



UNITED STATES  
DEPARTMENT OF VETERANS AFFAIRS

 UCSD



LUNG  
FORCE  
EXPO

## Lung Cancer Screening:

Maximizing Gain ... and *“Dealing with Pandora’s Box”*

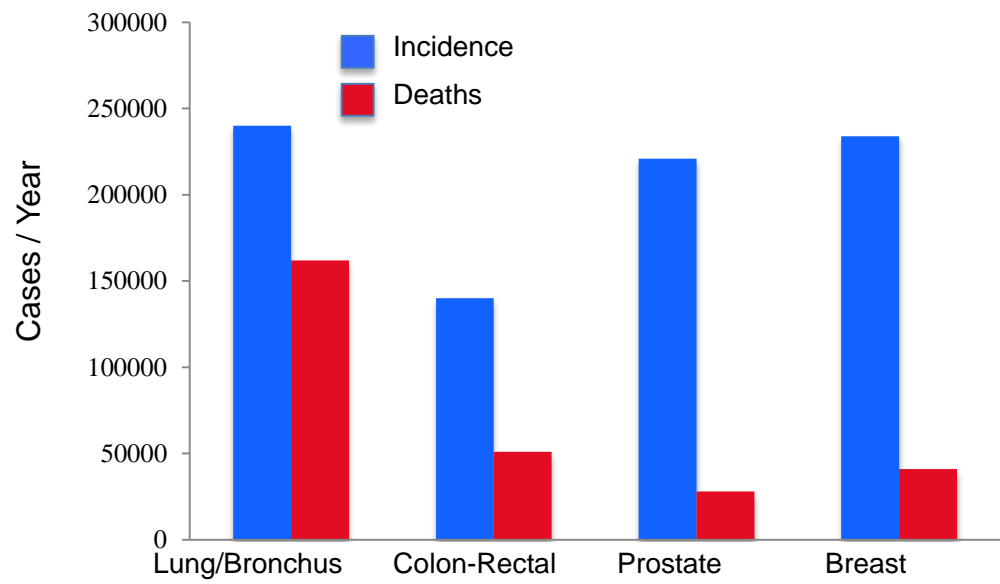
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# Lung Cancer

## Mortality: The Reality

- **Leading cause of cancer death**
- **U.S. 2015 estimate 158,040 deaths**
- **5-year survival ~17% at best**

- 1. Cessation “Front”**
- 2. Screening**  
(Lung: Low Dose CT Scanning)



Siegel RL, et al. CA Cancer J Clin, 2015

**Goal:** Early Surgical (or Radiotherapy-) Elimination of disease  
**Challenge:** Early metastatic aggression

# Why a Screening Program ?

## Other Considerations and **Screening**:

- Advanced stage at diagnosis is common  
(only about 30% stage I-II)
- Lung cancer screening may detect earlier-stage disease  
(when resection or curative radiation can achieve >50% long-term cure)

### **Principles of Screening**

- Diagnose disease early in asymptomatic patients.
- Detect diseases that respond better to early vs late treatment.
- Ensure the benefits of treating the small number of patients who will receive a disease diagnosis outweigh the harms associated with screening a large number of healthy individuals.

# Low-dose CT: The NLST – Some Facts

A Randomized Trial: NEJM August, 2011: NLST (USA)

Screened 53,454 patients (2002-2004 enrollment with f/u thru 2009)

**LDCT vs CXR yearly X3** in Hi Risk Population:

Heavy current or former smokers age **55 – 74** with **any use within last 15yrs**; and **>30 pack-yrs use**

“Low Dose” CT ? **Approx 1/5 amount of gamma irradiation** as conventional diagnostic chest CT

Lung Cancer Mortality and Screening Trial Success:

