Why IPN Programs are Needed Now More Than Ever

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Disclosures

- Member, Scientific Advisory Board, GO2 Foundation for Lung Cancer
- Consultant, Lung Ambition Alliance (includes AstraZeneca)

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Objectives

- Review incidence and significance of Incidental Pulmonary Nodules (IPNs)
- Outline opportunities and challenges in monitoring IPNs
- Discuss how an Incidental Pulmonary Nodule Program can improve the early detection of lung cancer
- Describe Nodule Tracking System and Lung Nodule Registry at National Jewish Health
- Describe valuable new resource – Best Practice Guide for Building Lung Cancer Early Detection Programs

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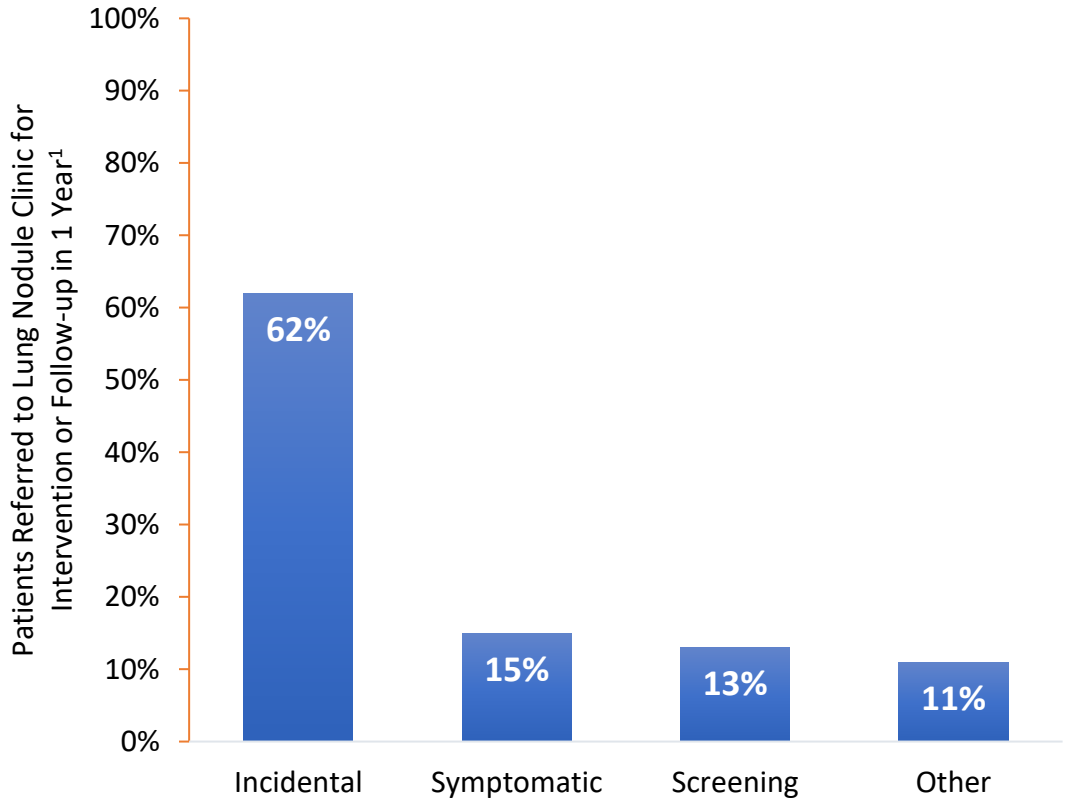
The Majority of Lung Nodules Are Incidentally Detected[1]

- In one study of 665 lung nodules[1,a]
  - 62% of lung nodules were incidentally detected on thoracic CT imaging for trauma, cardiac symptoms, or abdominal symptoms[1]
  - 15% were found In patients with symptoms attributed to lung disease[1]
  - 13% were identified in patients who qualified for annual LDCT screening[1,2,b]



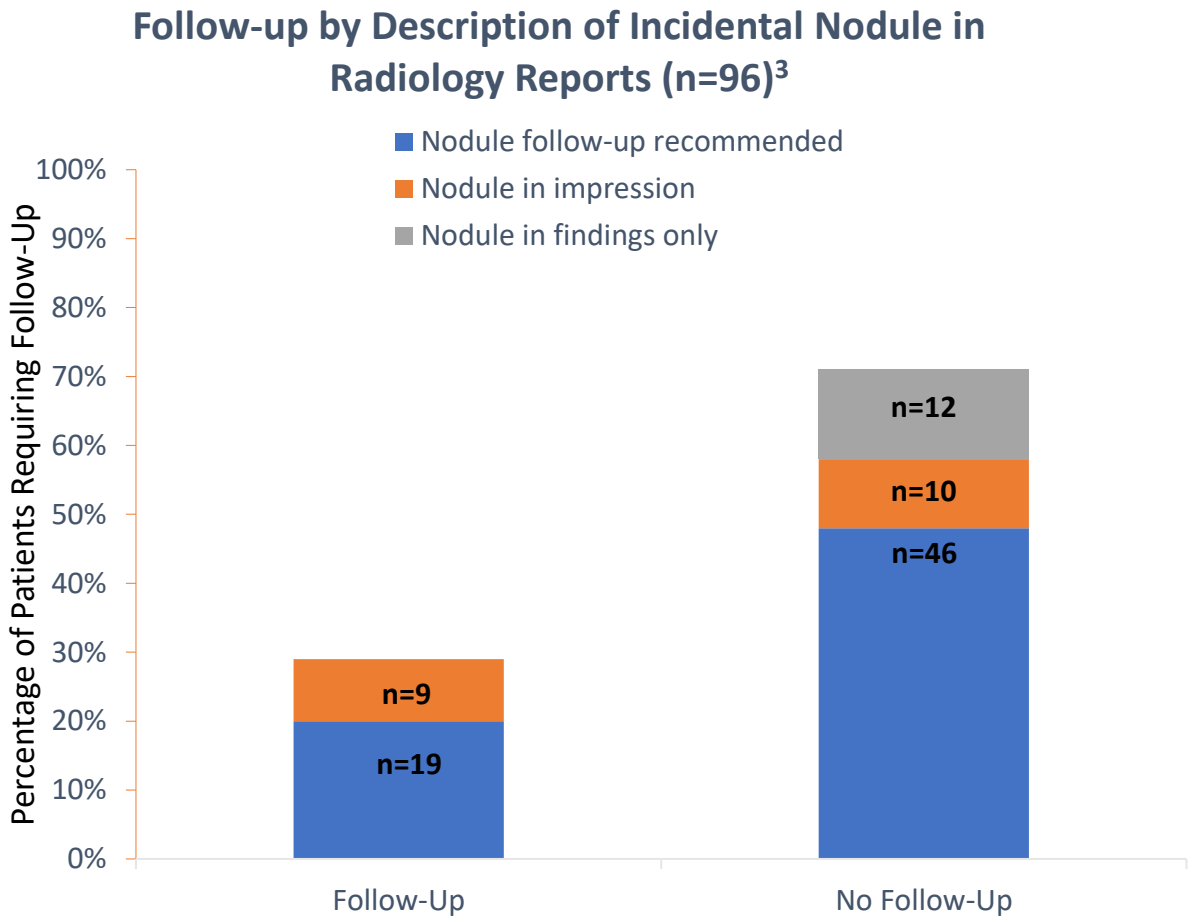
- [a]Retrospective analysis from a single-center, comprehensive lung nodule program at a community practice in Tennessee. [b]Adults aged 55-80 years who have a 30-pack year smoking history and currently smoke or have quit within the past 15 years. [c]Retropsective, observational study of chest CT imaging in KPSC, an integrated health care system, between 2006 and 2012.
- CT, computed tomography; LDCT, low-dose computed tomography.
- 1. LeMense GP, et al. *BMC Pulm Med*. 2020;20(1):115. 2. Moyer VA. U.S Preventative Services Task Force. *Ann Intern Med*. 2014;160(5):330-338. 3. Gould MK, et al. *Am J Respir Crit Care Med*. 2015;192(10):1208-1214.

