The Mid-South Miracle:

Implementing Structured Lung Cancer Care Delivery in a High-Risk Population

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DECLARATIONS

Chair: Board of Directors, Hope Foundation for Cancer Research (SWOG)

Co-chair: IASLC N-Staging Sub-Committee, IASLC Prognostic Factors Subcommittee; SWOG Early Lung Cancer Sub-Committee

Consultant: American Cancer Society, AstraZeneca, Genentech/Roche, National Cancer Institute

Member: Fleischner Society

Patents: Lymph node specimen collection kit, Method for lymph node analysis

Scientific Advisory Board: National Cancer Institute, Druckenmiller Center for Lung Cancer Research, MSKCC; GO2 Foundation; Lung Cancer Foundation of America; LUNGevity

Foundation; University of Pennsylvania Telehealth Research Center of Excellence (TRACE); Dartmouth Health Center of Biomedical Research Excellence (COBRE); Fred Hutch Cancer Center, Hutchinson Institute for Cancer Outcomes Research (HICOR); AstraZenaca US Lung Ambition Advisory Council; Median

Technologies, Nice, France.

Speaker: Medscape, Tryptych Healthcare Partners

Steering Committee: National Lung Cancer Round Table, NCI Cancer Prevention Steering Committee, Genentech Inc SKYSCRAPER-15 (G045006).

Stock: Eli Lilly, Gilead Sciences, Pfizer, Bridge Bio

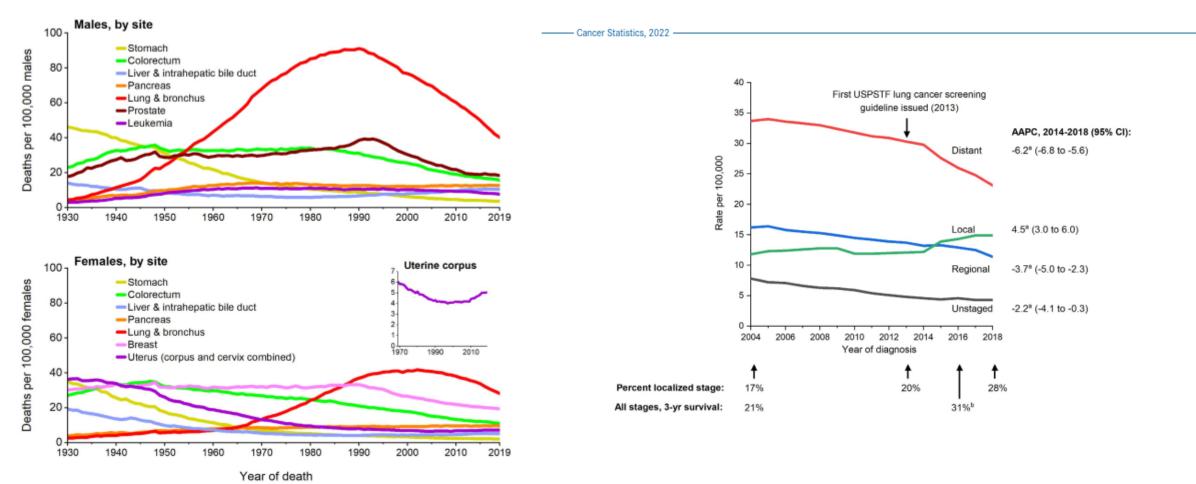


Take-Home Messages

- Lung Nodule Programs provide a robust, complementary, epidemiologically sound pathway to early lung cancer detection.
 - Provides access to early detection to a non-overlapping, high-risk population.
 - Concurrent deployment alleviates looming disparities inadvertently induced by LDCT.
 - Can be implemented even when LDCT unavailable.
- Multidisciplinary decision-making saves lives, synthesizes decision-making.
- Close attention to surgical quality a vital component for population impact.
- Program-based care creates the shortest pathway to population-level lung cancer outcomes improvement.
- The best treatment is a clinical trial; build clinical trials infrastructure where the population is.



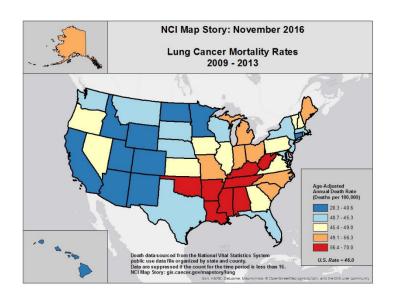
The Good News: Evolving US Lung Cancer Statistics

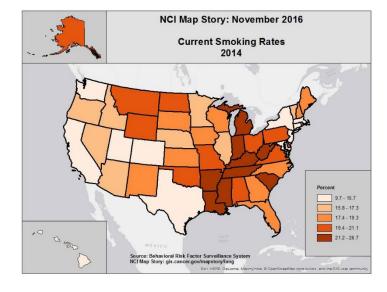


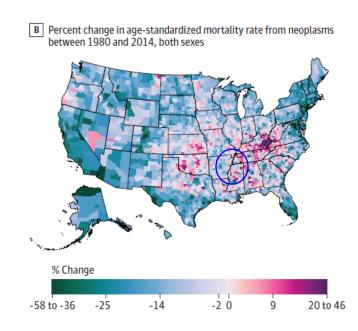
Siegel RL, Miller KD, Fuchs HE, Jemal A. Cancer statistics, 2022. CA Cancer J Clin. 2022 PMID: 35020204.



