PANEL DISCUSSION: SCREENING FOR LUNG CANCER

Anthony D Weaver MD

Disclosures

Anthony Weaver has no relationships to disclose.

Objectives

1. Analyze the current demographics of lung cancer in Kentucky.
2. Discuss current guidelines and recommendations for lung cancer screening
3. Review selected research on lung cancer screening
4. Suggest future directions

Objective 1

Analyze the current demographics of lung CA

Statistics: lung cancer

- leading cause of cancer deaths in the US
- In 2012, there were more than 225 000 new cases and more than 160,000 deaths
- Lung cancer deaths surpassed the total deaths from cancers of the breast, prostate, and colon combined.[1]

Lung Cancer, 2004-2008

Region	Incidence Rate	Mortality Rate
US*	**62.0**	**52.5#**
Kentucky**	**100.8**	**75.1**

The KY incidence is **62.6% HIGHER** than the US

The KY mortality is **43.0 % HIGHER** than the US

*Source: SEER*Stat 7.0.4 SEER 17 Registries
**Source: Kentucky Cancer Registry
#: Based on 2003-2007 rate

Kentucky Cancer Deaths per year 2006-2010

Lung and Bronchus	3416
Colon	881
Breast	597
Pancreas	507
Prostate	392
Leukemia	332
Non-Hodgkin Lymphoma	320
Ovary	212

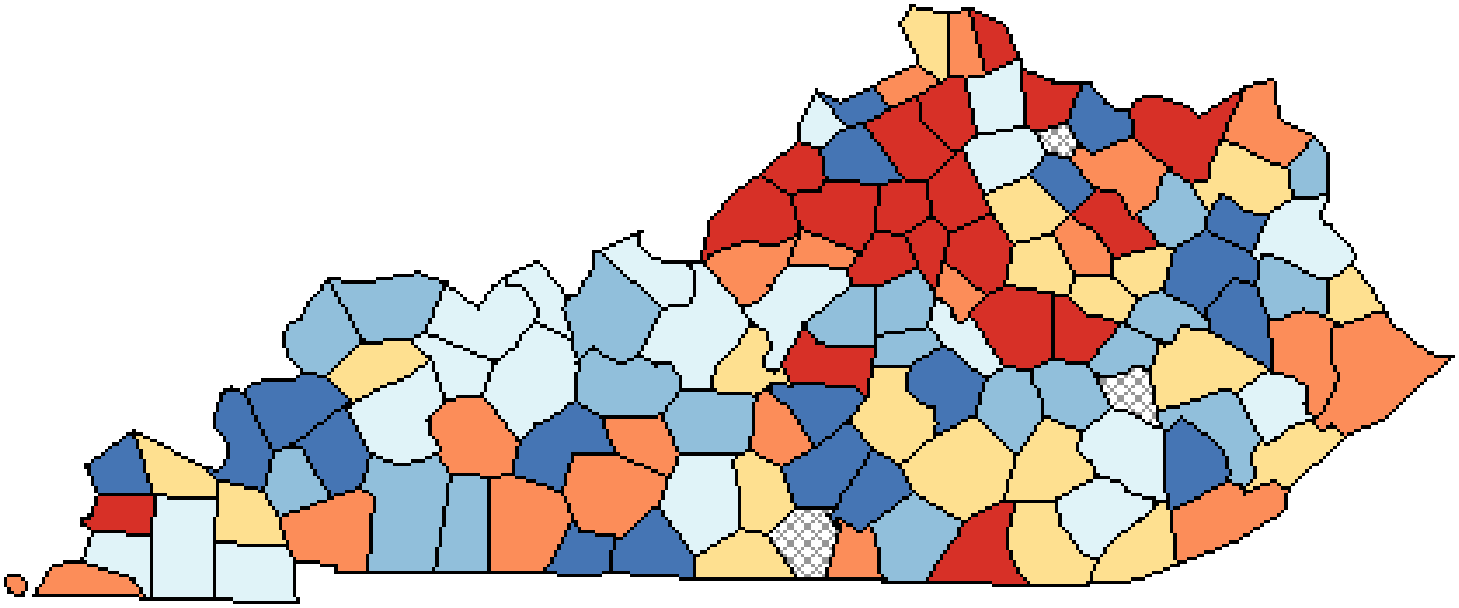
Lung/Bronchus Cancer

- All 120 counties' death rate above the US average.
- The death rate varies from 59 in Larue and Cumberland counties to 124 in Gallatin County.
- The highest rates are in eastern KY and Ohio, Butler, and Muhlenberg counties.

Incidence Rates† for Kentucky, 2003 - 2007

Breast

All Races (includes Hispanic), Female, All Ages



Age-Adjusted

Annual Incidence Rate

(Cases per 100,000)

Quantile Interval

- 130.7 to 165.7
- 122.4 to 130.6
- 114.8 to 122.3
- 106.4 to 114.7
- 95.5 to 106.3
- 59.8 to 95.4
- Suppressed */**

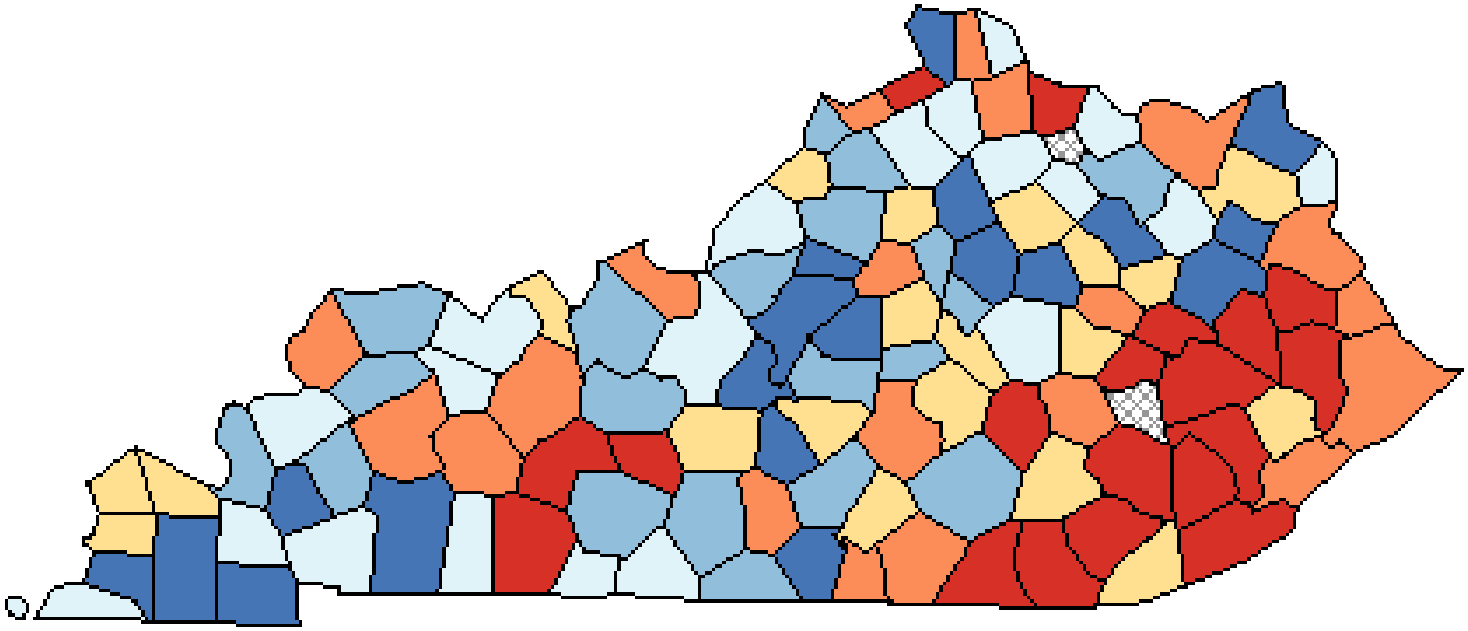
US (SEER + NPCR)
Rate (95% C.I.)
120.6 (120.4 - 120.9)

Kentucky
Rate (95% C.I.)
120.1 (118.2 - 122.1)

Incidence Rates† for Kentucky, 2003 - 2007

Lung & Bronchus

All Races (includes Hispanic), Both Sexes, All Ages



Age-Adjusted

Annual Incidence Rate

(Cases per 100,000)

Quantile Interval

- 116.8 to 157.0
- 109.6 to 116.7
- 101.6 to 109.5
- 96.1 to 101.5
- 89.1 to 96.0
- 68.8 to 89.0
- Suppressed */**

US (SEER + NPCR)	
Rate	(95% C.I.)
68.0	(67.9 - 68.2)

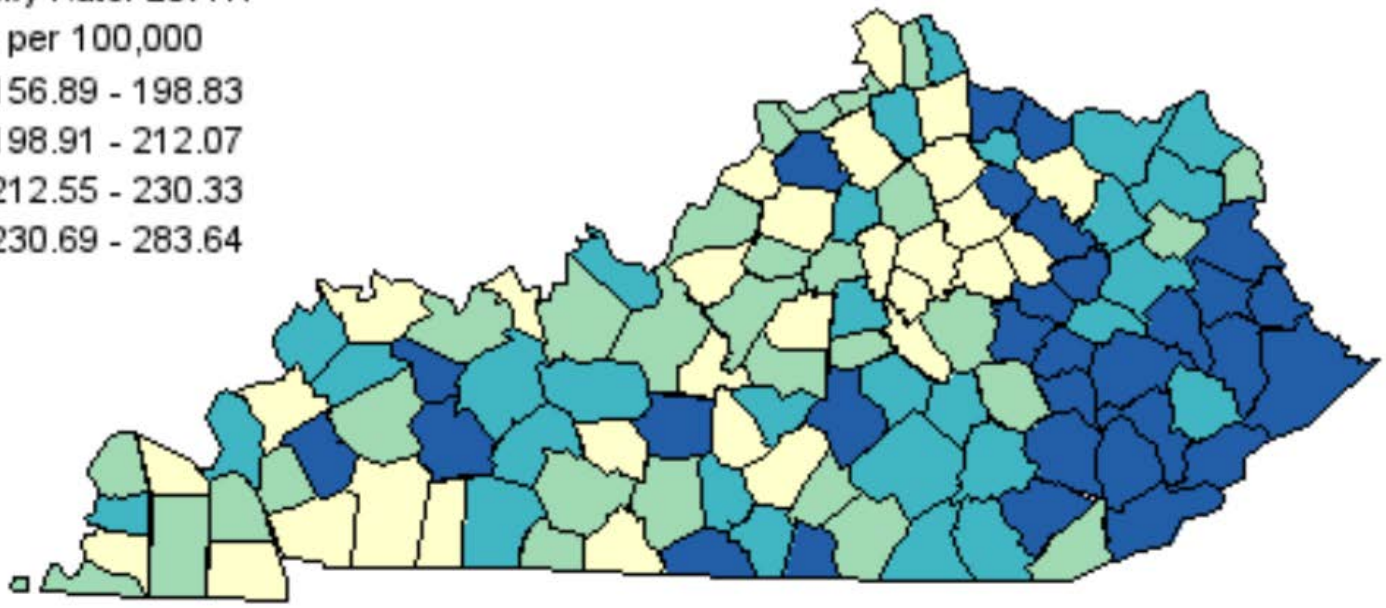
Kentucky	
Rate	(95% C.I.)
100.6	(99.2 - 101.9)