**20% relative reduction in mortality**

NNS: **Number needed to screen** w/ LDCT to prevent 1 lung cancer death: **320**

**Overall Mortality:**

LDCT group: significant **reduction: 6.7%**

**AT WHAT COST ??**

# “The Balance Sheet”

## Study Findings: Low-dose CT versus Chest X-ray screening

53,454 current and former smokers were randomly assigned to be screened once a year for 3 years with low-dose CT or chest X-ray. Here’s what happened after an average of 6.5 years:

|   | Low-dose CT<br>26,722 people |        | Chest X-ray<br>26,732 people |
|---|------------------------------|--------|------------------------------|
| <b>Benefit: How did CT scans help compared to chest X-ray, an ineffective screening test?</b>                 |                              |        |                              |
| 3 in 1,000 fewer died from lung cancer  | 18 in 1,000                  | versus | 21 in 1,000                  |
| 5 in 1,000 fewer died from all causes   | 70 in 1,000                  | versus | 75 in 1,000                  |
| <b>Harm: What problems did CT scans cause compared to chest X-ray?</b>  |                              |        |                              |
| 223 in 1,000 more had at least one false alarm  | 365 in 1,000                 | versus | 142 in 1,000                 |
| 18 in 1,000 more had a false alarm leading to an invasive procedure, such as bronchoscopy, biopsy, or surgery | 25 in 1,000                  | versus | 7 in 1,000                   |
| 2 in 1,000 more had a major complication from Invasive procedures   | 3 in 1,000                   | versus | 1 in 1,000                   |

### Possible patient thoughts/ considerations in discussing screening:

*“I as a patient appreciate 3 or 4 less deaths in every 1000 screenings – I might be one of the saves!”*

*“I don’t want to be among 39% with a Positive Test! ...invasive testing, and possible complications!?”*

*“I just don’t care to know ... Leave me alone!”*

# NLST “Translation” Critiques/Concerns

- Healthy-volunteer effect (bias results: more favorable since patients actively seek out care/diagnostic testing)
- Surgical expertise in centers was excellent  
*How is this a problem ?? Not reflective of nation-wide average...*
- Hi rate of false positive results  
*Must deal with heavy nodule follow-up*
- Radiation Effects?  
*Difficult to measure effects of (low-level) Rad. -- follow-up needed*

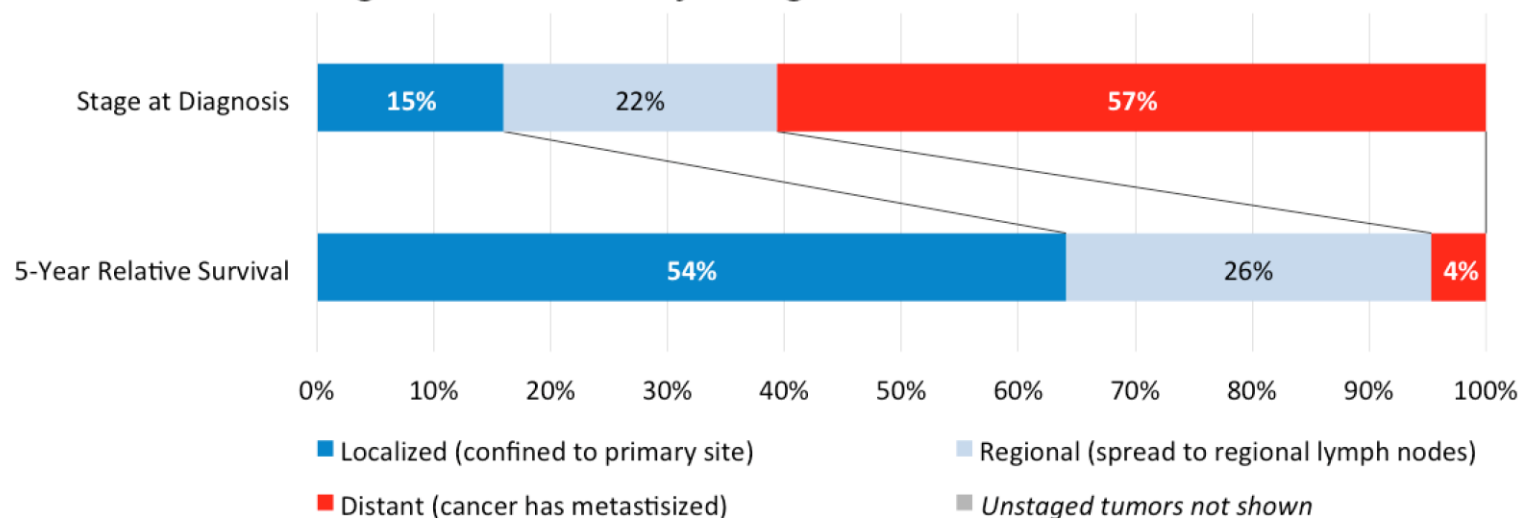
## Diagnosis of Lung Cancer:

