Lung Cancer Screening

Middlesex Hospital Total Lung Care Center
Megin Iaccarino RN, BSN
Lung Pathway Coordinator and Lung Nurse Navigator
Middlesex Hospital Cancer Center and Surgical Alliance
Lung Screening at Middlesex Hospital

- Low dose non-contrast chest CT
- Offered to individuals at high risk for lung cancer
  - Age 55-74 with at least a 30 pk/yr smoking history
  - Age 50-74 with at least a 20 pk/yr smoking history and an additional risk factor
    - Asbestos exposure, personal history of cancer, family history of lung cancer, radon exposure, military service
    - Second hand smoke exposure is not considered a risk factor
  - Must be a current smoker or have quit within the last 15 years
- Currently self-pay at $125, not covered by private insurance, Medicare or Medicaid
Program Logistics

- Primary Care Provider orders the screening
  - This ensures the patient receives follow-up care for any findings and that annual screenings are ordered
  - If the patient does not have a PCP, he/she will be assisted in finding one
  - If the patient does not have insurance he/she will be referred to the Community Health Center or ACA website
- Before the exam, the patient fills out a risk assessment questionnaire to ensure they are a high risk individual
- If the patient does not qualify for a screening, they are referred to the nurse navigator for explanation and further education
Program Logistics

- The results of the screening exams are sent to the ordering physician and nurse navigator.
- The nurse navigator contacts both the patient and the provider by letter with the results.
- If there is a positive finding, the PCP is contacted first to communicate this to the patient.
- The patient is then entered into the lung screening database to ensure appropriate follow-up care.
- The patient and provider are sent reminder letters when the next screening or follow-up exam is due.
- Smoking cessation is an integral part of a responsible screening program.
Role of the Nurse Navigator

- Available to patients and providers to answer any questions regarding screening
- Refers to smoking cessation and provides smoking cessation education when appropriate
- Community outreach and education
- Provider outreach and education
- Assists with recommended follow-up care
- For patients with positive screenings and newly diagnosed lung cancer, the navigator is available to assist through diagnosis, treatment and beyond
Negative Versus Positive Screenings

- NCCN provides very clear, specific guidelines for lung screening follow-up
- A nodule equal to or greater than 6 mm is considered a positive finding
  - The size of the nodule determines how follow up care is provided
  - The NCCN guidelines offer an easy to navigate algorithm
  - Any positive finding will be reviewed by the TLCC multidisciplinary team and recommendations will be provided to the ordering physician
- A screening with no nodules or with nodules less than 6 mm is considered a negative finding
  - The patient should continue to have annual screenings!
  - The majority of lung cancers detected through screening are found on subsequent exams
  - It is imperative the patient knows they will be screened annually
Lung Screening at Middlesex Hospital

- Program was initiated in June, 2012
- So far, we have screened 312 patients
- Of those 312 we have found 8 lung cancers
  - 6 stage I or II, surgically resected
  - One stage III, one stage IV
- We have also found one lymphoma, one thyroid cancer, and multiple incidental non-pulmonary findings prompting work-up
- Three biopsies have been performed with negative findings
Upcoming Screening Events

November is lung cancer awareness month

- All lung cancer screenings will be **50% OFF** ($62.50)
- All lung cancer screenings for veterans will be **FREE**
- Veterans Day (Tuesday November 11), 9-1 pm
  - Veterans health fair in the Cancer Center Atrium
  - Free on site screenings; no pre-registration required
- Wednesday Nov 12, 5:30-7 pm
  - Lung Cancer Support Group, Radiation Oncology Waiting Room
- Thursday November 13, 6-8 pm
  - Lung Cancer Vigil in the Cancer Center Atrium
  - An evening for all those affected by lung cancer
HONORING VETERANS

with LUNG CANCER SCREENINGS

CURRENT AND FORMER SMOKERS MAY QUALIFY FOR A FREE SCREENING CT SCAN!

FIND OUT AT OUR ANNUAL
Veterans Health Fair

Middlesex Hospital Cancer Center
Tuesday, November 11th | 9:00 a.m. - 1:00 p.m.
536 Saybrook Road | Middletown, CT | 06457

NO PREREgISTRATION REQUIRED!
With questions or for more information, please contact:
Megin Iaccarino | (860) 358-2066 | megin.iaccarino@midhosp.org

Light refreshments will be served! | All screening and testing free of charge.