Age-Adjusted Cancer Mortality Rates in Kentucky
All Sites, 2006-2010
By County
Age-Adjusted to the 2000 U.S. Standard Million Population

Kentucky Rate: 207.41

Rate per 100,000

- 156.89 - 198.83
- 198.91 - 212.07
- 212.55 - 230.33
- 230.69 - 283.64

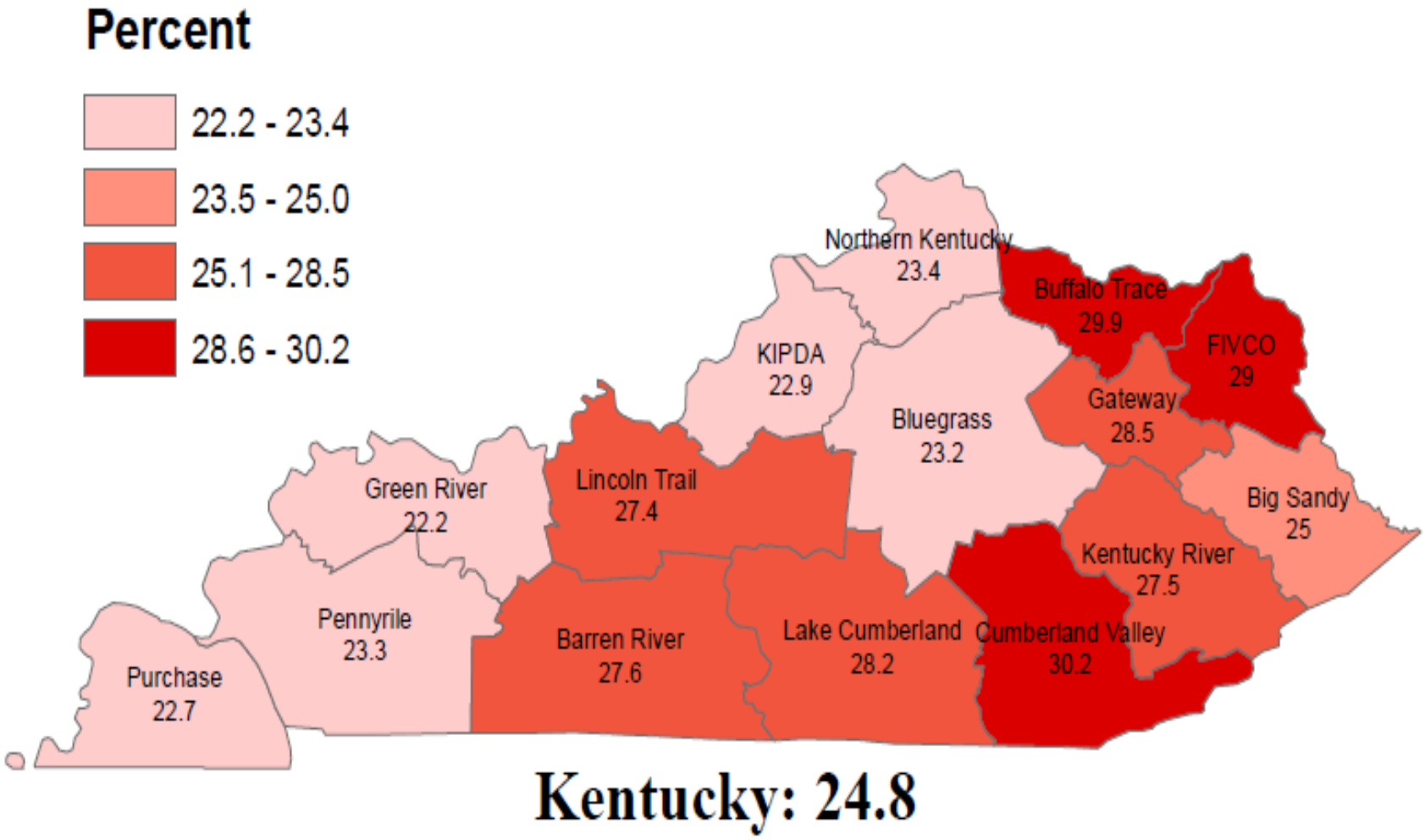


Data accessed July 1, 2013.
Based on data released May 2, 2013.

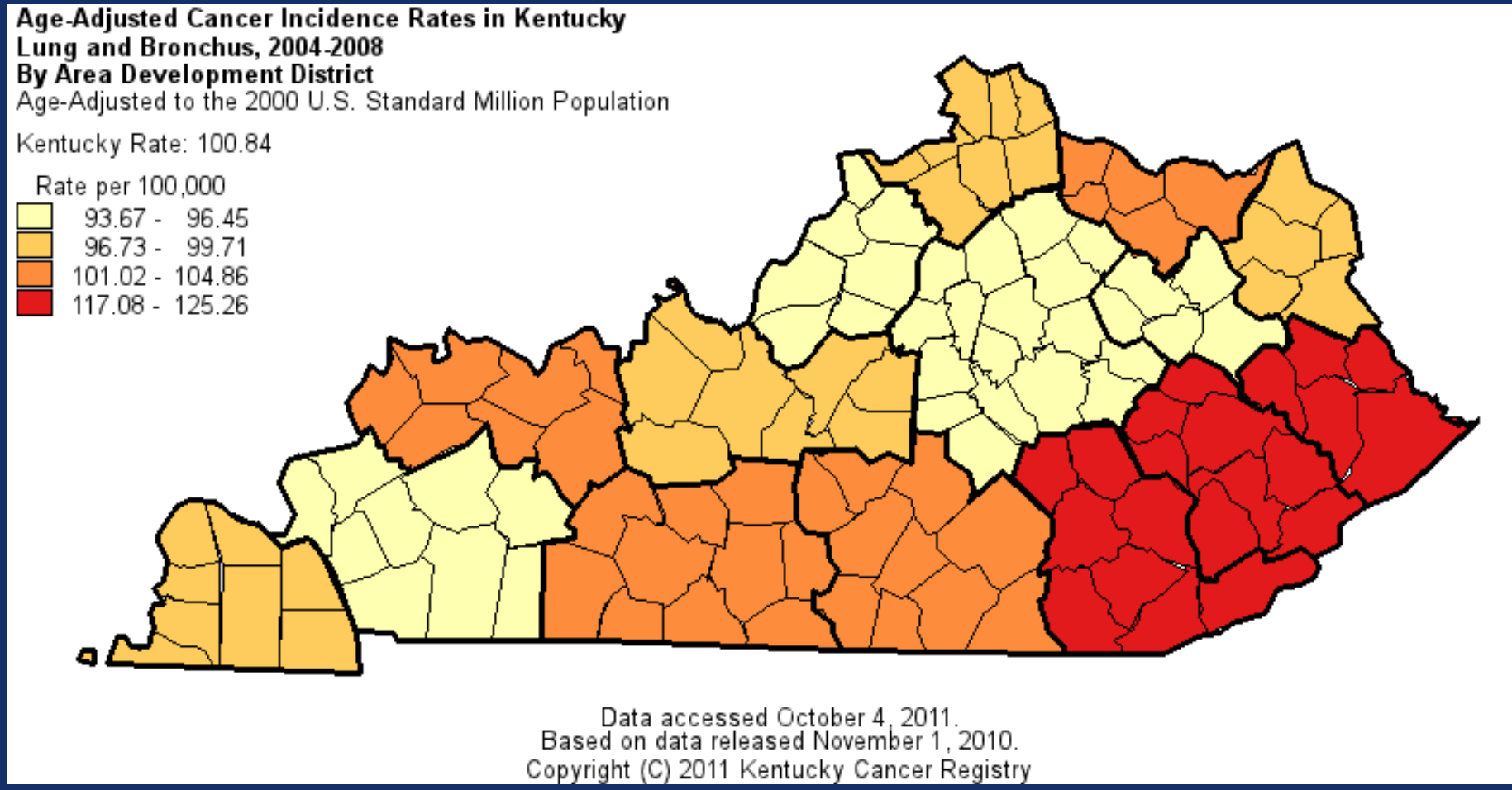
Smoking

- 90% of lung cancer related to smoking.
- The strongest determinant of lung cancer in smokers is duration of cigarette smoking, and the risk also becomes larger with the number of cigarettes smoked.
- Smoking causes lung cancer in both men and women.