LDCT group: 1060 w/ lung cancer: **649** after (+) screen, **347** after screening phase completed  
(**70%** diagnosed at early-stage I or II)

CXR group: 941 w/ lung cancer: **279** after (+) screen, **525** after screening phase completed  
(**57%** diagnosed at early-stage I or II)

## Survival

- Higher for cases diagnosed early
- Few cases diagnosed at early stage



## The Task Force Recommendation on Lung Cancer Screening With Low-Dose Computed Tomography

The USPSTF recommends annual screening for lung cancer with low-dose computed tomography (LDCT) in persons age 55 through 80 years with a 30 pack year history of smoking who are currently smoking or have quit within the past 15 years. Screening should be discontinued once the individual has not smoked for 15 years or develops a health problem significantly limiting either life expectancy or ability or willingness to undergo curative lung surgery.



# Enter the “Pandora’s Box” ...

- Risk:Benefit “trap” in a fragile/sick population?
- “New findings” on CT – “follow-up and what next...?”
- Many risks beyond tobacco exposure: Family history, Asbestos, COPD... **Screen?**



# Resources: “The Elements”

## People:

### Screening:

Pulmonary  
Radiology  
Primary Care

### Downstream Services:

Pulmonary/ Interventional  
Radiology/ Interventional  
Cardiothoracic Surgery  
Radiation Oncology  
Medical Oncology

## Screening Intake

- Qualification: USPHTF Tob/Age criteria
- No terminal illness or recent CT scans

## Nodule Protocol

- Referral from Pulm or Primary Care
- General flow through system with Algorithm

## LungRADS

- Database/program – Radiology software
- Dictation templates, Intake forms, patient letters

## Tumor Board

- Multidisciplinary Meeting: Dx-Stage, Treatment



*“A 3 Hour Tour...”*

## Research

- Can we “**Enrich**” who’s at risk?  
Improve **specificity** ??
- Patient Risk Calculator scores
- Other Nodule data
- Banked blood/urine/cells

# Early Challenges

*“The weather started getting rough...”*

## Follow-up and Communication

- Education, psychological support
- Patient understanding of flow within system
- Consequences of Poor Quality !

## Cost

- Data Entry, Scheduling, Coordinator(s)
- Consider downstream revenue (balance vs. cost)



## Integration

- Build-in program into targeted CT scans in lung disease patients (e.g., COPD)
- Primary Care
- Smooth integration of sub-specialty referrals for (+) Scans

## Practitioner Education

- Primary Care intake
- Primary Care follow-up of positive nodules <1cm
- Primary Care referrals to Pulmonary  
(nodules >1cm, growth, or hi-suspicion malignancy)

# Comprehensive Lung Cancer Screening Program...

*When all the following criteria are met:*

- Systematic way to **identify high-risk patients** who meet screening criteria
- Patient **education materials** for shared decision making
- Clinical **coordinators** to coordinate care of patients undergoing lung cancer screening
- **Smoking cessation program** – May save more lives than the Screening Program !!
- Standardized screening and **follow-up guidelines** (Radiology-LungRADS)
- Sufficient **capacity** in primary care, pulmonary, CT surgery, medical oncology
- **Tracking system/registry** for all patients in program  
(including those with nodules and incidental findings)
- Evaluation program to **monitor outcomes**

# Preperatory Considerations for Lung Cancer Screening

## First-thoughts on Scale and Safety in taking on a “Pilot” Effort:

Prelim West Haven VA experience (2014) – Roughly similar-size outpatient base as VA San Diego  
Over initial 6 months: Approx 1100 screened; 170 had a lesion >8mm size (Can we handle this?)