Incidental Pulmonary Nodules Are Rarely Followed Up Despite the Potential Benefits for Early Identification of Lung Cancers

Approximately **2 out of 3 patients** with incidentally detected pulmonary nodules **receive no clinical follow-up**[1-3]

0% follow-up has been observed when incidental nodules are **mentioned only in the findings section** of the radiology report[3]

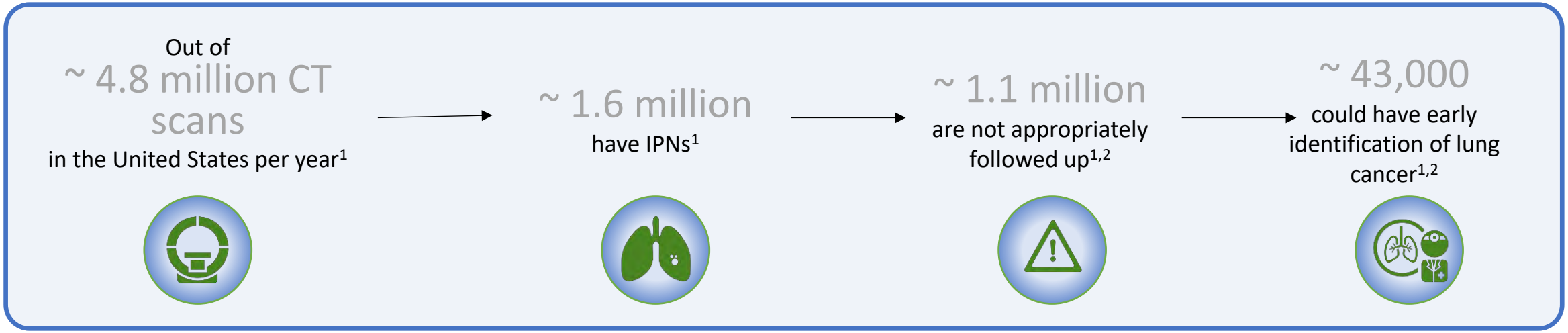
In 1 large study, the **mean time** from initial diagnosis of a pulmonary nodule **to first workup was 8 months**[2]



- 1. McDonald JS, et al. *Acad Radiol*. 2017;24(3):337-344. 2. Pyenson BS, et al. *J Health Econ Outcomes Res*. 2019;6(3):118-129. 3. Blagev DP, et al. *J Am Coll Radiol*. 2014;11(4):378-383.

Estimations Indicate That Improved Incidental Nodule Follow-Up Is Needed

- Based on the low rate of follow-up of incidental pulmonary nodules, we can estimate several lung cancer cases are missed at early-stage disease[1,2]
- 41% of NSCLC cases are identified at Stage IV disease, with a 5-year survival rate between <1% and 10%, while Stage IA disease has an incidence of 14% and can have a 5-year survival rate of up to 92%[3,4]



If follow-up was organized and consistent, more early-stage lung cancers could be identified

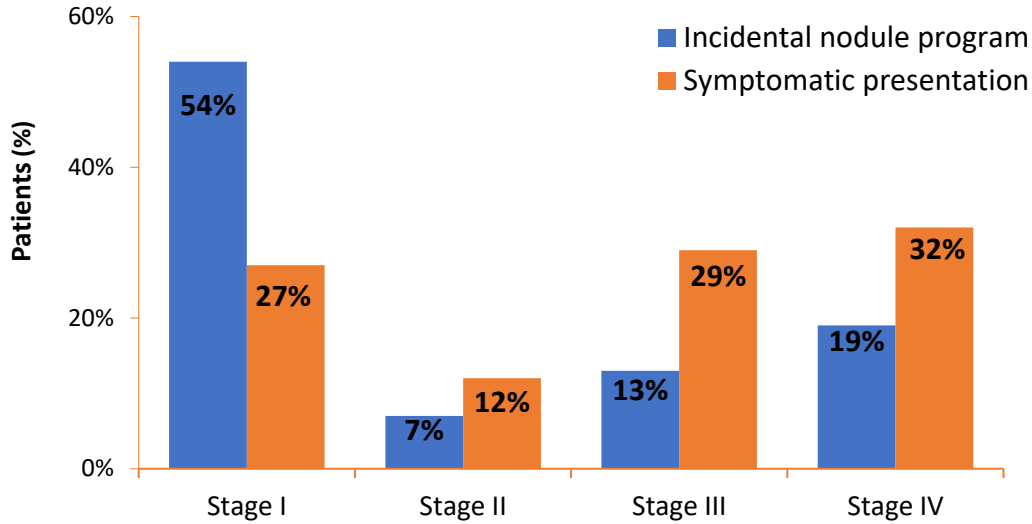
- CT, computed tomography; IPN, incidental pulmonary nodule; NSCLC, non-small cell lung cancer.
- 1. Gould MK, et al. *Am J Respir Crit Care Med*. 2015;192(10):1208-1214. 2. Blagev DP, et al. *J Am Coll Radiol.* 2014;11(4):378-383. 3. Heist RS, Engelman JA. *Cancer Cell*. 2012;21(3):448.e2. 4. Goldstraw P, et al. *J Thorac Oncol*. 2016;11(1):39-51.

Follow-up of Patients With Incidental Nodule Findings Increases Early-Stage Diagnoses[1]

Detection of **incidental nodules** on chest CT scans are common and **occur in ≈30% of all scans**[2]

Of an estimated **1.6 million patients with an incidental nodule** detected by chest CT scan in the US in 2010, **>63,000** received a **new lung cancer diagnosis within 2 years**[2]

Incidental Nodule Program Increased the Rate of Stage I Lung Cancer Diagnosis vs Symptomatic Presentation[a] (2016-2018)[1]



Robust management and follow-up of incidental nodules can lead to diagnosis of early-stage lung cancer in individuals who would not otherwise be considered high risk[1]

- [a]Symptomatic patients evaluated by a multidisciplinary committee.
- CT, computed tomography; US, United States.

- 1. Unpublished data shared with permission. Multidisciplinary Thoracic Oncology Program, Baptist Memorial Healthcare, Memphis, TN. 2. Gould MK, et al. *Am J Respir Crit Care Med*. 2015;192(10):1208-1214.