IT’S TIME TO SHINE.
Join us for the Shine A Light on Lung Cancer Vigil

Thursday, November 13, 2014
6:00 – 8:00 p.m.
Middlesex Hospital Cancer Center Atrium
536 Saybrook Road
Middletown, CT

Honor all those impacted by lung cancer.

Program includes:
- Keynote Speaker: Raymond Schoonmaker, M.D.,
  Middlesex Hospital Pulmonologist
- Guest Speakers: David Pearlstone, M.D., Middlesex Hospital
  Surgical Oncologist
  Miklos Fogarasi, M.D., Middlesex Hospital Oncologist
- Survivor speaker
- Sanctuary Bell Choir of Branford First Congregational Church
- Tribute and Lighting Ceremony

To register for this FREE event, or for more information, go to
www.shinealightonlungcancer.org.
Take Away Points

- Lung Cancer Screening Saves Lives
- Screening asymptomatic patients allows for the detection of lung cancer when it is a curable disease
- Smoking cessation is a crucial part of any responsible screening program
- Most lung cancers detected through screening are found on subsequent exams
- A NEGATIVE SCREENING DOES NOT MEAN YOU ARE IN THE CLEAR!
- Please ensure patients understand the need for annual screens
- The TLCC team is here to assist in any way possible
- Further questions please contact Megin Iaccarino at (860) 358-2066
Update on Lung Cancer Screening

○ Evidence for Screening with CT
○ Screening CT in your practice
○ Interpretation of the CT results
○ Different appearances of Early Lung Cancer

Michael Crain, MD
Chairman, Radiology Department
Total Lung Care Center
ELCAP – Early Lung Cancer Action Program
Began in 1992 at Cornell University

> Landmark Article - LANCET 1999:
Overall Design and Findings from Baseline Screening
Design: 1,000 smokers: Each got a CXR and Low Dose CT scan for 2 years.
27 lung cancers (23 stage 1) found by CT
7 lung cancers (4 stage 1) found by CXR
*Our findings suggest brighter prospects for cost-effective screening for lung cancer in people at high risk.*

> Landmark Article - NEJM 2006:
Survival of Patients with Stage I Lung Cancer Detected on CT Screening
Design: 32,000 smokers: Low Dose CT scans for 2 years
480 cancers (410 at baseline, 70 at follow-up – 15% of cancers found on follow-up).
10 year lung-cancer specific survival rate for these 480 patients – 80%
410 of the 480 cancers were Stage 1 (85%)
10 year lung-cancer specific survival rate for resected Stage 1 cancers – 92%.
*Annual CT screening can detect lung cancers that are curable.*
NLST - National Lung Screening Trial
2002 - 2010

> Landmark Article - NEJM 2011:
Reduced Lung Cancer Mortality with Low Dose Computed Tomographic Screening.

Design: 50,000 smokers (2002-2004), ½ got CXR and ½ got CT annually for 3 years, and observe deaths in each group.

Endpoint: 20% difference in the 2 groups, which occurred in 2010.

> CT group: 360 died of lung CA (CT found 420 Stage 1 cancers & 230 higher Stage cancers)
> CXR group: 440 died of lung CA (CXR found 90 Stage 1 cancers & 190 higher Stage cancers)

*Screening with the use of Low Dose CT reduces mortality from Lung Cancer.*

Note: About 25% of the Lung Cancers were found at each follow-up CT exam.
Conclusion

Lung Cancer Screening Saves Lives

With Annual Screening – 80% cure rate
Without Annual Screening – 15% cure rate
Breast Cancer

- USA Population at Risk: 60 million women (40 – 75 y/o)
- LifeTime Risk of Breast Cancer: 12%
- 230,000 new cases; 40,000 deaths (60% found at Stage 1)
- Mammography: finds 1 breast cancer per 200 exams (.05% of exams)
- Exam Time: 15 minutes.
- Radiation dose: 1 mSv.
- USPSTF – B Rating (50-75 y/o), C Rating (40-50 y/o).