- High likelihood of intervention by Pulm/Rad/IR/Surg Svcs.
- If we “scale” our effort to 1/4 this size – Reasonable goal to safely start at Primary Care level

### CLINICAL EFFECTIVENESS

Kim A. Eagle, MD, and Elizabeth A. Jackson, MD, MPH, Section Editors

THE AMERICAN  
JOURNAL of  
MEDICINE®

## Implementation of an Electronic Clinical Reminder to Improve Rates of Lung Cancer Screening

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## - To “oil” our system:

*Initiated Lung Cancer Screening in Pulmonary Clinic*  
Integrated Nurse Manager

# Team and Resources

## Team:

Pulm Section, Nurse Manager, Radiology, Primary Care *Informatics, Leadership support!*

**LDCT requirement;** Challenge in blocking **full-dose CT scans** outside of Pilot effort

## Radiology partnership and Resources:

- Buy-in from Readers – Adoption of LungRADS LDCT scoring
- Scanners: current status = one part-time; 2<sup>nd</sup> dedicated coming (Started: ~ 2 LDCTs/week)

### ***Protocol: LDCT Acquisition Parameters***

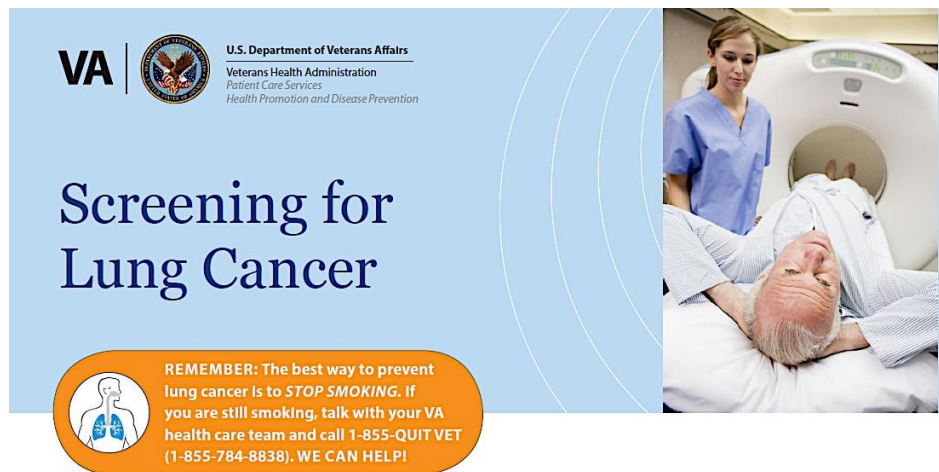
|                          |  |
|--------------------------|--|
| Scout                    | PA to reduce breast dose   |
| kVp                      | 120  |
| mAs                      | no more than about 25 for average size patients<br>no more than about 50 for obese patients<br><br>alternatively use automatically variable mA to achieve less than 3 mGy dose |
| Detectors                | 16 or more so study can be acquired in one breath hold   |
| Detector collimation     | between .625 and 1 mm  |
| Reconstruction thickness | 1 to 1.25  |



# Individual Patient Informing/Reporting/Actions

## Provider/ patient Discuss in clinic

- Inform eligibility: Benefits/Risks discussion (Handout)



VA | U.S. Department of Veterans Affairs  
Veterans Health Administration  
Patient Care Services  
Health Promotion and Disease Prevention

## Screening for Lung Cancer

REMEMBER: The best way to prevent lung cancer is to *STOP SMOKING*. If you are still smoking, talk with your VA health care team and call 1-855-QUIT VET (1-855-784-8838). WE CAN HELP!