Why IPN Programs are Needed Now

- Outlook for lung cancer has improved dramatically over the last 5 years due to screening and treatment advances
- Lung Cancer still remains the #1 cancer killer
- Identifying lung cancer early is cost effective
- Lung cancer screening only reaches a small part of the population
- More and more cancers are being identified in people who have formerly smoked or never smoked
- We know how to manage lung nodules but need better systems in place for managing follow-up
- Clinicians are now more comfortable with the idea of follow-up CT and not immediate work-up
- Effective IPN Programs can result in stage shift to earlier stage lung cancers

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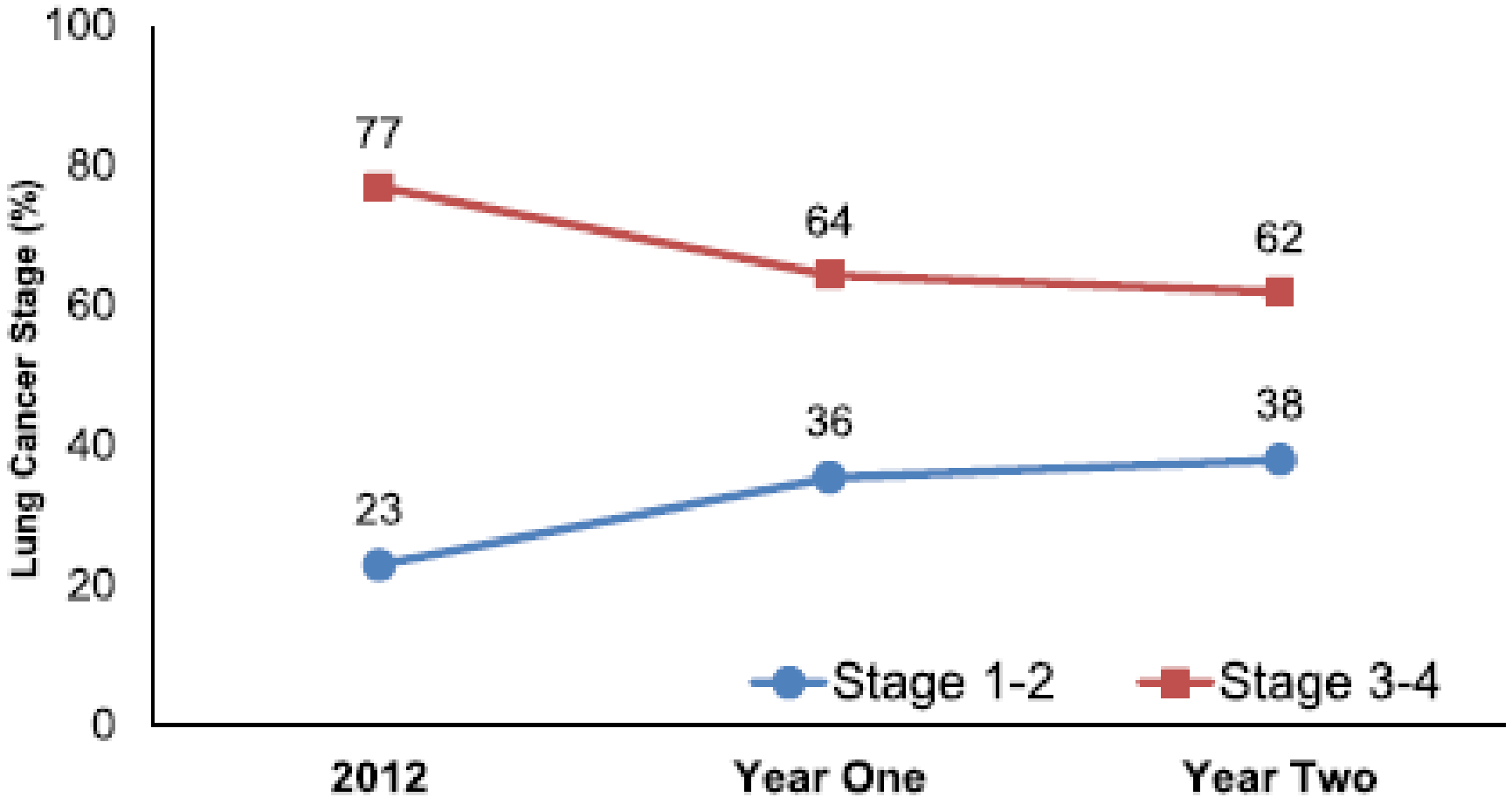
Stage Shift with Comprehensive IPN Program



LeMense GP, et al. *BMC Pulm Med*. 2020

Screening & IPN Programs in the DELUGE Study

- Lung cancer screening & lung nodule programs are complementary for the early detection of lung cancer, crossing populations of *different cancer risk*, *race/ethnicity,* and *insurance profiles*
- Early detection when curative-intent treatment is more likely & safer, has better outcomes & is less expensive
- Real-life prospective observation trial: 2015-2021 & 22,866 patients @Baptist Memorial Health Care Corporation
- Compared 3 models: 1) Screening Program 2) Nodule Program 3) Multidisciplinary Thoracic Oncology Program

	N	Lung Cancer Diagnosed		Cancer Stage (p < 0.0005)		Curative Intent Surgery (p=.0001)	Postop 120 Day Mortality (p=.0053)	Survival Rates (p<.0001)		LCS Eligible	Smoking	Race & Ethnicity	Insurance
		N	% of all cancers	I & II	IV			3-yrs	5-yrs	USPSTF '13/'21	Current/Former/Never (P<.0001)	White/Black/Hispanic (P=.0005)	Medicare/Medicaid/ Commercial (P<0.0001)
Screening	5659	150	8.1%	61%	19%	47%	0%	80%	76%	89% / 91%	67%/32%/.3%	80%/18%/.3%	62%/3%/34%
Nodule	15461	698	37.6%	60%	20%	42%	4%	64%	60%	43% / 49%	28%/37%/28%	66%/29%/1.4%	49%/2%/38%
MTOC	1766	1010	54.4%	44%	29%	32%	8%	49%	44%	43% / 52%	38%/40%/21%	67%/30%/1.7%	34%/14%/48%
Total	22866	1858	100%	51%	25%	37%		57%	53%	46% / 54%			

Osarogiagbon et al. *J Clin Oncol* 2022

Why Now? Additional Opportunities

- More advanced treatment options including surgical techniques and radiation therapy that are less invasive and with less co-morbidity
- Availability of risk stratification models to tailor appropriate management and avoid unnecessary procedures
- Improved CT technology and AI tools are available to more accurately characterize nodules and measure growth
- Recognition of importance of multidisciplinary teams to help guide management and treatment decision
- More and more chest imaging is being performed such a Coronary CTA which is not surprisingly leading to the identification of more pulmonary nodules