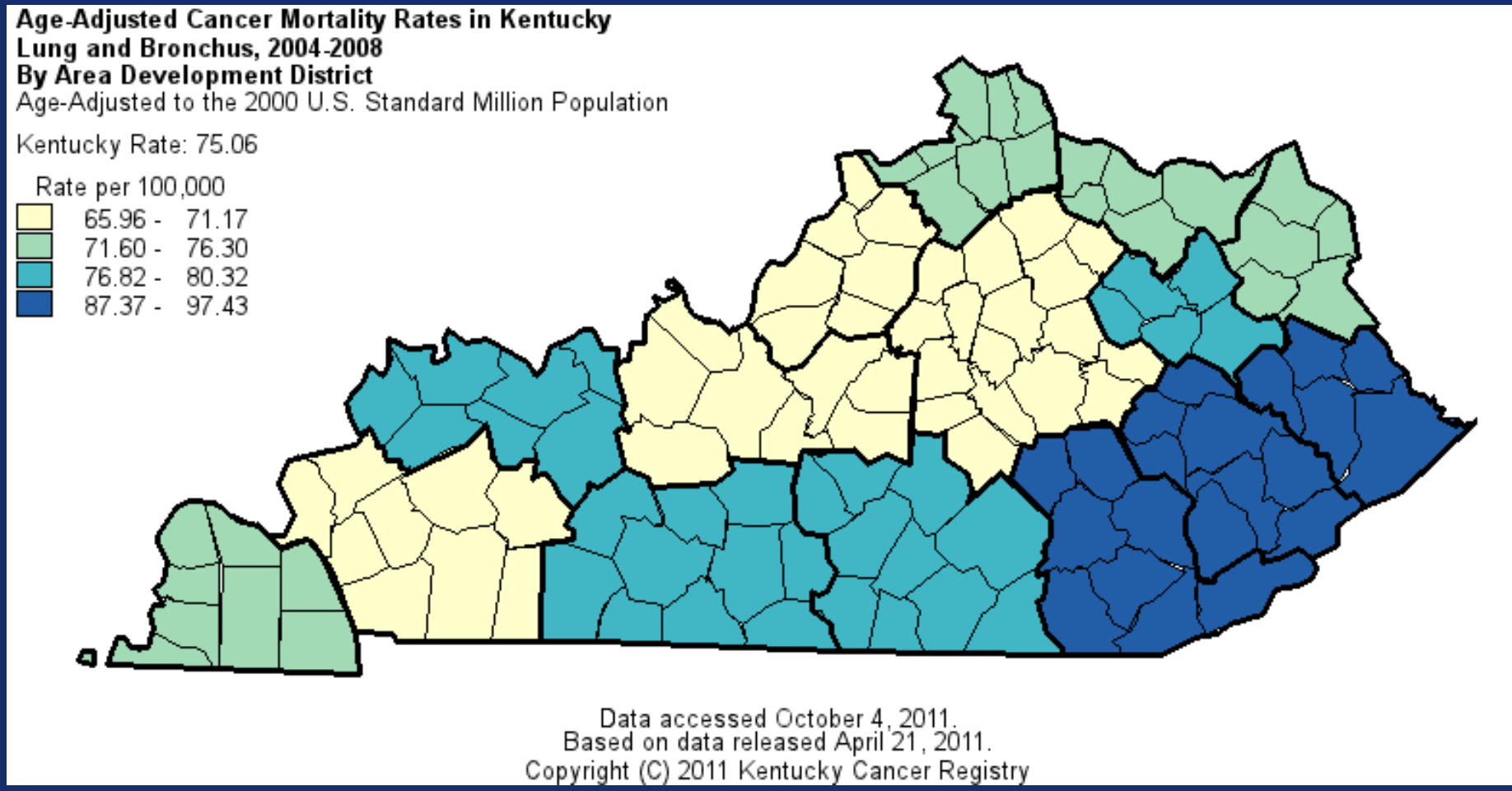
Prevalence of Current Smoking by Area Development District, 2010



Lung Cancer Incidence by Area Development District, 2004-2008



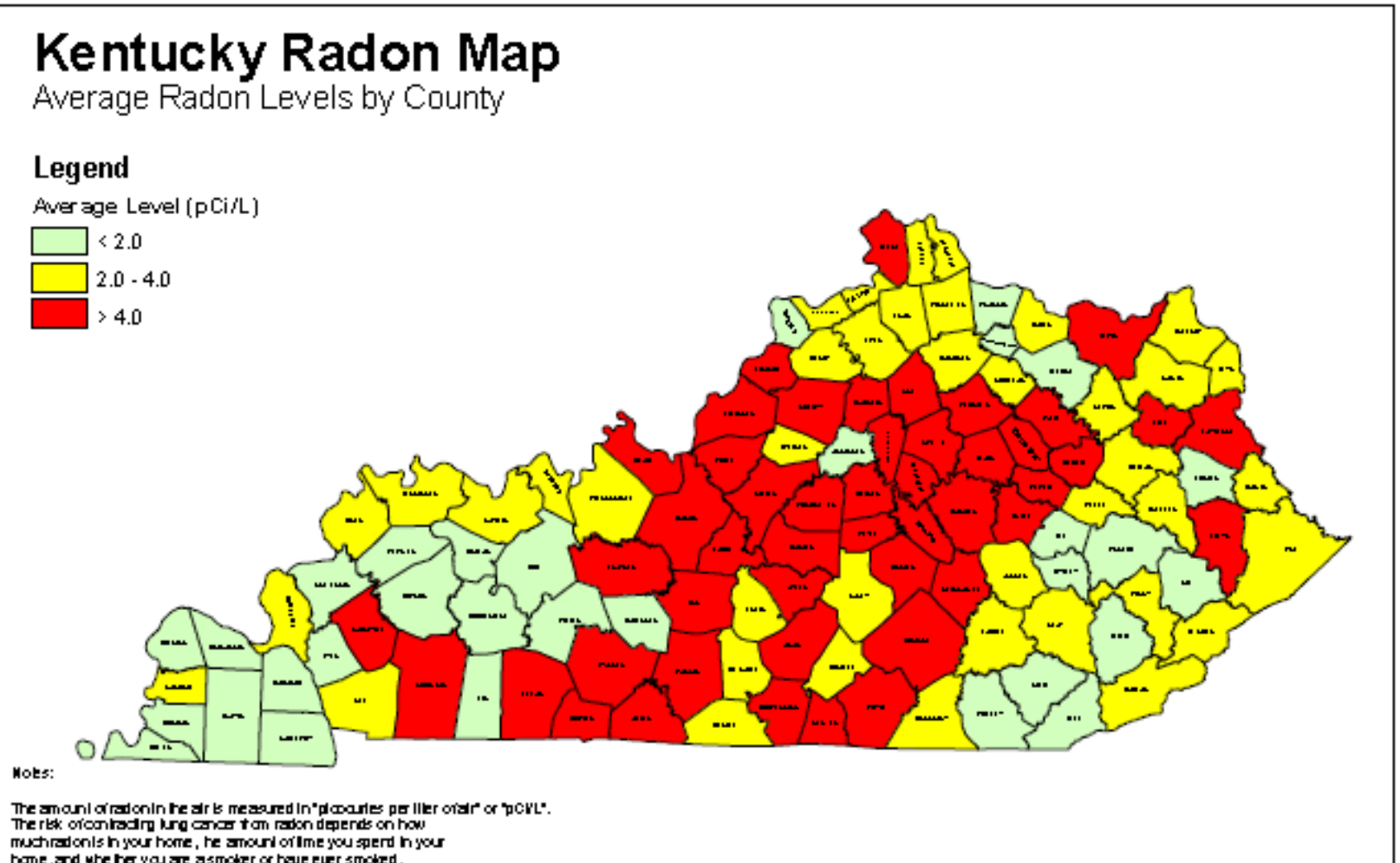
Lung Cancer Mortality by Area Development District, 2004-2008



Other Risk Factors

- Radiation therapy in both Hodgkin lymphoma and breast cancer.
- Environmental toxins: second-hand smoke, asbestos, radon, metals (arsenic, chromium, and nickel), ionizing radiation, and polycyclic aromatic hydrocarbons.
- Pulmonary fibrosis —risk increased about 7X
- HIV infection
- Genetic factors —clearly established familial risk.
- Dietary factors — (antioxidants, cruciferous vegetables, phytoestrogens) may reduce the risk of lung cancer, but trials in high-risk patients have not been successful.

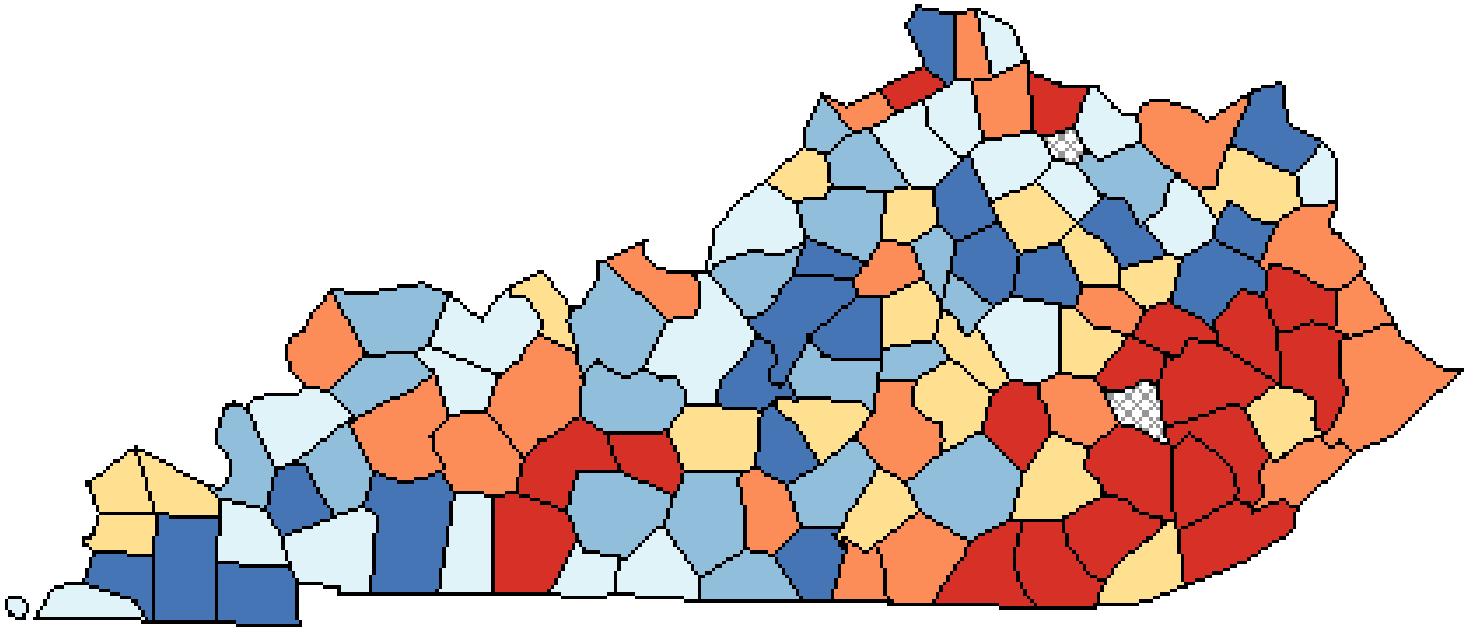
Radon?