### Should I be screened for lung cancer?

You should consider being screened if you have all three of these risk factors:

### Why do we not screen everyone?

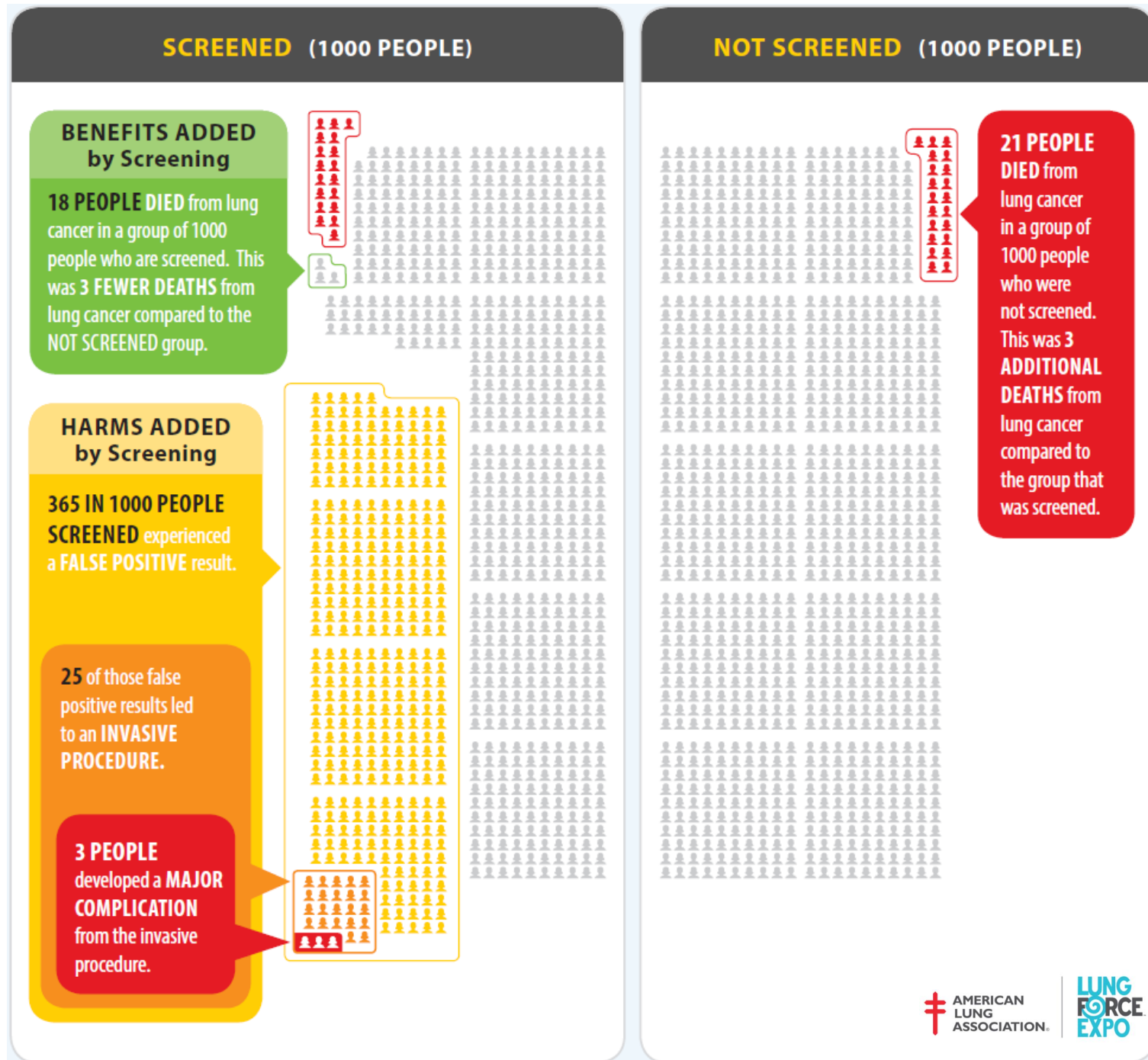
- There is no proof from research that it is best to screen everyone.
- Screening everyone can cause more harm than good. False alarms lead to more testing and risk of harm.