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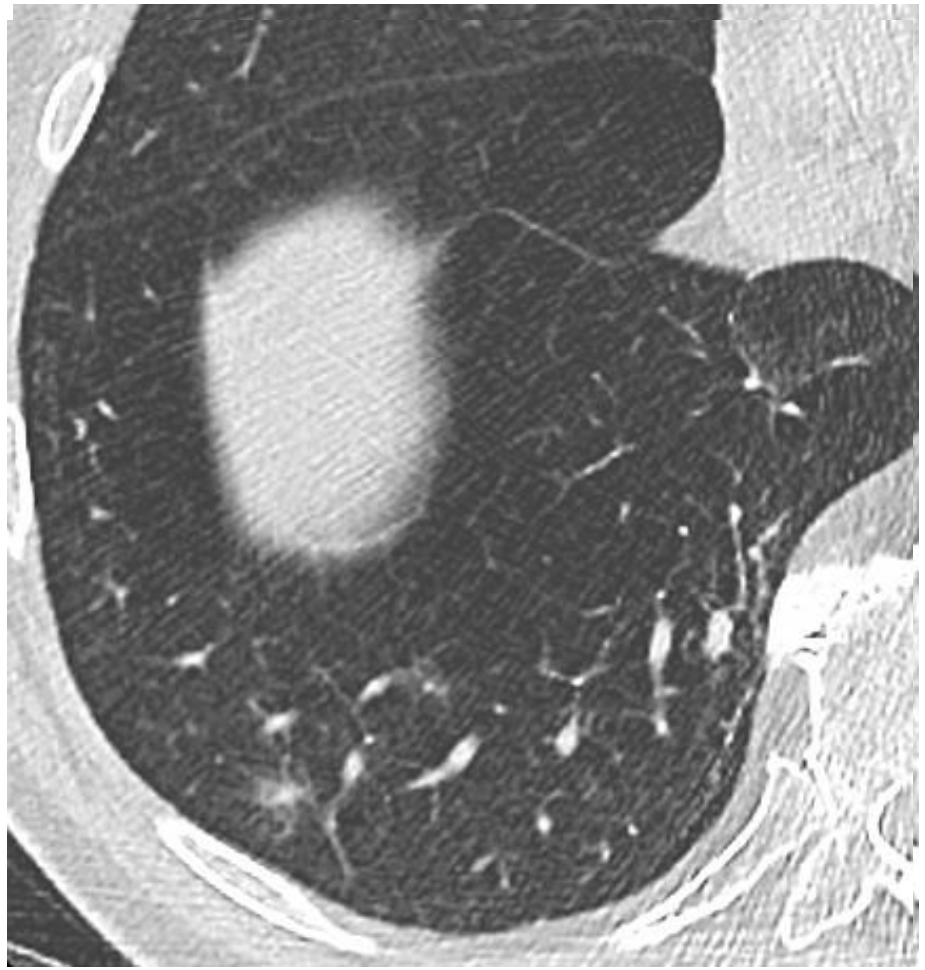
Part solid nodule on
Calcium Scoring CT 12/24/24

Outside Prior
Chest CT 1/27/23



Challenges in IPN Management

- Not all nodules require follow-up
- Many indeterminate nodules can be managed with CT monitoring and do not require immediate escalation of care to PET or biopsy – it is important to have an IPN program to help guide this care and decide which nodules need immediate intervention and which can be monitored with CT follow-up
- Some malignant nodules, such as some subtypes of adenocarcinoma that appear as pure ground glass nodules, are very indolent and may be better managed with follow-up CT than aggressive treatment

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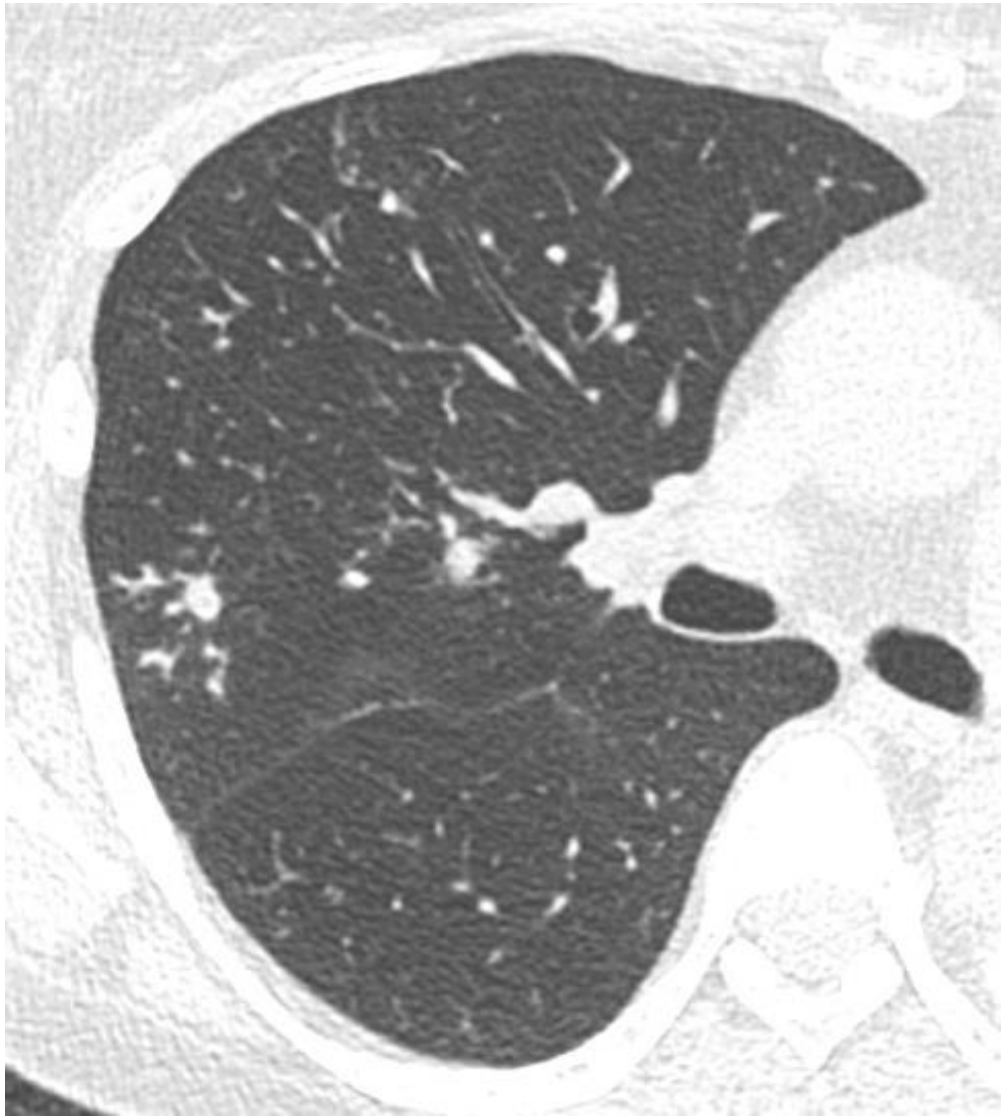
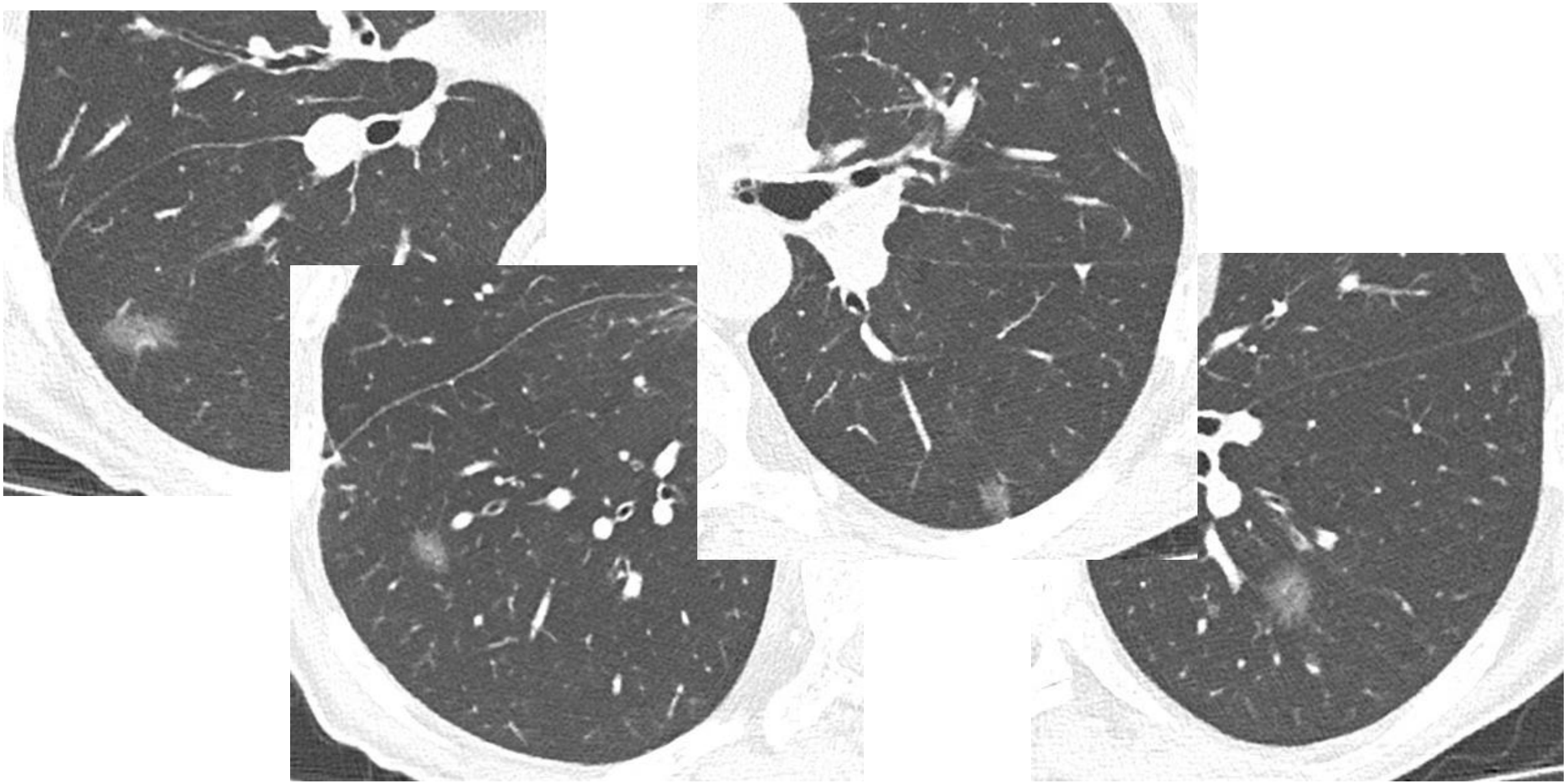
Not all nodules require follow-up