Kentucky Radon Map
Average Radon Levels by County
Legend
Average Level (pCi/L)
< 2.0
2.0 - 4.0
> 4.0
Notes:
The amount of radon in the air is measured in "picocuries per liter of air" or "pCi/L".
The risk of contracting lung cancer from radon depends on how
much radon is in your home, the amount of time you spend in your

Incidence Rates† for Kentucky, 2003 - 2007

Lung & Bronchus

All Races (includes Hispanic), Both Sexes, All Ages



Age-Adjusted

Annual Incidence Rate

(Cases per 100,000)

Quantile Interval

- 116.8 to 157.0
- 109.6 to 116.7
- 101.6 to 109.5
- 96.1 to 101.5
- 89.1 to 96.0
- 68.8 to 89.0
- Suppressed */**

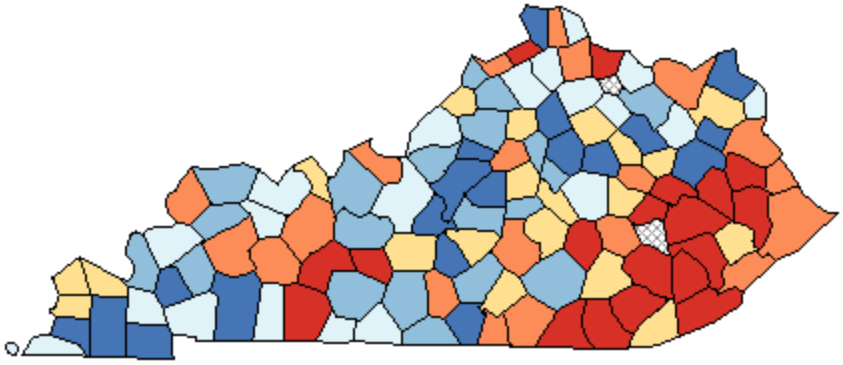
US (SEER + NPCR)	
Rate	(95% C.I.)
68.0	(67.9 - 68.2)

Kentucky	
Rate	(95% C.I.)
100.6	(99.2 - 101.9)

Incidence Rates† for Kentucky, 2003 - 2007

Lung & Bronchus

All Races (includes Hispanic), Both Sexes, All Ages



Age-Adjusted

Annual Incidence Rate

(Cases per 100,000)

Quantile Interval

- 116.8 to 157.0
- 109.6 to 116.7
- 101.6 to 109.5
- 96.1 to 101.5
- 89.1 to 96.0
- 68.8 to 89.0
- Suppressed * /**

US (SEER + NPCR)
Rate (95% C.I.)
68.0 (67.9 - 68.2)

Kentucky
Rate (95% C.I.)
100.6 (99.2 - 101.9)

Created by statecancerprofiles.cancer.gov on 09/21/2010 10:33 pm.
State Cancer Registries may provide more current or more local data.
Data presented on the State Cancer Profiles Web Site may differ from statistics reported by the State Cancer Registries (for more information).

† Incidence rates (cases per 100,000 population per year) are age-adjusted to the 2000 US standard population (19 age groups: <1, 1-4, 5-9, ... , 80-84, 85+). Rates are for invasive cancer only (except for bladder which is invasive and in situ) or unless otherwise specified. Rates calculated using SEER*Stat. Population counts for denominators are based on Census populations as modified by NCI. The US populations included with the data release have been adjusted for the population shifts due to hurricanes Katrina and Rita for 62 counties and parishes in Alabama, Mississippi, Louisiana, and Texas The 1969-2007 US Population Data File is used with SEER November 2009 data. The 1969-2006 US Population Data File is used with NPCR data November 2008/January 2009 data.

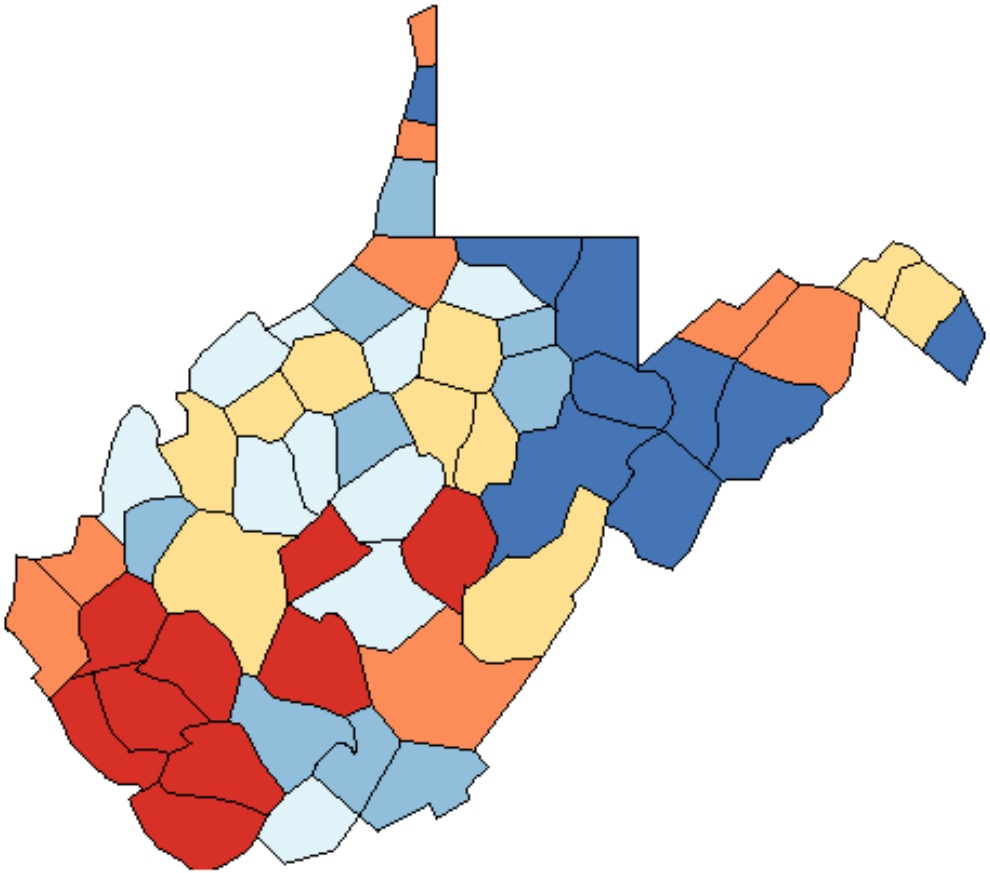
* Data have been suppressed to ensure confidentiality and stability of rate estimates. Counts are suppressed if fewer than 16 cases were reported in a specific area-sex-race category.

** Data have been suppressed for states with a population below 50,000 per sex for American Indian/Alaska Native or Asian/Pacific Islanders because of concerns regarding the relatively small size of these populations in some states.

Incidence Rates† for West Virginia, 2003 - 2007

Lung & Bronchus

All Races (includes Hispanic), Both Sexes, All Ages



Age-Adjusted

Annual Incidence Rate

(Cases per 100,000)

Quantile Interval

- 102.9 to 134.7
- 94.1 to 102.8
- 88.5 to 94.0
- 81.7 to 88.4
- 72.6 to 81.6
- 48.0 to 72.5

US (SEER + NPCR)
Rate (95% C.I.)
68.0 (67.9 - 68.2)

West Virginia
Rate (95% C.I.)
90.4 (88.6 - 92.2)

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State Cancer Registries may provide more current or more local data.

Data presented on the State Cancer Profiles Web Site may differ from statistics reported by the State Cancer Registries (for more information).

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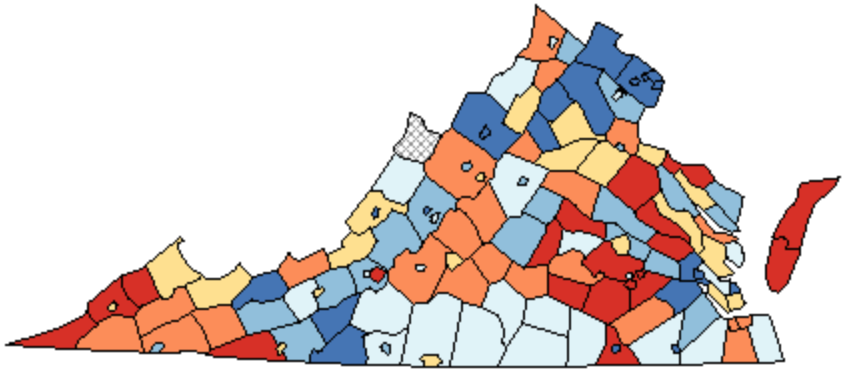
Incidence Rates† for Virginia, 2003 - 2007

Lung & Bronchus

All Races (includes Hispanic), Both Sexes, All Ages



Age-Adjusted

Annual Incidence Rate

(Cases per 100,000)

Quantile Interval

- 89.3 to 117.6
- 79.5 to 89.2
- 73.3 to 79.4
- 68.1 to 73.2
- 58.2 to 68.0
- 37.3 to 58.1
- Suppressed * /**

US (SEER + NPCR)
Rate (95% C.I.)
68.0 (67.9 - 68.2)

Virginia
Rate (95% C.I.)
68.4 (67.5 - 69.2)

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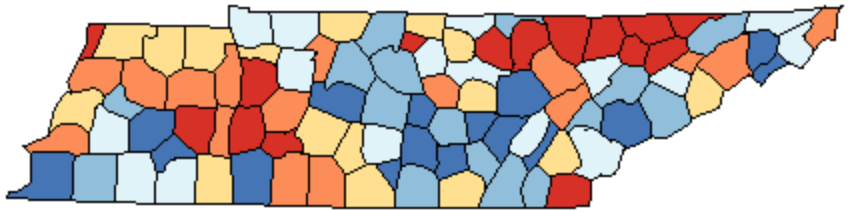
State Cancer Registries may provide more current or more local data.
Data presented on the State Cancer Profiles Web Site may differ from statistics reported by the State Cancer Registries (for more information).