- Scan obtained: Patient informed by Pulmonary Fellow with follow-up secured. (Radiology Report has LungRADS score and Recommendation)
- A formal Radiology letter to provider/patient needed  
Esp. upon Primary Care Implementation
- **Pulm Diagnostic Clinic** referral for “Positive Lesions” with >1-2% risk

# Risk/ Benefit:

An honest discussion with patients regarding the benefits vs. harms  
“Shared Decision-making”

Different patients will have different values and risk tolerance





# Implementation

## Ordering and Notification with Follow-Up:

- CPRS Order with automatic notification to Nurse Case Manager (+ ordering provider)
- Patient approved (criteria) and Protocol-entered by Radiologist → Scheduled → Scanned

Order an Imaging Procedure

Imaging Type: CT SCAN

Imaging Procedure: LUNG CA SCREEN PILOT LDCT

Reason for Study (REQUIRED - 64 characters maximum):

Clinical History (Optional):

- Patient must be 55 - 80 years of age
- Patient must be either a current tobacco smoker or former smoker that quit < 15 years ago
- The patient's tobacco-exposure history must be > 30 pack-years
- No life-limiting condition (such as cancer) may be present.

Date Desired: [ ] Urgency: ROUTINE Transport: AMBULATORY

Category: OUTPATIENT Submit To: COMPUTERIZED TOMOGRAPHY

Exams Over the Last 7 Days: [ ]

Isolation:  Isolation

Pregnant:  Yes  No  Unknown

PreOp Scheduled: [ ]

LUNG CA SCREEN PILOT LDCT [ ] Accept Order [ ] Quit

- LungRADS reporting with score and recommendation on Report to Ordering Provider/ Team