New tree-in-bud nodularity 12/20/24

Prior 11/22/23

Multiple bilateral ground glass nodules, stable over time



Incidental Lung Nodule Follow-up

- There is considerable variation among radiologists in how they report and manage lung nodules
- Follow-up is less likely to happen:
  - When IPNs are mentioned only in the Findings section of a report and not in the Impression
  - When there is no convenient infrastructure embedded in the dictation system for radiologists to provide follow-up recommendations
- Without clear concise recommendations from the radiologists, clinicians are relying on software tools with NLP to identify suspicious nodules
- Radiologists can adopt a standardized approach to nodule reporting and tracking and provide a valuable front-end to IPN Programs

Pyenson BS, et al. *J Health Econ Outcomes Res*. 2019; Blagev DP, et al.. *J Am Coll Radiol*. 2014; McDonald JS, et al. *Acad Radiol*. 2017; Dyer et al, *J Am Coll Radiol* Feb 2021

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IPN Programs

Advantages	Challenges
CT already done	Numerous referring providers including ER
No “Eligibility” criteria	No pre-imaging commitment to diagnosis and treatment
Routine Chest CTs and CTAs	Often no dedicated staff or resources
Very high volume performed	Need system for tracking follow-up
High yield due large volume	
Established guidelines available (Fleischner)	

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IPN Management Program at National Jewish Health

- Development of Tracker phrase system based on Fleischner Society guidelines
- Radiologists provide Tracker phrases at the end of their reports which initiates the tracking process
- Tracker phrases are imported into NJH Lung Nodule Registry
- The Registry monitors patient compliance with needed follow-up
- Patients with suspicious nodules are reviewed at weekly Suspicious Nodule Conference

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Lung Nodule Registry Process

- Registry is facility-built SQL database
- Imports Tracker phrases from radiology reports
- Determines patient's lung cancer risk (high or not high) based on EHR data
- Calculates due date for follow-up CT
- Generates monthly report of patients who are one month overdue for follow-up CT
- Reminder letter generated to patient with copy sent to referring provider

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Menu of Tracker Phrases based on 2017 Fleischner Society Guidelines

For CT Follow-up:

- Track 3
- Track 6
- Track 12
- Track 12opt
- Track ad hoc

For Other Actions:

- Track Dx
- Track Complete
- Track Amend

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Sample Tracker Phrases

Voice Command	Cryptic Phrase	Print out on CT looks like this:
Track 3	**(Track 3)**	**Reduced-dose Chest CT is recommended in 3 months**
Track 12	**(Track 12)**	**Reduced-dose Chest CT is recommended in 12 months**
Track Diagnostic	**(Track Dx)**	**Diagnostic studies such as PET-CT or tissue sampling are recommended. If such studies are not clinically indicated or feasible, reduced dose Chest CT is recommended in 3 months.**
Track Complete	**(Track Complete)**	**Further follow-up of the lung nodules(s) is not recommended at this time.**

IMPRESSION:

1. Mild emphysema compatible with smoking related lung disease.
2. 8.5 mm solid nodule in the left lower lobe. Recommend follow-up chest CT in 3 months.

LUNG NODULE RECOMMENDATION (**Track3**)(for NJH Patient Tracking System)
The recommendation for follow-up interval is based on Fleischner Society guidelines. Clinical indications may supersede the recommendations.

Recommend reduced-dose chest CT in 3 months.