† Incidence rates (cases per 100,000 population per year) are age-adjusted to the 2000 US standard population (19 age groups: <1, 1-4, 5-9, ... , 80-84, 85+). Rates are for invasive cancer only (except for bladder which is invasive and in situ) or unless otherwise specified. Rates calculated using SEER*Stat. Population counts for denominators are based on Census populations as modified by NCI. The US populations included with the data release have been adjusted for the population shifts due to hurricanes Katrina and Rita for 62 counties and parishes in Alabama, Mississippi, Louisiana, and Texas The 1969-2007 US Population Data File is used with SEER November 2009 data. The 1969-2006 US Population Data File is used with NPCR data November 2008/January 2009 data.

* Data have been suppressed to ensure confidentiality and stability of rate estimates. Counts are suppressed if fewer than 16 cases were reported in a specific area-sex-race category.

** Data have been suppressed for states with a population below 50,000 per sex for American Indian/Alaska Native or Asian/Pacific Islanders because of concerns regarding the relatively small size of these populations in some states.

Age-Adjusted Death Rates for Tennessee, 2003 - 2007
Lung & Bronchus
All Races (includes Hispanic), Both Sexes, All Ages



Age-Adjusted
Annual Death Rate
(Deaths per 100,000)

Quantile Interval

- 85.4 to 119.7
- 78.6 to 85.3
- 74.4 to 78.5
- 66.5 to 74.3
- 61.3 to 66.4
- 48.3 to 61.2

United States
Rate (95% C.I.)
52.5 (52.4 - 52.6)

Tennessee
Rate (95% C.I.)
67.7 (66.7 - 68.6)

Healthy People 2010
Goal 03-02
44.9

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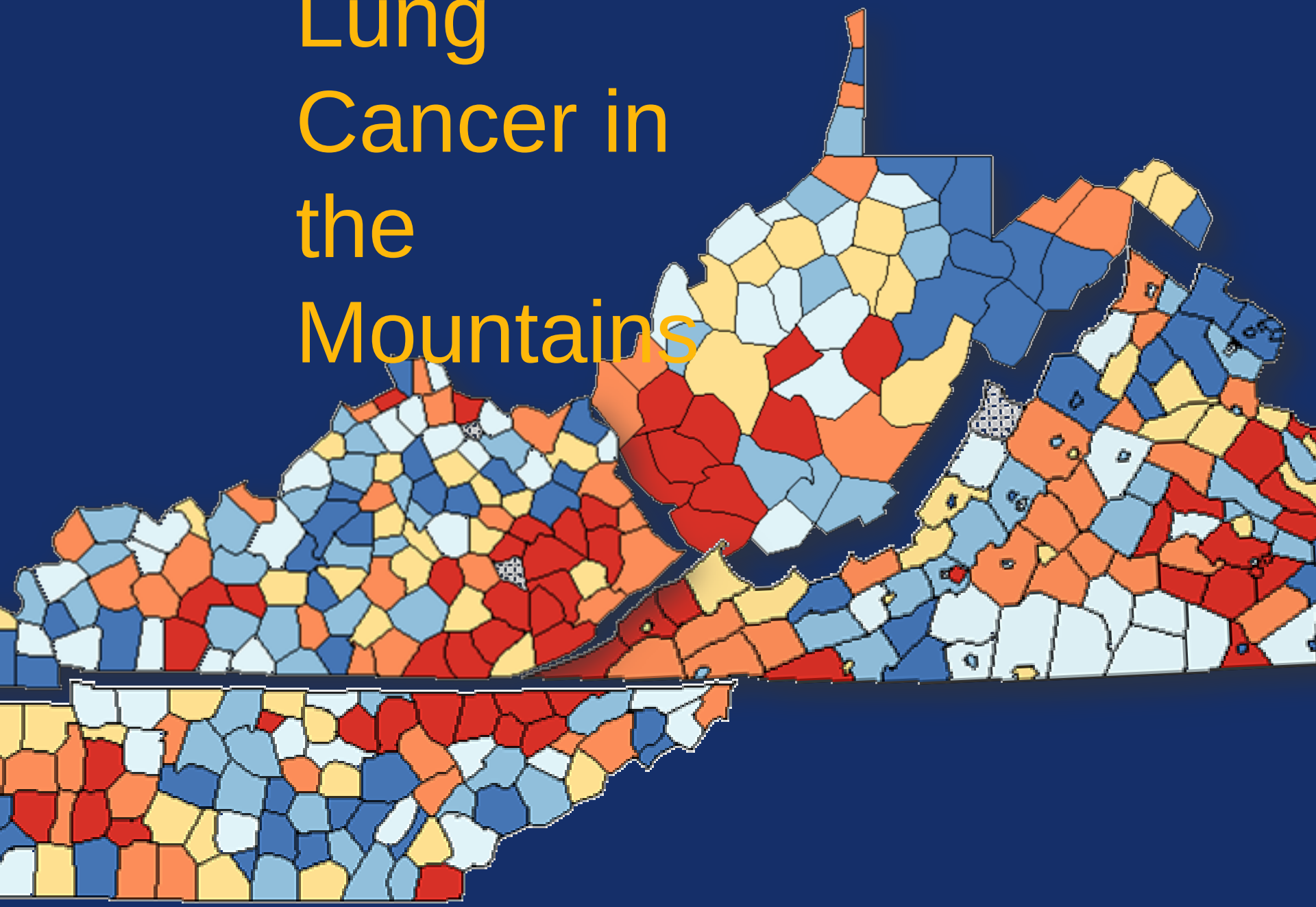
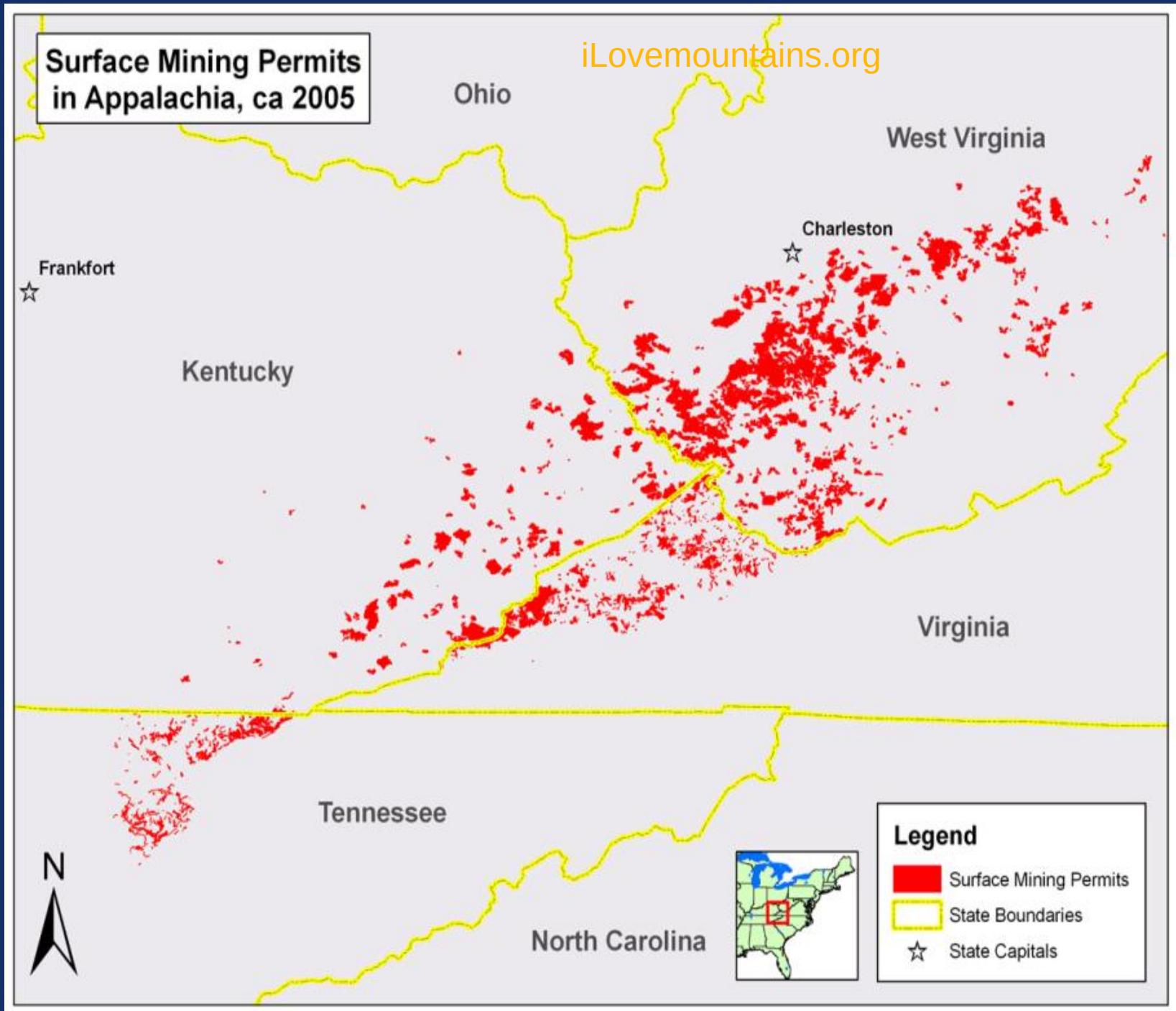
State Cancer Registries may provide more current or more local data.
Data presented on the State Cancer Profiles Web Site may differ from statistics reported by the State Cancer Registries (for more information).
Source: Death data provided by the National Vital Statistics System public use data file. Death rates calculated by the National Cancer Institute using SEER*Stat . Death rates (deaths per 100,000 population per year) are age-adjusted to the 2000 US standard population (19 age groups: <1, 1-4, 5-9, ... , 80-84, 85+). The Healthy People 2010 goals are based on rates adjusted using different methods but the differences should be minimal. Population counts for denominators are based on the Census 1969-2006 US Population Data File as modified by NCI.
The US populations included with the data release have been adjusted for the population shifts due to hurricanes Katrina and Rita for 62 counties and parishes in Alabama, Mississippi, Louisiana, and Texas.
Healthy People 2010 Goal 03-02 : Reduce the lung cancer death rate to 44.9.
Healthy People 2010 Objectives provided by the Centers for Disease Control and Prevention .

