Lessons from BI-RADS: Infrastructure to Foster Quality Assurance and Follow-Through in Lung Cancer Screening
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Disclosures
- No financial disclosures
- I believe in screening smokers for:
  - Lung cancer
  - COPD & chronic lung diseases
  - Heart disease

Objectives
- Identify lung cancer prevention program components
- Understand organizational strategy for LDCT screening
- Understand BI-RADS application to lung cancer screening

Lung Cancer Prevention Program
- Smoking cessation is primary prevention
- LDCT is secondary prevention
- Education for patients, advocates, and physicians

LDCT Screening Program

Lung Cancer Screening Program
- Physician champions (at least 2 disciplines)
- Available CT scanner follow time
- Database
- Program coordinator-navigator
- Standardized reporting system
- Education and outreach to PCP and public
- Integrated smoking cessation counseling
- Multidisciplinary steering committee
Organizational Strategy

- Accountable care
- Evidence-based medicine
- Institutional buy-in
  - Top down and bottom up
  - Utilize underutilized resources
  - Create computer-based infrastructure

Organizational Strategy

- Self-pay programs
  - Volume inversely proportional to charge
  - $350 trickle
  - ≤$200 moderate volume
  - $0 charge to patient points to future
    - 9 million Americans meet current criteria

Organizational Strategy

- Economics of no-charge to patient
  - Increasing third-party coverage in 2014
  - HR benefit package with smoking cessation and LDCT
    - Within institution
    - Within community served
  - LDCT short-term follow-up in program

Organizational Strategy

- Build an enthusiastic team
  - Administration
  - Radiologists
  - Specialists—pulmonary, surgery, oncology
  - Support Staff—IT, system navigation, technologists

Organizational Strategy

- Primary Care Physicians
  - CME educational program
  - Project impact and follow-up for practice
  - Educational materials for patients
  - Easy order process
  - Easy to understand results

Lahey Health

- Largest clinical pilot screened 1500
- Initiated to increase CT scan utilization
- Institutional model of accountable care
- Sense of urgency → open in 6 weeks
- Program materials available on-line

Lahey Health
Rescue Lung, Rescue Life

- 40+ documents available on-line
  - Modeling software
  - Database (MQSA notification/follow-up)
  - Brochures and educational materials
  - Lahey Lung-Rads system documents
  - Letters for patients and physicians


Lahey Health Steps

1. Rescue Lung, Rescue Life
2. Steering Committee
3. Hospital Mission
4. Approval
5. CME campaign
6. Lung-Rads & infrastructure
7. Quality and Safety Metric
8. Pilot
9. Research
10. Steering Committee Governance


Lahey PCP Reassurance

- Individual PCP panel: 2500 patients
  - ~75 patients - high risk qualified for screen
  - ~20 patients - screen positive lung nodule
  - ~5 patients - potentially significant incidental findings
- Experience with 100 screenings per wk
  - 27 positive, 7 potential significant finding and 1 cancer per week

Lahey Lung-Rads Implementation

<table>
<thead>
<tr>
<th>Category</th>
<th>Screen Results</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Negative</td>
<td>1 year</td>
</tr>
<tr>
<td>2</td>
<td>Indeterminate</td>
<td>Interim CT</td>
</tr>
<tr>
<td></td>
<td>Likely benign</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Positive screen</td>
<td>Interim CT</td>
</tr>
<tr>
<td></td>
<td>Nodule likely</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Positive Screen</td>
<td>Refer to pulmonologist</td>
</tr>
<tr>
<td></td>
<td>Suspicious finding</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Positive Screen</td>
<td>Refer to interdisciplinary oncology team</td>
</tr>
<tr>
<td></td>
<td>Lung Cancer</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Significant incidental abnormality</td>
<td>Contact PCP</td>
</tr>
</tbody>
</table>