Track Dx

- The radiologists flag nodules as suspicious for malignancy with the use of “Track Dx”
- CTs assigned this phrase indicate the need for immediate work-up such as PET-CT, biopsy, or surgical referral
- The patients are automatically referred to weekly Multidisciplinary Suspicious Nodule Conference
- Approximately 30% of Track Dx nodules are diagnosed with lung cancer

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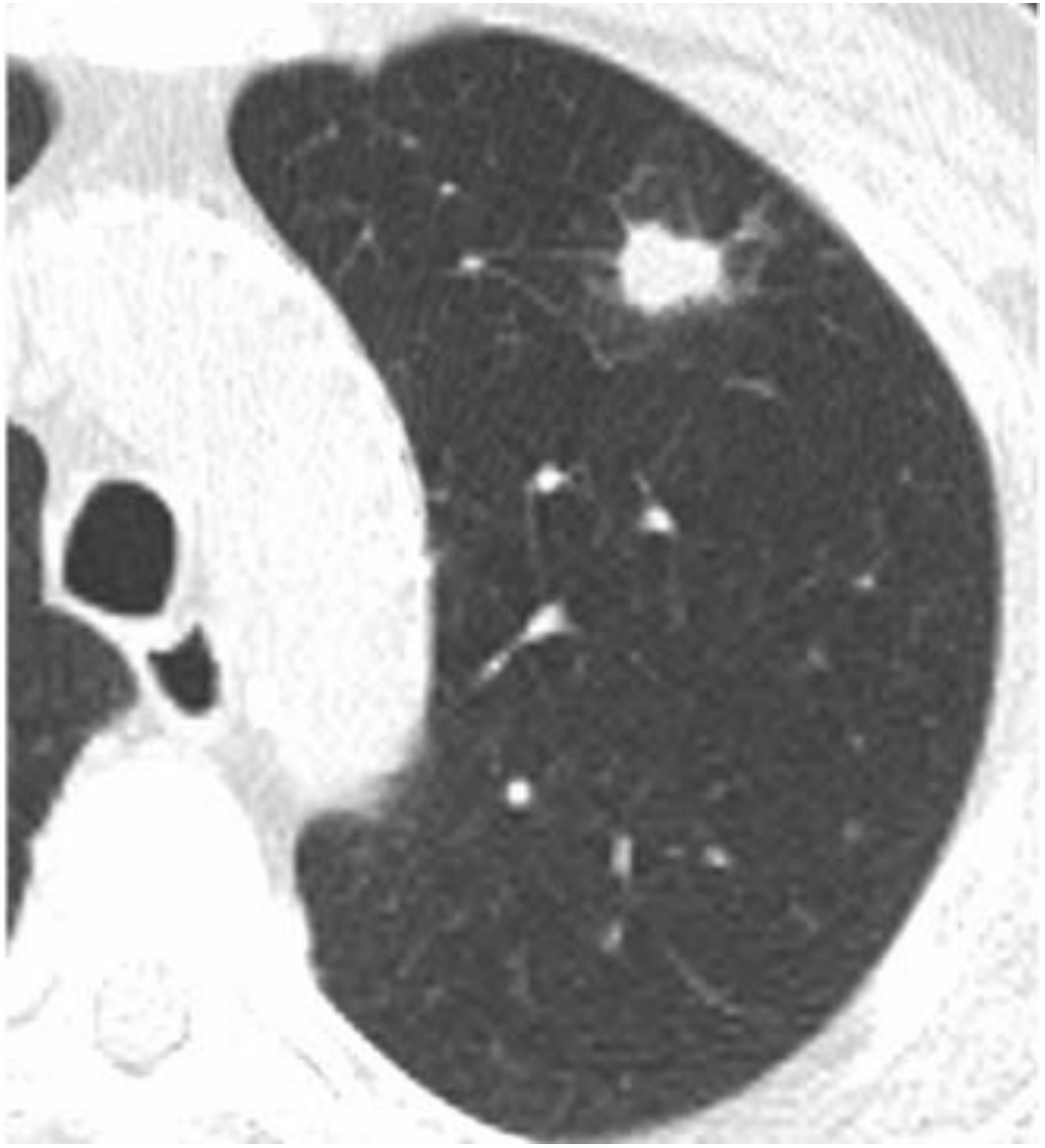
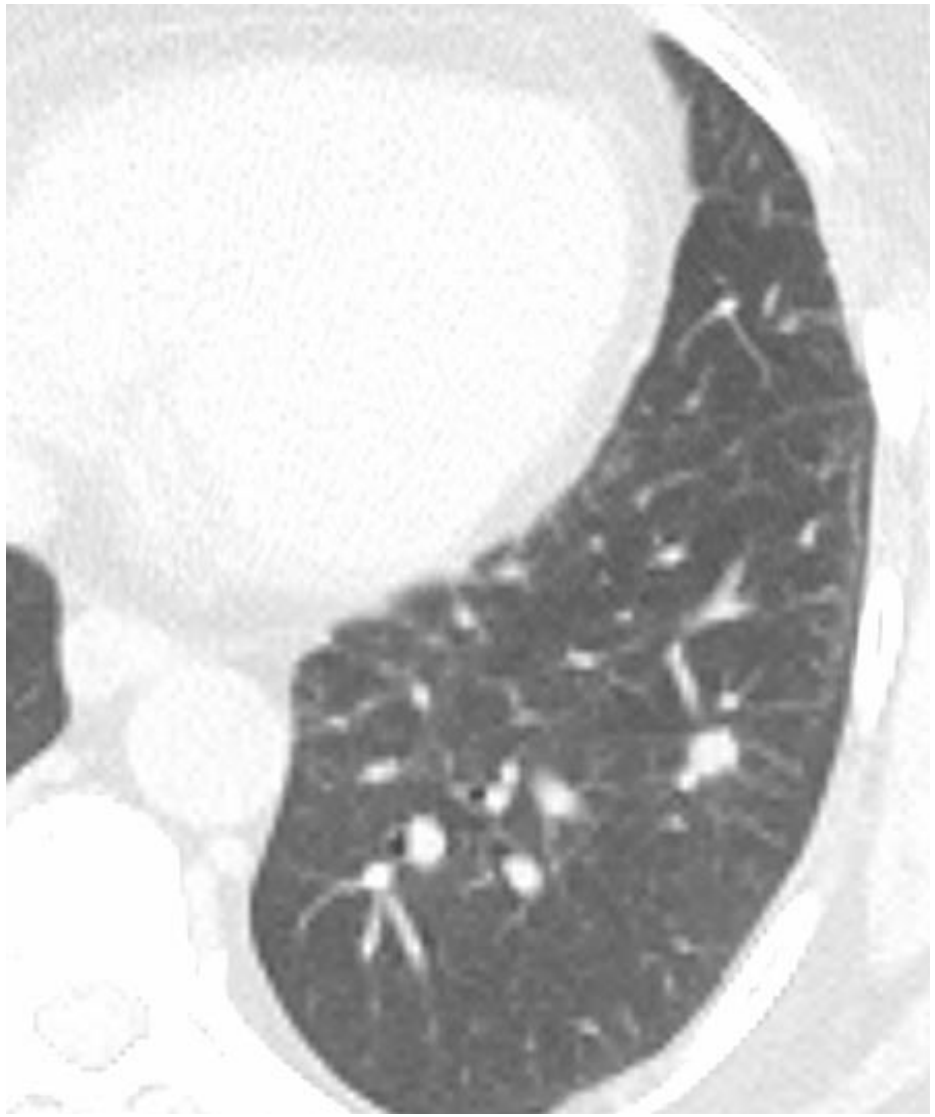
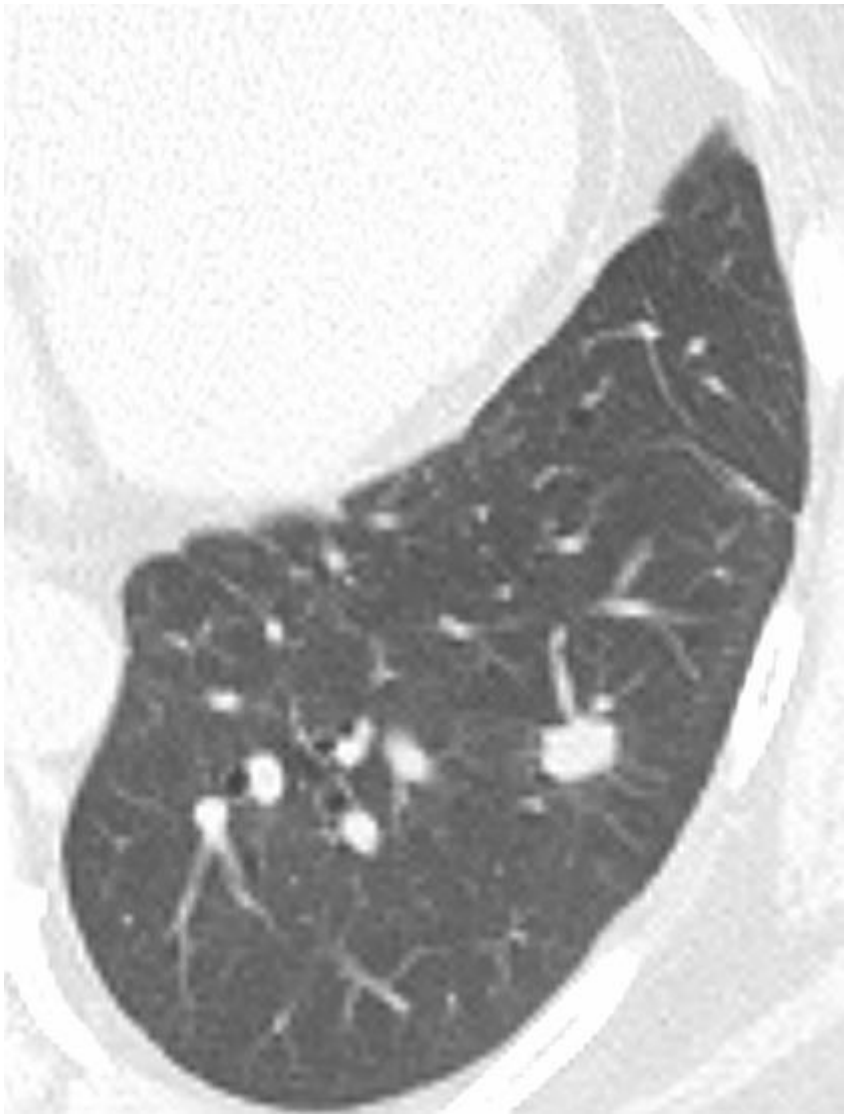
Track Dx Nodule