Lung Cancer in the Mountains




Surface Mining Permits in Appalachia, ca 2005
iLovemountains.org
Ohio
West Virginia
Charleston
Frankfort
Kentucky
Virginia
Tennessee
North Carolina
N
Legend
Surface Mining Permits
State Boundaries
State Capitals

Objective 2

Discuss current guidelines and recommendations for lung cancer screening

USPSTF

- The USPSTF recommends annual screening for lung cancer with low-dose computed tomography (LDCT) in
  - adults aged 55 to 80 years
  - who have a 30 pack-year smoking history and
  - currently smoke or have quit within the past 15 years.
  - Screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery.
  - (B recommendation)

U.S. Preventive Services Task Force

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Draft Recommendation Statement

I would like to comment on the draft Recommendation Statement.

What is in a Recommendation Statement?

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Note: This draft Recommendation Statement is not the final recommendation of the U.S. Preventive Services Task Force. This draft is distributed solely for the purpose of pre-release review. It has not been disseminated otherwise by the USPSTF. It does not represent and should not be interpreted to represent a USPSTF determination or policy.

This draft Recommendation Statement is based on an evidence review that was published on July 30, 2013 (available at http://www.uspreventiveservicestaskforce.org/uspstf13/lungcan/lungcanart.htm).

The USPSTF makes recommendations about the effectiveness of specific preventive care services for patients without related signs or symptoms.

It bases its recommendations on the evidence of both the benefits and harms of the service, and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.

The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decisionmaking to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.

This draft Recommendation Statement is available for comment from July 30 until August 26, 2013 at 5:00 PM ET. You may wish to read the entire Recommendation Statement before you comment. A fact sheet that explains the draft recommendations in plain language is available here.

Table 2: What the Grades Mean and Suggestions for Practice

Grade	Definition
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

AMERICAN LUNG ASSOCIATION

USPSTF Recommendation for Lung Cancer Screenings: Implications for Coverage in Health Insurance Plans

The United States Preventive Services Task Force issued a new 'B' recommendation for lung cancer screenings on December 30, 2013 for those at high risk. Under the Affordable Care Act, a recommendation of an 'A' or 'B' grade will have implications for insurance coverage for many Americans. Below is an explanation of these implications for various types of insurance.

On April 30, 2014, the Centers for Medicare & Medicaid Services (CMS) will be convening a Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) meeting to review all the available data, prior to making its final coverage decision.

Plan/Type of Plan	Popu			verage Requirement
Traditional Medicare	Ages			meline of National Coverage s
Medicare Advantage	Ages Adva			
Traditional Medicaid	Lowe childr disabl			
Medicaid Expansion	Incon Pover chosen to expand Medicaid), including childless adults			ired by January 1, 2015
State Health Insurance Marketplace Plans	Mostly the unemployed, self-employed, part-time workers, and employees of small companies. Individuals and families who make up to 400% of the Federal Poverty Level are eligible for subsidies	Coverage is required	No	Coverage required by January 1, 2015
Small Group and Individual Plans (outside Marketplaces)	Mostly the unemployed, self-employed, part-time workers, and employees of small companies.	Coverage is required	No	Coverage required by January 1, 2015
Large Group and Self-Insured Plans	Employees of large employers (over 50 employees), member of unions	Coverage is required	No	Varies depending on the beginning of plan years – sometime in 2015.

Updated 12/30/2013

From: **Computed Tomography Screening for Lung Cancer**

JAMA. 2013;309(11):1163-1170. doi:10.1001/jama.2012.216988

Table 3. Computed Tomography Screening Recommendations

Organizations	Primary Population for Screening		Other Populations for Screening	
	Recommendations	AHA Level of Evidence[a]	Recommendations	AHA Level of Evidence[a]
American Association for Thoracic Surgery (AATS)	Aged 55-79 y ≥30 Pack-years of smoking	B	Aged ≥50 y ≥20 Pack-years of smoking Additional risk factor(s)[b] or Lung cancer survivor ≥5 y	B C
American College of Chest Physicians (ACCP) and American Society of Clinical Oncology (ASCO)	Aged 55-74 y ≥30 Pack-years of smoking Former smokers must have quit within past 15 y	B[c]	NR	NA
American Cancer Society	Aged 55-74 y ≥30 Pack-years of smoking Former smokers must have quit within past 15 y	B	NR	NA
National Comprehensive Cancer Network (NCCN)	Aged 55-74 y ≥30 Pack-years Former smokers must have quit within past 15 y	B	Aged ≥50 y ≥20 Pack-years of smoking Additional risk factor(s)[d]	B

Abbreviations: NA, not applicable; NR, not recommended for other populations.

[a] American Hospital Association (AHA) level of evidence: A, multiple populations evaluated; data derived from multiple randomized trials or meta-analysis; B, limited populations evaluated; data derived from single randomized trial or nonrandomized studies; C, very limited populations evaluated; only consensus opinion of experts, case studies, or standard of care.

[b] Additional risk factors for lung cancer defined by AATS include chronic obstructive pulmonary disease, environmental and occupational exposures, any prior cancer or thoracic radiation, and genetic or family history.

[c] Although ACCP and ASCO evaluated more than 1 randomized trial, their recommendations are graded B because they were based on a single randomized trial (other studies were deemed "too small, too preliminary, or too poorly designed to support meaningful conclusions").[47]

[d] Additional risk factors for lung cancer defined by NCCN include cancer history, lung disease history, family history of lung cancer, radon exposure, and occupational exposure.

AAFP (2013)

- T*he evidence is insufficient to recommend for or against* screening … (Grade: I recommendation)
- AAFP has significant concern with basing such a far reaching and costly recommendation on a single study.
- The NLST, conducted in major medical centers…, has not been replicated in a community setting.
- The long term harms of radiation exposure… unknown.

AAFP (2013)

- The USPSTF recommends annual CT screening even though the NLST trial was only 3 scans
- NNS to prevent one lung cancer death over 5 years and 3 screenings is 312.
- NNS to prevent one death by any cause is 208 over 5 years in the NLST trial.
- 40% will have a positive result requiring follow-up. The harms of these follow-up interventions in …the community is not known.
- "The cost-effectiveness of low-dose CT screening must also be considered in the context of competing interventions, particularly smoking cessation."

Objective 3

Review selected research on lung cancer screening

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 AUGUST 4, 2011 VOL. 365 NO. 5

Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening

The National Lung Screening Trial Research Team*

ABSTRACT

BACKGROUND

Marty Driesler Lung Cancer Project: Results of Lung Cancer Screening in Rural Kentucky

UK HealthCare Markey Cancer Center

Eric Bensadoun[1], Michael Brooks[1], Stacey Slone[1], Andre Baron[1], Bin Huang[1] David Mannino[1], Edward Hirschowitz[1], Anthony Weaver[2], Amtullah Khan[3], Jason Castle[4], J.D. Miller[5], Amanda Wiggins[1], Susanne Arnold[1]

University of Kentucky, Lexington, Kentucky; 2 - St. Claire Regional Medical Center, Morehead, Kentucky; 3 - Lake Cumberland Regional Medical Center, Somerset, Kentucky; 4 - Highlands Regional Medical Center, Prestonsburg, Kentucky; 5 - Appalachian Regional Healthcare, Inc., Hazard, Kentucky.

UK University of Kentucky

ABSTRACT

Background: Southeastern Kentucky has one of the highest incidence rates of lung cancer in the United States. Computed tomography (CT) scan screening for lung cancer offers the promise of early diagnosis and improved outcomes, however, this remains unproven as the results of the large, randomized National Lung Screening trial are pending.

Objective: The Marty Driesler Lung Cancer Project was developed to assess the feasibility of CT screening in rural Kentucky in a high risk population selected on the basis of residence in a geographic region with a documented high incidence of lung cancer, and the presence of a combination of smoking history and airways obstruction on pulmonary function testing. In addition, all recruiting and testing was to be performed locally in southeastern Kentucky.

Methods: From 2005 to 2008 patients were recruited and screened for eligibility by telephone. Eligible subjects were between 55 to 75 years of age and were either current or former smokers (<10 years of cessation) with a >30 pack-years smoking history. These subjects were invited to one of four participating regional centers for pulmonary function testing. Those subjects who had an FEV1/FVC<70% underwent non-contrasted, low-dose spiral CT scans annually for three years. All research procedures were performed at the community hospital centers.

Results: A total of 955 individuals were screened for eligibility by telephone and 626 (65%) were eligible. Of those subjects 531 had pulmonary function testing and 254 of these subjects had FEV1/FVC<70%. These 227 subjects were enrolled in the screening study and were scheduled to have CT scans annually for three years. The baseline (prevalence) CT examination identified 37 (16%) patients with at least one non-calcified nodule > 4mm and 3 (1.2%) cases of lung cancer. During the next two annual (incidence) screening examinations an additional 9 patients with non-calcified nodules were identified and one more case of lung cancer was diagnosed. To date a total of 46 (20%) non-calcified nodules > 4mm have been identified, and six (2.6%) cases of lung cancers have been diagnosed (two synchronous primaries in one patient). Five of the lung cancers have been adenocarcinomas (all stage 1A) and two were squamous cell carcinoma (stages 1A and 2B)

Conclusion: CT screening for lung cancer in a rural, high-risk population using regional community hospital partners is feasible. The frequency of nodule detection remains substantial, and despite selecting a high risk population the rates of lung cancer detection were lower than might have been expected based on prior screening studies.