Lahey Population and Results

- NCCN Guidelines
  - 55 – 75 yrs old
  - 30 pk-yrs smoking
  - Quit < 15 yrs ago if not current smoker
- Compared results of 100 employee screens to NCCN
  - 100 Pilot cases
  - 70 Category 1
  - 4 Category 2
  - 18 Category 3
  - 1 Category 4
  - 25% have nodule f/u
  - 96% benign
  - Category 2 + S = 1/3

Lahey Patient Satisfaction Survey

- Post LDCT phone call from patient navigator or CT lung program coordinator
  - Did PCP request office appointment prior to screening?
  - Was staff concerned for your comfort?
  - Would you recommend program?
  - Do you have suggestions on how to improve our program?
BI-RADS®

- Breast Imaging Reporting and Data System
- Quality assurance tool
- Standardize mammographic reporting
- Reduce confusion in breast imaging interpretations
- Facilitate outcome monitoring
- Action oriented
- Familiar to PCP and radiologist
- Adaptable over time

BI-RADS® and MQSA

- Input from wide variety of stakeholders
- ACR Mammo Accreditation Program (1987)
- ACR BI-RADS Committee (1988)
- MQSA (Mammography Quality Standards Act of 1992) mandated accreditation and certification for all mammography facilities
- 1999 MQSA rules mandated BI-RADS
- Quality Determinants of Mammography provided performance benchmarks

BI-RADS® Central Value

- Lexicon descriptors
  - Precisely defined
  - Tied through literature to breast cancer risk
  - Proper term leads to logical final assessment and appropriate management recommendation
  - BI-RADS® decreases variability in reporting
  - BI-RADS® facilitates communication and pathology-radiology correlation
  - BI-RADS® facilitates research as well audits and quality assurance activities

Generalized LungRADS Framework

<table>
<thead>
<tr>
<th>Category</th>
<th>Assessment</th>
<th>Example</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Incomplete</td>
<td>Previously reported indeterminate nodule</td>
<td>Deferred until comparison</td>
</tr>
<tr>
<td>1</td>
<td>Negative</td>
<td>Nodule smaller than screening threshold</td>
<td>Complete annual LDCT according to guidelines</td>
</tr>
<tr>
<td>2</td>
<td>Benign</td>
<td>Calcified nodule, stable over prescribed time</td>
<td>Complete annual LDCT according to guidelines</td>
</tr>
<tr>
<td>3</td>
<td>Probably Benign</td>
<td>Solid nodule, stable over prescribed time</td>
<td>Interval short-term follow-up 6-12 months</td>
</tr>
<tr>
<td>4</td>
<td>Suspicious</td>
<td>Nodule of size, stable over prolonged time</td>
<td>Refer to specialist for consultation</td>
</tr>
<tr>
<td>5</td>
<td>Known Malignancy</td>
<td>Enlarging nodule, calcified mass, solid component in LCN</td>
<td>Biopsy, surgical excision, chemotherapy, radiation, and/or endocrine therapy</td>
</tr>
</tbody>
</table>

Letters may be used for other findings

Clinical LDCT Program Summary

- Risk assessment and smoking cessation
- Guidelines-based LDCT exam
- Low-dose CT examination ≤ 1.5 mSv
- Standardized communication
  - Patient & physician
  - Facilitate follow-up
  - CT scans and further diagnostic care

LDCT Program Workflow
**Solid Nodule on LDCT**

- ≤ 4 mm
- > 4–8 mm: Annual LDCT
- > 8 mm: LDCT in 3–6 mo
- No increase: Annual LDCT
- Increase: Consider PE/CT
- Low suspicion: No further testing
- High suspicion: Surgery recommended

- Solid Endobronchial
- Bronchoscopy recommended

**GGN and Part-solid Nodules**

- ≤ 4 mm
- > 4–10 mm: LDCT in 3–6 mo
- > 10 mm: Surgery recommended
- No lung cancer
- Limited growth in size
- Surgically excised
- Long cancer confirmed

**Online Resources**

**Screening:**

**Smoking Cessation:**

**References**