Track 12



12 months later
now Track Dx



Weekly Nodule Conference Summary

LAST name	MRN	Date of Interpretation @ NJH	Date of Outside exam (if appropriate)	Lung RADS	Tracker Phrase	Size (mm)	Location	Tammimagi Risk %	Vancouver Probabil of Malig %	Referring Provider	Recommendation
XXXXXX	XXXXXXX	9/13/2021		4B		23	LLL	1.6	29.5	XXX	Rad rec: Tissue sampling Conf rec: CT-guided biospy
XXXXXX	XXXXXXX	9/9/2021		4A		10	RUL	1.3	13.5	XXX	Rad rec: Follow-up CT in 3 months Conf rec: Follow-up CT in 3 months
XXXXXX	XXXXXXX	9/9/2021		4X		27	LUL	5.5	36.6	XXX	Rad rec: Tissue sampling Conf rec: Referral to IP for Bronchoscopy
XXXXXX	XXXXXXX	9/8/2021		4B		15	RLL	3.9	32.4	XXX	Rad rec: Follow-up CT in 4-6 weeks Conf rec: Follow-up CT in 4-6 weeks
XXXXXX	XXXXXXX	9/13/2021	8/30/2021		Trackdx	9	RUL		16.4	XXX	Rad rec: PET/CT Conf rec: PET-CT and referral to IP
XXXXXX	XXXXXXX	9/9/2021	7/30/2021		Trackdx	17	LUL		59.3	XXX	Rad rec: Tissue sampling Conf rec: Follow-up CT in 3 months
XXXXXX	XXXXXXX	9/9/2021			Trackdx	14	LLL		9.5	XXX	Rad rec: Tissue sampling Conf rec: Referral to Rad Onc
XXXXXX	XXXXXXX	PET-CT 9/13/2021			Trackdx	15 (SUV 3)	LLL		16.6	XXX	Rad rec: Tissue sampling Conf rec: Referral to Thoracic Surgery

The NJH Experience

- We found a 41% increase in timely follow-up after implementation of the Tracker Phrase System and Lung Nodule Registry
- The Tracker System has been used consistently by our radiologists since 2011 and has been easily adopted by new radiologists
- The addition of simple tracker phrases provide clear messaging in radiology reports that can imported into a Lung Nodule Registry
- The computerized registry allows patient follow-up to be tracked and automatic communication when exams are overdue.

Dyer et al, *J Am Coll Radiol* Feb 2021

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Impact of Tracking System on Stage of Lung Cancer

- Retrospective review of 937 cases of primary lung cancer, 2008 – 2016 with at least one chest CT performed at NJH
- Patient excluded if Lung Cancer Screening CT, if first and only CT resulted in immediate cancer diagnosis, if last chest CT > 2.5 years since cancer diagnosis
- Of 314 remaining patients with diagnosed with Lung Cancer, 200 were Early Stage (Stage I) and 114 were Later Stage (Stages II – IV or not staged)