Lung Cancer

- USA Population at Risk: 50 million smokers & ex-smokers
- LifeTime Risk of Lung Cancer: 15%
- 220,000 new cases; 150,000 deaths (15% found at Stage 1)
- Low Dose CT: finds 1 breast cancer per 65 exams (1.5% of exams)
- Exam Time: 5 minutes.
- Radiation dose: 1.5 mSv.
- USPSTF – B Rating (55-80 y/o).

Background Yearly Radiation

3 mSv
Current Standard of Practice

> Appropriate Women should get annual Breast Cancer Screening.

> Appropriate Smokers/Ex-Smokers should get annual Lung Cancer Screening.

> A significant number of Lung Cancers are identified on subsequent annual exams.
  - Identify changes in the nodule size.
  - Identify new Lung Cancers that develop during the year (Interval Cancer).
ACR LungRADs

> Landmark Article - JACR August 2014:

Performance of ACR Lung-RADS in a Clinical CT Lung Screening Program

Design: 2,000 Lung Cancer Screening CT exams, correlate nodule size and cancer detection.

Nodule > 4mm positive: 25% of exams
Nodule > 6mm positive: 10% of exams

*If nodules < 6mm were followed at 1 year, no cancers were missed.*

- 1 year f/u-------------------------90% of exams
- 6 month f/u-----------------------6% of exams
- 3 month f/u, PET, biopsy---------4% of exams

LungRADs CATEGORIES

1: Normal-----------------------------1 year f/u
2: Benign: <6mm nodules--------------1 year f/u
3: Probably Benign: 6-8mm nodules----6 month f/u
4A: Suspicious: 8-15mm nodules-------3 month f/u or PET
4B: Very Suspicious: >15mm nodules----biopsy

(Additional symbol: S - other significant findings)
Middlesex Lung Cancer Screening

Selected Cases
Stage 1a Lung Cancer
Ground Glass Opacity – Stage 2 Lung Cancer
Larger Multifocal Mass – Stage 1 Lung Cancer
8mm Lung Nodule

Stage 4 Lung Cancer
Stage 3 Lung Cancer

2 Months later
CT Guided Biopsy - Negative
2013
LungRADs 2
4mm nodule

2014
LungRADs 4
7mm nodule

Stage 1a
Interval Lung Cancer At 1 year Follow-up
Lung Cancer: 3mm to 7mm in 4 years
Current Certification

Lung Cancer Alliance
SCREENING CENTER OF EXCELLENCE
Offering Responsible Screening & Care

Application Pending

DESIGNATED AMERICAN COLLEGE OF RADIOLOGY Lung Cancer Screening Center
References

Early Lung Cancer Action Project: Overall Design and Findings from Baseline Screening
Lancet: Henschke, EI et al.
July 1999

Survival of Patients with Stage I Lung Cancer Detected on CT Screening
Henschke, EI et al.
October 2006

Reduced Lung Cancer Mortality with Low Dose Computed Tomographic Screening
NEJM: Berg, CD et al
August 2011

Performance of ACR Lung-RADS in a Clinical CT Lung Screening Program
JACR: McKee, BJ et al.
August 2014

ACR LungRADs: www.acr.org/Quality-Safety/Resources/LungRADS
There are nodules, and there are NODULES

Raymond Schoonmaker, M.D.
Lung Cancer Typically Diagnosed At a Late Stage

Lung Cancer Stage at Diagnosis

1) Analysis of lung cancer patient volumes at an academic medical center that sees 5,508 new patients per year; calculations based on 453 new diagnoses of lung cancer.
Early Detection Saves Lives

Shift in Stage of Diagnosis Due To CT Screening

Change in Number of Lung Cancer Patients Diagnosed by Stage

Stage A: 434%
Stage B: (25%)
Stage C: (93%)
The Fleischner Society pulmonary nodule recommendations are used for follow-up and management of pulmonary nodules smaller than 8mm detected incidentally on non-screening CT.
Nodule size (mm) less than or equal to 4
- low risk patients: no follow-up needed
- high risk patients: follow-up at 12 months and if no change, no further imaging needed

Nodule size >4-6 mm
- low risk patients: follow-up at 12 months and if no change, no further imaging needed
- high risk patients: initial follow-up CT at 6-12 months and then at 18-24 months if no change

