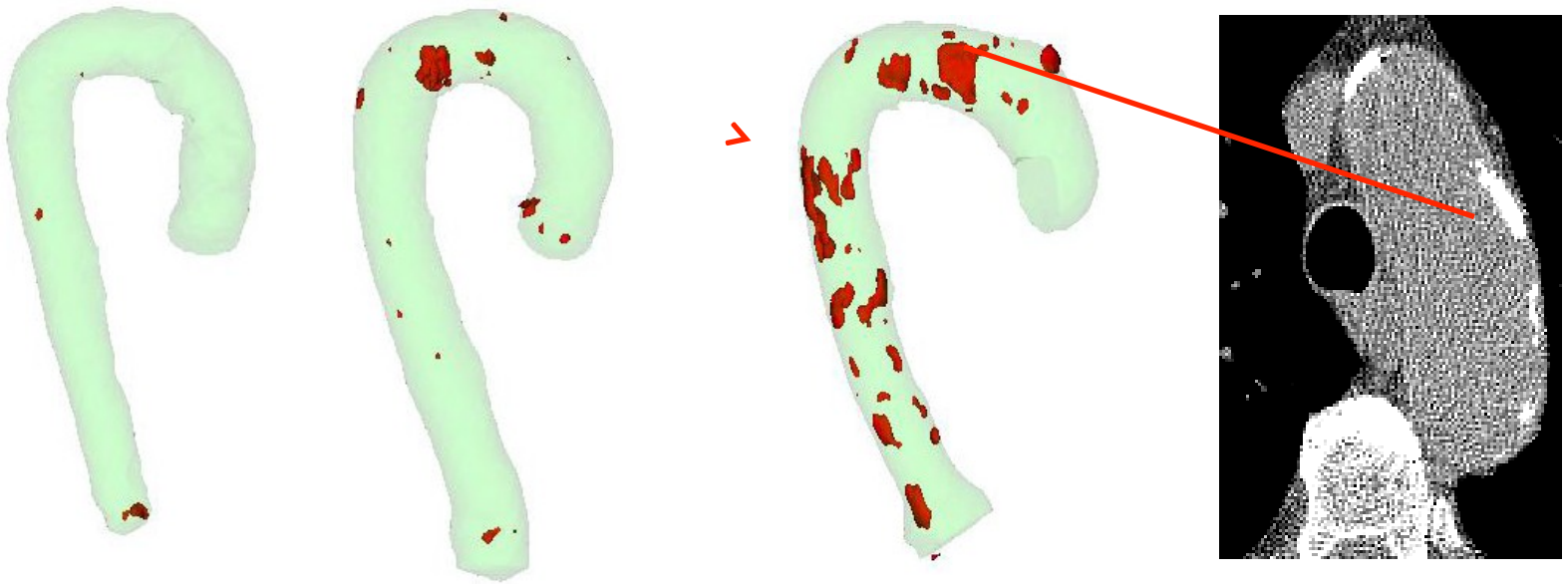
solid nodule(s): < 6 mm new < 4 mm
part solid nodule(s): < 6 mm total diameter on baseline screening
non solid nodule(s) (GGN): < 20 mm OR ≥ 20 mm and unchanged or slowly growing
category 3 or 4 nodules unchanged for ≥ 3 months

- Continued annual screening with LDCT in 12 months

Risk prediction of vascular events

- Previously demonstrated relationship between extent of SHTS exposure and coronary artery calcification
- Relationship established between extent of aortic calcification and future vascular events
- We wanted to determine if there was a relationship between SHTS exposure and extent of aortic calcification

Automated aortic calcification detection in low-dose chest CT images



AS=302 AS=3311 AS=9088

Figure 1. First three images: 3D visualization of segmented aorta (green) and aortic calcification (red) of 3 different cases and their respective Agatston score (AS). Last image is an axial slice of aortic arch with calcification and it corresponds to the 3rd visualization.

Radiology

What We Can and Cannot See Coming[1]

Christoph I. Lee, MD
Howard P. Forman, MD, MBA

From our first days of residency, we are trained to report on all of the findings that we see on each chest CT studies. Since no additional imaging is needed, these techniques appear to be cases of getting something

1 . Budoff MJ , Hamirani YS , Gao YL , et al . Measurement of thoracic bone mineral density with quantitative CT . Radiology 2010 ; 257 (2): 434 – 440 .
2 . Shemesh J , Henschke CI , Shaham D , et al . Ordinal scoring of coronary artery calcifi cations on low-dose CT scans of the chest is predictive of death from cardiovascular disease . Radiology 2010 ; 257 (2): 541 – 548 .
3 . Gondrie MJ , Mali WP , Jacobs PC , Oen AL , van der Graaf Y ; PROVIDI Study Group . Cardiovascular disease: prediction with ancillary aortic findings on chest CT scans in routine practice . Radiology 2010 ; 257 (2): 549 – 559 .

Proposition

- On the basis of these three reports (1–3), we are now venturing beyond the usual expectations for our imaging interpretations and, to some extent, potentially answering new questions that may not have been explicitly asked. This paradigm shift allows for a rich avenue of further research and development. Rather than shying away from this new responsibility, the radiology leadership should embrace the possibility of adding a new dimension to our profession…In doing so, we can also expand our role and value in the overall well-being of patients in the current climate of health care reform.

Category S (Other)

modifier - may add on to category 0-4 coding

- As appropriate to the specific finding

The end

Initiative for Early Lung Cancer Research on Treatment (IELCART)

- 1. Does limited lung (i. e. sublobar) resection provide similar outcomes as lobectomy ("usual care")?
- 2. Is it sufficient to remove the cancer itself or is it necessary to also remove associated mediastinal lymph nodes ("usual care") which adds operative time and morbidity?
- 3. When is it reasonable for "watchful waiting" of certain very indolent subtypes of Early LC rather than to perform immediate surgery ("usual care")? And, for those slow-growing subtypes, what should trigger surgery?
- 4. Under what circumstances should radiotherapy rather than surgery be considered?