Carr et al *JTOCRR* 2022

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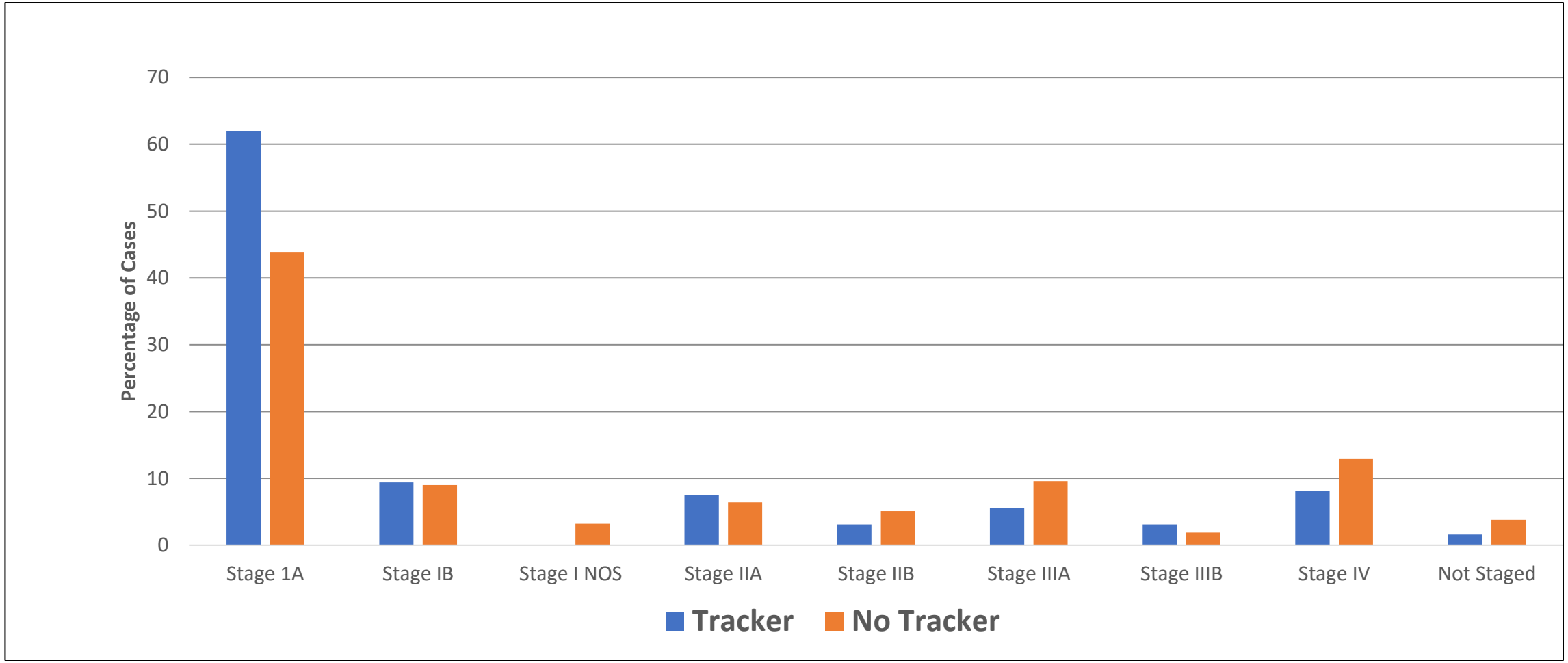
IPNs: Cancers by Stage, Tracker vs No Tracker



Tagging System by Radiologists in large health care system

- Intervention: Radiologists added “#PUL”tags (PUL 0 – 6 and PUL X) to radiology reports for chest CTs
- 39409 patients had tagged CT reports over 2 years
- 1105 (2.8%) new primary lung cancer diagnoses within 120 days of suspicious nodule identification
- Tagging system (with multidisciplinary review and case management) was found to have high sensitivity (74%) and low number needed to diagnose (2.7) for identifying new lung cancer

Dusendang et al, *Perm J* 2021

American Cancer Society | NATIONAL LUNG CANCER ROUNDTABLE

Best Practice Guide for Building Lung Cancer Early Detection Programs

How to Use This Guide

This guide is organized into three sections representing the phases of developing a lung cancer early detection program, each of which contains several activities. If you are starting a lung cancer early detection program from the very beginning, it is recommended to work through the sections in order, recognizing that the activities within or across sections can often be worked on simultaneously. If you already have a lung cancer early detection program, many of the components may already be in place; in this case, choose the sections that are most applicable to your program.

PHASE 1

Needs Assessment and Making the Case

- Define Your Community Need
- Define Your Health System or Facility Benefits
- Identify Your Clinician Champion(s)
- Identify Key Supporters and Influencers
- Making the Case to Leadership

PHASE 2

Program Planning

- Identify Your Planning Team and Key Partners
- Define and Develop Program Model
- Design Clinical Workflow
- Build Administrative Infrastructure
- Identify Technology Infrastructure Needs and Potential Solutions
- Define Key Performance Indicators

PHASE 3

Implementation and Sustainability

- Develop Your Education and Engagement Plan
- Run a Pilot
- Monitor Program Outcomes
- Support Adherence to Recommended Follow-up

Basic Models for IPN Management

Health System/Facility IPN Management Program Responsibility

- Patient and CT ordering provider are informed about IPN by the radiology report; when the ordering provider is not the PCP, the program staff also includes them in communications.
- Program team orders and manages the follow-up diagnostic tests or referrals within the health system or externally, depending on available expertise, and tracks patients to ensure that care is occurring on a timely basis.
- Referring provider and/or patient's PCP are informed about next steps as care management occurs and may provide important information about the patient's comorbidities or patient preferences based on their established relationships.
- When IPNs are detected during hospitalization or an ED visit, the program staff make sure that the PCP is aware of the IPN and next steps. When the patient has no PCP, the staff works directly with the patient, or works to establish a PCP for the patient.
- Program tracks quality of care metrics.

Ordering Provider Responsibility

- Provider who ordered the radiology exam and patient both receive the radiology report describing the IPN and recommended follow-up.
- The ordering provider is responsible for either completing next steps for diagnostic tests or specialist referrals with patient discussion, or handing off care to the patient's PCP to complete if the ordering provider is not the PCP.

Shared Responsibility

- Ordering provider of the radiology exam and patient both receive the radiology report describing the IPN and next steps in management, and the ordering provider receives an additional communication by a radiologist or radiology practice staff.
- Radiology practice or the health system/facility supports navigation by tracking to make sure the follow-up or referral occurred with reminders to ordering providers and/or patient and may actively schedule the next test or referral.

Lung Cancer Screening	IPN Management

Elements for Radiology Reporting Workflow

- Lung-RADS® templates and/or structured reporting tool
- Reporting system that standardizes tagging of chest CT and other radiology examination reports describing IPNs by the interpreting radiologist or other physician
- Future tools currently under development: Using natural language processing, AI technology, and algorithms to identify and alert clinical team for review

Considerations for Selecting Patient Management and Data Tracking Software

- Feasibility of implementation
- Cost
- Functionality and interoperability with existing technology
- Impact on workflow
- Detection and reporting of findings
- Submission to registries
- Performance measurement and metrics reporting
- Training and support
- Future development plans
- End-user interface and ease of use
- Data collection capabilities
- Manual entry requirements
- End-user autonomy over platform configuration and letter updates
- Security of both system and personal health information (PHI)

Summary

- Incidental Lung Nodules are common but follow-up is often variable or lacking
- Improved technology and more widespread use of chest CT indicate need for IPN programs now, more than ever!
- Appropriate management of IPNs through an IPN Program can lead to a stage shift to early stage lung cancer
- An IPN Program is an important adjunct to LCS and essential for the Early Detection of Lung Cancer

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