Nodule size >6-8 mm
- low risk patients: initial follow-up CT at 6-12 months and then at 18-24 months if no change
- high risk patients: initial follow-up CT at 3-6 months and then at 9-12 and 24 months if no change

Nodule size >8 mm
- either low or high risk patients
  - follow-up CTs at around 3, 9, and 24 months
  - dynamic contrast enhanced CT, PET, and/or biopsy

Note: newly detected indeterminate nodule in persons 35 years of age or older.
- **low risk patients:** minimal or absent history of smoking and or other known risk factors
- **high risk patients:** history of smoking or of other known risk
NOTE: nonsolid, partially solid, or ground-glass nodules may require longer follow-up to exclude indolent adenocarcinoma

NOTE: guidelines do NOT apply to the following groups:
- known or suspected cancer outside of the lungs
- patients younger than 35 years of age
- patients with unexplained fever
The most important thing to look at on a patient’s X-ray is the last one.

The majority of stage one lung cancers are found on subsequent films.
Figure Legend:

All-cause survival among patients with screen-detected cancer, by age group.
<table>
<thead>
<tr>
<th>Measure</th>
<th>Ages 55-64</th>
<th>Ages 65-74</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung cancer prevalence</td>
<td>0.7%</td>
<td>1.5%</td>
</tr>
<tr>
<td>Number needed to screen</td>
<td>364</td>
<td>245</td>
</tr>
<tr>
<td>Positive predictive value</td>
<td>3.0%</td>
<td>4.9%</td>
</tr>
<tr>
<td>False-positive rate</td>
<td>22%</td>
<td>27.7%</td>
</tr>
<tr>
<td>Surgical procedure rate</td>
<td>1%</td>
<td>1.2%</td>
</tr>
<tr>
<td>Invasive procedures</td>
<td>2.7%</td>
<td>3.3%</td>
</tr>
<tr>
<td>Complications rate</td>
<td>9.8%</td>
<td>8.5%</td>
</tr>
<tr>
<td>Major complications rate</td>
<td>1.9%</td>
<td>3.4%</td>
</tr>
</tbody>
</table>
**NCCN Guidelines Version 1.2015**

**Lung Cancer Screening**

**EVALUATION OF SCREENING FINDINGS**

- **<6 mm**
  - Annual LDCT for 2 years (category 1) and suggest annual LDCT until patient no longer eligible for definitive treatment

- **6-8 mm**
  - LDCT in 3 mo

- **>8 mm**
  - Consider PET/CT

**Solid or partially solid nodule**

- **Solid endobronchial nodule**
  - LDCT in 1 mo (immediately after vigorous coughing)

**FOLLOW-UP OF SCREENING FINDINGS**

- **Annual LDCT for 2 years (category 1) and suggest annual LDCT until patient no longer eligible for definitive treatment**

- **If no increase in size, LDCT in 6 mo**

- **If increase in size**
  - Surgical excision

- **Low suspicion of lung cancer**
  - LDCT in 3 mo

- **Suspicion of lung cancer**
  - Biopsy or surgical excision

- **No cancer**
  - If no resolution, Bronchoscopy

- **Cancer confirmed**
  - See appropriate NCCN Guidelines
Insurance Coverage and Statistics

Gean Brown, MSN, RN, OCN
Clinical Manager Cancer Center
& Surgical Alliance
Early Detection Boosts Cost-Effectiveness

Compares Favorably Compared to Other Screening Types

Screening Cost Effectiveness

Cost Per Life-Year Saved

Compares the costs and health effects of an intervention to assess the extent to which it can be regarded as providing value for money.

Milliman Actuarial Analysis

- Original study in 2012, repeated in 2014 of the effects of LDCT lung cancer screening on outcomes and cost.