# "LungRADS: Radiology Service/Reading and Follow-Up

| Category                      | Category Descriptor  | Category | Findings  | Management   | Probability of Malignancy  | Estimated Population Prevalence |
|-------------------------------|--|----------|---|--|--|---------------------------------|
| Incomplete                    | -  | 0        | prior chest CT examination(s) being located for comparison<br>part or all of lungs cannot be evaluated  | Additional lung cancer screening CT images and/or comparison to prior chest CT examinations is needed  | n/a  | 1%                              |
| Negative                      | No nodules and definitely benign nodules   | 1        | no lung nodules<br>nodule(s) with specific calcifications: complete, central, popcorn, concentric rings and fat containing nodules  |  |  |                                 |
| Benign Appearance or Behavior | Nodules with a very low likelihood of becoming a clinically active cancer due to size or lack of growth                                    | 2        | solid nodule(s):<br><div style="border: 1px solid blue; padding: 2px; display: inline-block;">                     &lt; 6 mm<br/>new &lt; 4 mm                 </div><br>part solid nodule(s):<br><div style="background-color: #e0ffe0; padding: 2px; display: inline-block;">                     &lt; 6 mm total diameter on baseline screening                 </div><br>non solid nodule(s) (GGN):<br><div style="background-color: #e0e0ff; padding: 2px; display: inline-block;">                     &lt; 20 mm OR<br/>≥ 20 mm and unchanged or slowly growing                 </div><br>category 3 or 4 nodules unchanged for ≥ 3 months | <div style="border: 1px solid blue; padding: 5px; display: inline-block;">                     Continue annual screening with LDCT in 12 months                 </div>                       | < 1%   | 90%                             |
| Probably Benign               | Probably benign finding(s) - short term follow up suggested; includes nodules with a low likelihood of becoming a clinically active cancer | 3        | solid nodule(s):<br><div style="border: 1px solid red; padding: 2px; display: inline-block;">                     ≥ 6 to &lt; 8 mm at baseline OR<br/>new 4 mm to &lt; 6 mm                 </div><br><div style="background-color: #e0ffe0; padding: 2px; display: inline-block;">                     part solid nodule(s)<br/>                     ≥ 6 mm total diameter with solid component &lt; 6 mm OR<br/>new &lt; 6 mm total diameter                 </div><br>non solid nodule(s) (GGN) ≥ 20 mm on baseline CT or new  | <div style="border: 1px solid red; padding: 5px; display: inline-block;">                     6 month LDCT                 </div>  | <div style="border: 1px solid red; border-radius: 50%; padding: 5px; display: inline-block;">                     1-2%                 </div>  | 5%                              |
| Suspicious                    | Findings for which additional diagnostic testing and/or tissue sampling is recommended   | 4A       | solid nodule(s):<br><div style="border: 1px solid red; padding: 2px; display: inline-block;">                     ≥ 8 to &lt; 15 mm at baseline OR<br/>                     ! growing &lt; 8 mm OR<br/>new 6 to &lt; 8 mm                 </div><br><div style="background-color: #e0ffe0; padding: 2px; display: inline-block;">                     part solid nodule(s):<br/>                     ≥ 6 mm with solid component ≥ 6 mm to &lt; 8 mm OR<br/>with a new or growing &lt; 4 mm solid component                 </div><br>endobronchial nodule  | <div style="border: 1px solid red; padding: 5px; display: inline-block;">                     3 month LDCT; PET/CT may be used when there is a ≥ 8 mm solid component                 </div> | <div style="border: 1px solid red; border-radius: 50%; padding: 5px; display: inline-block;">                     5-15%                 </div> | 2%                              |
|                               |  | 4B       | solid nodule(s)<br>≥ 15 mm OR<br>new or growing, and ≥ 8 mm<br>part solid nodule(s) with:<br>a solid component ≥ 8 mm OR<br>a new or growing ≥ 4 mm solid component   | chest CT with or without contrast, PET/CT and/or tissue sampling depending on the *probability of malignancy and comorbidities. PET/CT may be used when there is a ≥ 8 mm solid component.   | > 15%  | 2%                              |
|                               |  | 4X       | Category 3 or 4 nodules with additional features or imaging findings that increases the suspicion of malignancy   |  |  |                                 |
| Other                         | Clinically Significant or Potentially Clinically Significant Findings (non lung cancer)  | 5        | modifier - may add on to category 0-4 coding  | As appropriate to the specific finding   | n/a  | 10%                             |
| Prior Lung Cancer             | Modifier for patients with a prior diagnosis of lung cancer who return to screening  | C        | modifier - may add on to category 0-4 coding  | -  | -  | -                               |

# Individual Patient Reporting and Actions

## - Notification and Follow-up in Pilot Program

- (1) Positive report (LungRADS 2,3,4A-C: Addended to clinic note and notification by Active Diagnostic Clinic Fellow)
- (2) Negative report (LungRADS 1: Addend note and “No Lung Cancer – Now What?” flyer sent to Patient)



**VA** |  U.S. Department of Veterans Affairs  
Veterans Health Administration  
Patient Care Services  
Health Promotion and Disease Prevention

## My Lung Cancer Screening Did Not Show Lung Cancer: *Now What?*

**Your lung cancer screening CT scan did NOT show lung cancer. Now is a good time to decrease your risk for lung cancer.**