THE MARTY DRIESLER PROJECT SITES

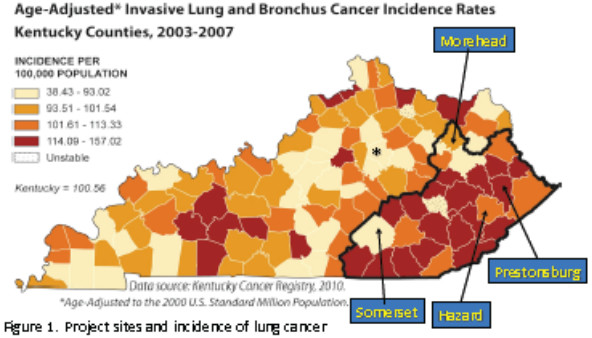


Figure 1. Project sites and incidence of lung cancer

OBJECTIVES

The project was a prospective observational cohort study of three yearly low dose screening computed tomography (CT) scans of the chest with two more years of follow-up by phone survey. Study objectives were:

1. Feasibility of CT screening in rural Appalachia
2. Rate of non-calcified nodule detection
3. Rate of completion of 3 scans and follow-up period or recommended action after abnormal scan

METHODS

- Subjects were screened for eligibility by phone.
- Eligible subjects were invited to one of four participating regional centers for pulmonary function testing.
- Subjects with an FEV1/FVC<70% underwent non-contrasted, low-dose spiral CT scans annually for three years, as well as biospecimen collection.
- All research procedures were performed at the community hospital centers
- All CT scans were interpreted by local radiologists, with oversight central radiologist
- Positive screening CT scan = at least one non-calcified nodule > 4mm in diameter
- Positive screen ended participation in screening study
- Recommendations for evaluation of nodule per Fleischner Society guidelines sent to referring MD
- Calcified nodules and non-calcified nodules ≤ 4mm were allowed to remain in the study

ENTRY CRITERIA AND STUDY TIMELINE

Inclusion criteria	Exclusion criteria
Age 55-75	Patient requiring oxygen supplementation
Current or former smokers (quit < 15 years) with > 30 pack-year smoking history	Life expectancy < 5 years
FEV1/FVC <70%	Current or prior history of lung cancer
	Prior history of any cancer within 5 years (excluding non-melanoma skin cancer)
	Inability to lie flat with arms raised above the head
	CT scan within 1 year of enrollment

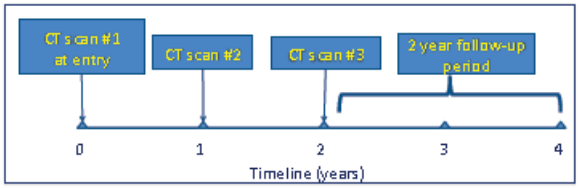


Figure 2. Study timeline

RESULTS

Characteristics (n=227)	No. (%)
Gender (male/female)	115/112
Age (years)	
55-60	78 (34%)
61-64	76 (34%)
65-75	73 (32%)
Smoking status	
Current	142 (63%)
Former	85 (37%)
Pack-years, mean (range)	65 (35-216)
FEV1/FVC ratio Mean (range)	60.0 (22.3-70.2)
Race	
Caucasian	98.4%
Other	1.6%

Table 1. Subject Characteristics

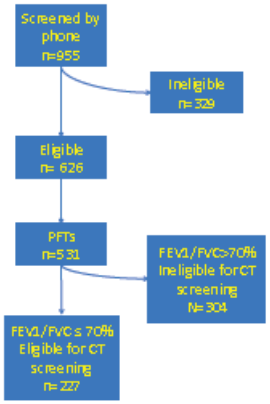


Figure 3. Accrual

RESULTS

Screening CT	Expected No.	Withdrew or lost to f/u	Screened No. (%)	Positive scan (nodules >4mm) No. (%)
1st	227	0	227 (100%)	37 (16%)
2nd	190	31	159 (84%)	3 (2%)
3rd	156	23	133 (85%)	6 (5%)

Table 2. Compliance and screen positivity

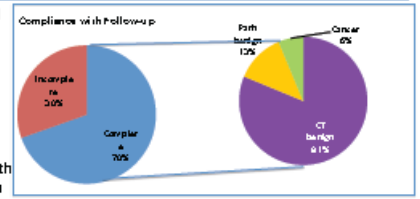


Figure 4. Compliance with follow-up recommendation

Subjects screened	Total subjects with nodules or lung abnormalities	Non-calcified nodule > 4 mm No. (%)	Subjects with no lung findings	Lung cancer detected No. (%)
227	140 (62%)	46 (20%)	87 (38%)	6 (2.6%)

Table 3. Nodule detection rates

Cases	Screening CT No.	Tumor Diameter (mm)	Tumor Histology	Stage TNM
1	1	10	Adenocarcinoma	1A (T1aN0Mx)
2	1	10	Adenocarcinoma	1A (T1aN0Mx)
3	1	18	Adenocarcinoma	1A (T1aN0Mx)
		20	Bronchioalveolar	1A (T1aN0Mx)
4*	3	28	Squamous cell	1A (T1bN0Mx)
5*	3	35	Squamous cell	2A(T2aN1Mx)
6*	3	20	Adenocarcinoma	1A (T1aN0Mx)

Table 4. Characteristics and stage of cancers detected * found after 3rd CT scan

	Yr 1	Yr 2	Yr 3	Total
Total scans	227	159	133	519
Percentage Clinically Significant Discrepancies	13.24%	3.44%	10.95%	9.21%
* Clinically significant discrepancies affecting follow-up recommendations				

Table 5. Discrepancy of CT scan readings between local and central radiologist

CONCLUSIONS

- CT screening for lung cancer in a rural community based setting is feasible with 70% compliance with recommended follow-up
- The rate of nodule detection (20%) and lung cancer (2.6%) are similar to NLST
- No improvement in lung cancer detection rate in subjects with FEV1/FVC < 70%
- Whether outcomes similar to the NLST can also be achieved in the community setting remains to be determined
- Variability in the interpretation screening CT by local radiologists with a discrepancy rate of 9% and 3/6 cancers initially missed
- In patients with nodules:
  - Recommendations from local radiologists may vary from Fleischner guidelines
  - Inconsistency in following recommendations by referring physicians
- Interventions to educate radiologists and primary care physicians regarding CT scan interpretation and implementation of Fleischner guidelines within a high incidence lung cancer and histoplasmosis population are warranted

Funded in part by the Kentucky Lung Cancer Research Program, HRSA, CDC, MCC

Special thanks to Lana Sutherland and Susan Reno for their assistance with this project

Box 1. Entry Criteria for National Lung Screening Trial

Age 55-74 years

Smoking history

- ≥30 Pack-years[a]
- Former smokers must have quit within past 15 years

Exclusions

- Previous lung cancer
- Other prior cancer (except nonmelanoma skin cancer) in past 5 years
- Chest computed tomography within past 18 months
- Hemoptysis
- Unexplained weight loss >15 lb in past year
- Metallic implants or devices in chest or back
- Requirement for home oxygen supplementation
- Pneumonia or other acute respiratory tract infection treated with antibiotics in past 12 weeks

[a] Pack-years refers to number of cigarette packs smoked per day (20 cigarettes per pack) multiplied by the number of years of smoking.

MDLCP Entry Criteria

Entry Criteria and Study Timeline

Inclusion criteria	Exclusion criteria
Age 55-75	Patient requiring oxygen supplementation
Current or former smokers (quit <15 years) with > 30 pack-year smoking history	Life expectancy < 5 years
FEV1/FVC <70%	Current or prior history of lung cancer
	Prior history of any cancer within 5 years (excluding non-melanoma skin cancer)
	Inability to lie flat with arms raised above the head
	CT scan within 1 year of enrollment

Screening

- LCST: Three yearly screenings with either low dose CT or PA/Lat CXRs and followed for 3.5 years
- MDLCP: Three yearly screenings with low dose CT at community hospitals, with central review

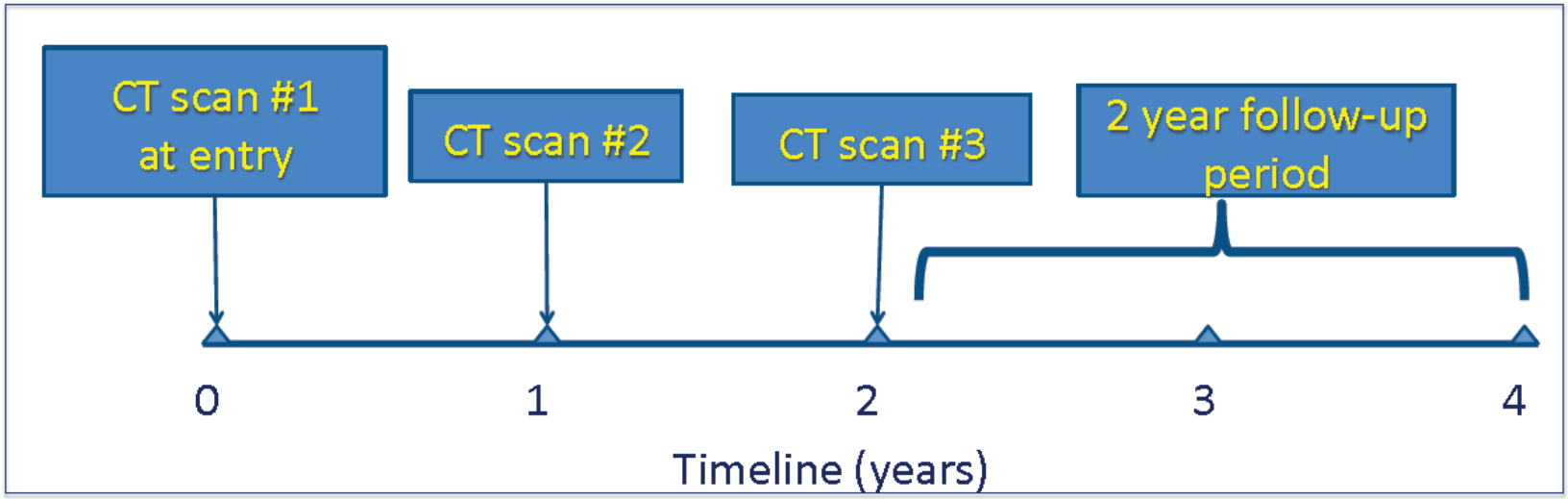


Figure 2. Study timeline

Table 2. Results of Three Rounds of Screening.*

Screening Round	Low-Dose CT				Chest Radiography			
	Total No. Screened	Positive Result	Clinically Significant Abnormality Not Suspicious for Lung Cancer	No or Minor Abnormality	Total No. Screened	Positive Result	Clinically Significant Abnormality Not Suspicious for Lung Cancer	No or Minor Abnormality
			no. (% of screened)				*no. (% of screened)*	
T0	26,309	7191 (27.3)	2695 (10.2)	16,423 (62.4)	26,035	2387 (9.2)	785 (3.0)	22,863 (87.8)
T1	24,715	6901 (27.9)	1519 (6.1)	16,295 (65.9)	24,089	1482 (6.2)	429 (1.8)	22,178 (92.1)
T2	24,102	4054 (16.8)	1408 (5.8)	18,640 (77.3)	23,346	1174 (5.0)	361 (1.5)	21,811 (93.4)

* The screenings were performed at 1-year intervals, with the first screening (T0) performed soon after the time of randomization. Results of screening tests that were technically inadequate (7 in the low-dose CT group and 26 in the radiography group, across the three screening rounds) are not included in this table. A screening test with low-dose CT was considered to be positive if it revealed a nodule at least 4 mm in any diameter or other abnormalities that were suspicious for lung cancer. A screening test with chest radiography was considered to be positive if it revealed a nodule or mass of any size or other abnormalities suspicious for lung cancer.