If all eligible Medicare beneficiaries had been screened and treated consistently from age 55 years, approximately 358,134 additional individuals with current or past lung cancer would be alive in 2014

- Authors concluded that offering LDCT screening as an insurance benefit would save lives at low cost compared to routine screenings for other cancers

Source: Pynnonen B et al., "An Actuarial Analysis Shows That Offering Lung Cancer Screening as an Insurance Benefit Would Save Lives at Relatively Low Cost" Health Affairs 31(4); Oncology Roundtable interviews and analysis.
Not a Significant Volume Burden

10M individuals at “high-risk” for developing lung cancer, according to NLST estimates

Apply 3-5% volume estimate to market, or physician panel size

1,000 x 5% = 50 patients

Primary physician patient panel of 1,000 patients can potentially have about 50 patients that would be eligible for lung CT screening
The Centers for Medicare & Medicaid Services (CMS) convened a Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) meeting to advise CMS on coverage decisions for LDCT screening in the Medicare population.

For the question “How confident are you that there is adequate evidence to determine if the benefits outweigh the harms of lung cancer screening with LDCT in the Medicare population?”, the MEDCAC panel's average response was 2.2 on a scale of 1 (low confidence) to 5 (high confidence). The panel members also had an average response of 2.3 to the question of how confident they were that the harms of lung cancer screening could be minimized in the Medicare population.
Some of the concerns expressed by the MEDCAC panel did not pertain directly to age but to more general issues involving quality control of screening and potential “indication creep” (screening being disseminated to lower-risk populations).

However, many of the concerns were directly related to age and the uncertainty about the effectiveness and potential for harms in the population of persons aged 65 years or older.
The primary source of evidence for LDCT effectiveness was the NLST, and because only 25% of the NLST participants were aged 65 years or older at randomization, there were reservations about whether the overall NLST results could be applied to the Medicare-aged population. Specific concerns were raised that older persons might have substantially more comorbid conditions, with more harms from diagnostic work-ups, more frequent ineligibility for curative surgery for screen-detected cancer, and increased postsurgical mortality compared with younger eligible persons.
Comparative Effectiveness of Lung Cancer Screening in Medicare vs. Non-Medicare Populations

The table below highlights some of the major findings from the new analysis of the NLST data. The most compelling statistic from this new analysis is that it requires 119 fewer screening patients to prevent a lung cancer death in the Medicare population than in the comparison cohort (245 v. 364).

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Medicare Age Group</th>
<th>55-64 Age Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients needed to prevent 1 lung cancer death</td>
<td>245</td>
<td>364</td>
</tr>
<tr>
<td>Lung cancer prevalence</td>
<td>1.5%</td>
<td>0.7%</td>
</tr>
<tr>
<td>Positive Predictive Value</td>
<td>4.9%</td>
<td>3.0%</td>
</tr>
<tr>
<td>False-positive rate</td>
<td>27.7%</td>
<td>22.2%</td>
</tr>
<tr>
<td>Surgical procedure rate</td>
<td>1.2%</td>
<td>1%</td>
</tr>
<tr>
<td>Complications rate</td>
<td>8.5%</td>
<td>9.8%</td>
</tr>
<tr>
<td>Major complications rate</td>
<td>3.4%</td>
<td>1.9%</td>
</tr>
<tr>
<td>Invasive procedures</td>
<td>3.3%</td>
<td>2.7%</td>
</tr>
</tbody>
</table>
Age is a major risk factor for many types of cancer, so it is unsurprising that older patients with greater smoking pack-years are more likely to benefit from lung cancer screening than their younger counterparts.
In a special communication published in *JAMA Internal Medicine*, Douglas Wood writes that the NLST clearly established that the benefits of screening were greater than the risks: “the balance was not close, with a substantial improvement in lung cancer mortality among screened patients.” He argues that the “unintended consequences of screening... can be reasonably mitigated by well-constructed policies and disciplined control within screening programs.” Guidelines from professional societies will help ensure the safe and effective implementation of screening programs, he writes.

Wood further notes that 70% of lung cancer is found in the Medicare population — people who are 65 years or older. “CMS should cover low-dose CT,” he writes, “thus avoiding the situation of at-risk patients being screened up to age 64 through private insurers and then abruptly ceasing screening at exactly the ages when their risk for developing lung cancer is increasing.”
CMS Decision Due Mid November

- January 2015, Private Insurance will cover.
- NLST criteria will be followed.
- Self pay no longer available
- Final CMS Decision - February 2015
Please screen eligible patients **NOW**

Lives can and will be saved
References


Questions