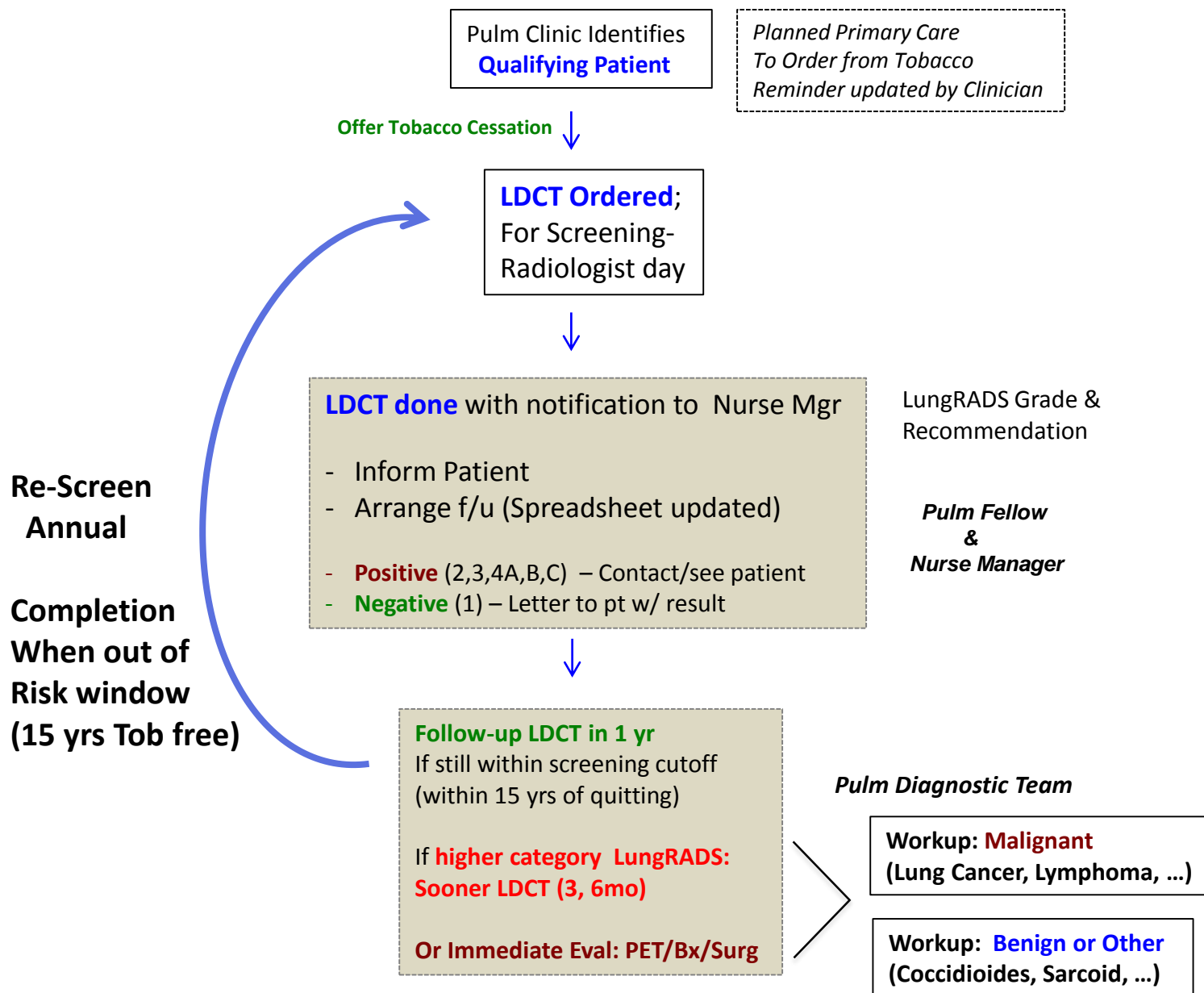
- This result does not mean that you will never get lung cancer.
- Talk with your health care team about when you should be screened again.

**Help to quit smoking for good is available!**

Quitting smoking isn't easy and many smokers who want to quit have tried many times before. The good news is that we know more now about what helps smokers quit than we ever have.

- If you think that you may be ready to talk with someone about quitting smoking, or if you need help to stay quit, make an appointment to talk

# VASDHS Lung Cancer Screening Process Flowchart: Current State



# Take-Home Points

- Implementing a lung cancer screening program involves a **complex program of care** to coordinate services and track findings.
- Approximately **two-thirds of Veteran individuals screened** have abnormal findings, some of which required tracking and clinical follow up.
- If lung cancer screening is implemented, **resource needs will be significant**.
- **Smoking Cessation** is the most important intervention to prevent lung cancer (and decrease the morbidity and mortality associated with lung cancer).
- There is ongoing discussion to formulate **guidance** for how a nation-wide facility such as the VA might implement lung cancer screening.
- Individual facilities may vary due to geographic risks and facility-specific expertise. Coordinator and **specialty-specific downstream resources** are key.

**THANK YOU !**