Subjects screened	Total subjects with nodules or lung abnormalities	Non-calcified nodule > 4 mm No. (%)	Subjects with no lung findings	Lung cancer detected No. (%)
227	140 (62%)	46 (20%)	87 (38%)	6 (2.6%)

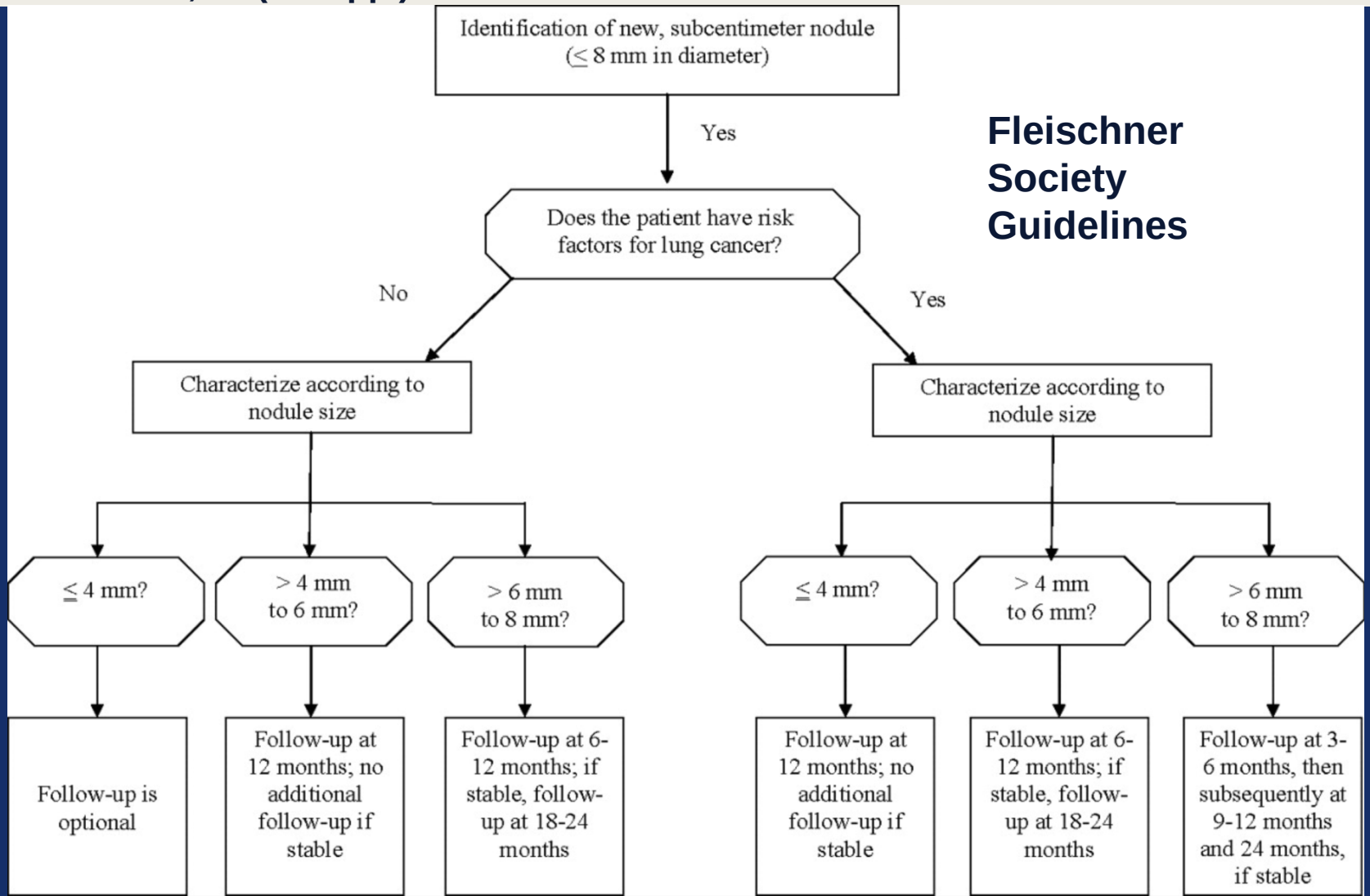
Problems with Community-based screening

- Variability in the interpretation screening CT by local radiologists with the discrepancy rate of 9% and 3/6 cancers initially missed
- In patients with nodules:
  - Recommendations from local radiologist may vary from Fleischner guidelines
  - Inconsistency by referring physicians in following recommendations

	Yr 1	Yr 2	Yr 3	Total
Total scans	227	159	133	519
Percentage Clinically Significant Discrepancies	13.24%	3.44%	10.95%	9.21%
* Clinically significant discrepancies affecting follow-up recommendations				

Evaluation of Patients With Pulmonary Nodules: When Is It Lung Cancer?*: ACCP Evidence-Based Clinical Practice Guidelines (2nd Edition)

Chest. 2007;132(3_suppl):108S-130S. doi:10.1378/chest.07-1353



Fleischner Society Guidelines

Current Practice on F/U of nodules

Research

JAMA Intern Med. Published online April 7, 2014.

Original Investigation

Resource Use and Guideline Concordance in Evaluation of Pulmonary Nodules for Cancer
Too Much and Too Little Care

Renda Soylemez Wiener, MD, MPH; Michael K. Gould, MD, MS; Christopher G. Slatore, MD, MS; Benjamin G. Fincke, MD; Lisa M. Schwartz, MD, MS; Steven Woloshin, MD, MS

IMPORTANCE Pulmonary nodules are common, and more will be found with implementation of lung cancer screening. How potentially malignant pulmonary nodules are evaluated may affect patient outcomes, health care costs, and effectiveness of lung cancer screening programs. Guidelines for evaluating pulmonary nodules for cancer exist, but little is known about how nodules are evaluated in the usual care setting.

OBJECTIVE To characterize nodule evaluation and concordance with guidelines.

Supplemental content at jamainternalmedicine.com

Too Much and Too Little Care

- Reviewed records of 300 adults with pulmonary nodules from 15 VA's

20%	$\leq$ 4 mm
45%	5-8 mm
36%	> 8 mm

- Median # of tests =2 (benign nodule), 8 (cancer)
- Median total F/U = 13 mo. (<1mo.-8.5 yrs)
- 4/13 nodules resected were benign
- 8/46 with invasive testing had complications

Conclusions

- 55.3% of patients received appropriate evaluation, 17.8% over-evaluated, and 26.9% under-evaluated.
- "It is important for clinicians to recognize that there is a real gap between care that is currently being delivered to patients with pulmonary nodules and what clinical practice guidelines considered optimal care"

ONLINE FIRST

Benefits and Harms of CT Screening for Lung Cancer

A Systematic Review

Peter B. Bach, MD, MAPP
Joshua N. Mirkin, BA
Thomas K. Oliver, BA
Christopher G. Azzoli, MD
Donald A. Berry, PhD
Otis W. Brawley, MD
Tim Byers, MD, MPH
Graham A. Colditz, MD, DrPH
Michael K. Gould, MD, MS
James R. Jett, MD
Anita L. Sabichi, MD
Rebecca Smith-Bindman, MD

Context Lung cancer is the leading cause of cancer death. Most patients are diagnosed with advanced disease, resulting in a very low 5-year survival. Screening may reduce the risk of death from lung cancer.

Objective To conduct a systematic review of the evidence regarding the benefits and harms of lung cancer screening using low-dose computed tomography (LDCT). A multisociety collaborative initiative (involving the American Cancer Society, American College of Chest Physicians, American Society of Clinical Oncology, and National Comprehensive Cancer Network) was undertaken to create the foundation for development of an evidence-based clinical guideline.

Data Sources MEDLINE (Ovid: January 1996 to April 2012), EMBASE (Ovid: January 1996 to April 2012), and the Cochrane Library (April 2012).

Study Selection Of 591 citations identified and reviewed, 8 randomized trials and 13 cohort studies of LDCT screening met criteria for inclusion. Primary outcomes were lung cancer mortality and all-cause mortality, and secondary outcomes included nodule detection, invasive procedures, follow-up tests, and smoking cessation.

JAMA May 20, 2012, Vol 307, No. 22

Conclusion

"Screening a population of individuals at a substantially elevated risk of lung cancer most likely could be performed in a manner such that the benefits that accrue to a few individuals outweigh the harms that many will experience.

However, there are substantial uncertainties regarding how to translate that conclusion into clinical practice."

Lung Cancer: Why the Guilt Trip?

- Memorial Sloan-Kettering survey
- 2000 lung cancer patients
- 84% current non-smokers
- "… people who start smoking are generally 12 or 13years old… They were targeted."
- "We are going to be faced with an epidemic of lung cancer for a decade or more if every single person stops smoking today."

Objective 4

Suggest future directions

SUGGESTIONS

- We should be screening for lung cancer in Kentucky, particularly Eastern Kentucky
- Scans should be done locally, with oversight
- There should be at a minimum a registry, but preferably an organized network for managing positive screens
- Talk to Whitney Jones about starting a statewide cancer screening program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POLYPOSIS
COMMONWEALTH OF KENTUCKY
UNITED WE STAND
DIVIDED WE FALL

Weaver's wish list

- Statewide smoking ban
- $.50 per pack increase in state cigarette tax
- Kentucky Medicaid pays for lung cancer screening, but demands accountability
- Lung cancer biospecimen bank with statewide specimen collection
- Research into the determinants of lung cancer in high risk counties (?Mountain Top Removal?)