Epidemiology of Lung Cancer in the US: A Tale of Geographic Disparity

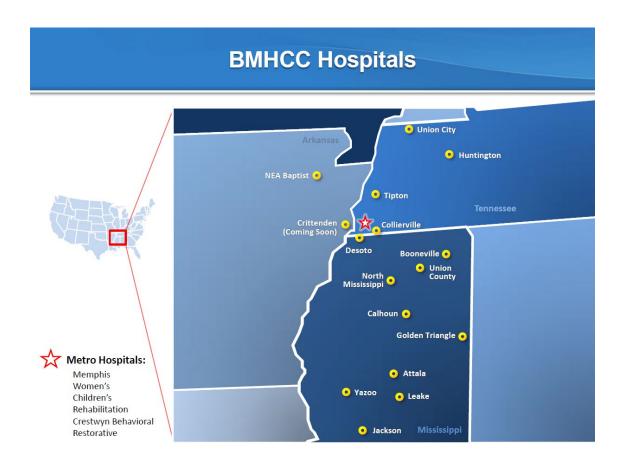






Trends and Patterns of Disparity in Cancer Mortality Among US Counties. Mokdad AH et al, JAMA.2017; 317(4):388-406.

If BMHCC was a state....



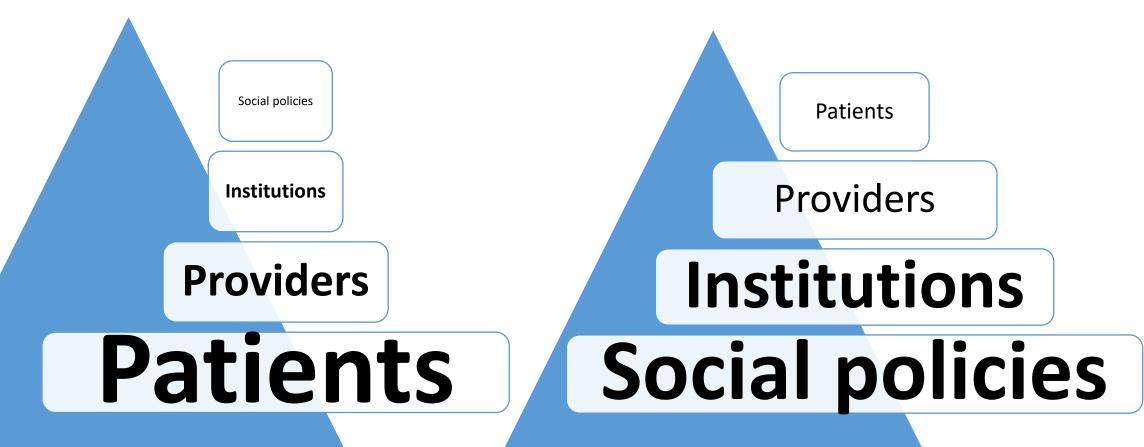
	State	Estimated new lung cancer cases, 2020 ¹	NCI-Designated Cancer Center?
37	Nebraska	1270	1
38	New Hampshire	1220	1
	BMHCC	1200 - 1300	0
39	New Mexico	1040	1
40	Idaho	990	0
41	Rhode Island	920	0
42	Delaware	890	0
43	Hawaii	870	1
44	Montana	770	0
45	Utah	730	1
46	South Dakota	590	0
47	Vermont	570	0
48	North Dakota	460	0
49	Alaska	400	0
50	Wyoming	320	0
	DC	300	1

¹ Siegel RL, Miller KD, Jemal A. Cancer Statistics, 2020. CA Cancer J Clin 2020;70:7-30



Get Better.

Inverse proportionality between number of targets and intervention leverage



Number of intervention targets

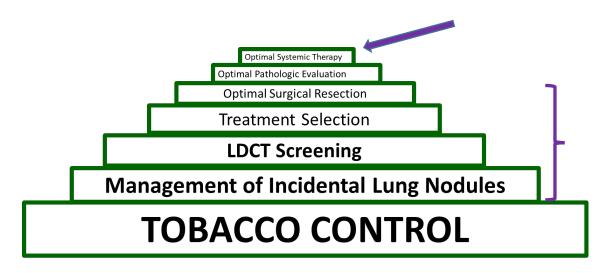
Impact of intervention target

Implementing The Mid-South Miracle:

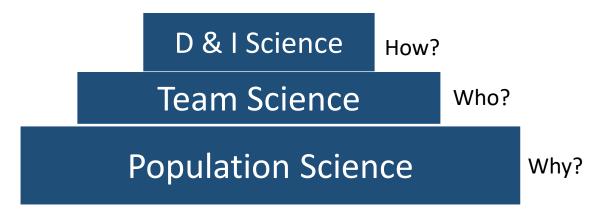
Goal: Reduce Lung Cancer Mortality >25% Over 10 Years

Objectives: sustained, rigorous implementation of seven specific clinical programs

The Population Impact Pyramid



A Three-Tiered Approach



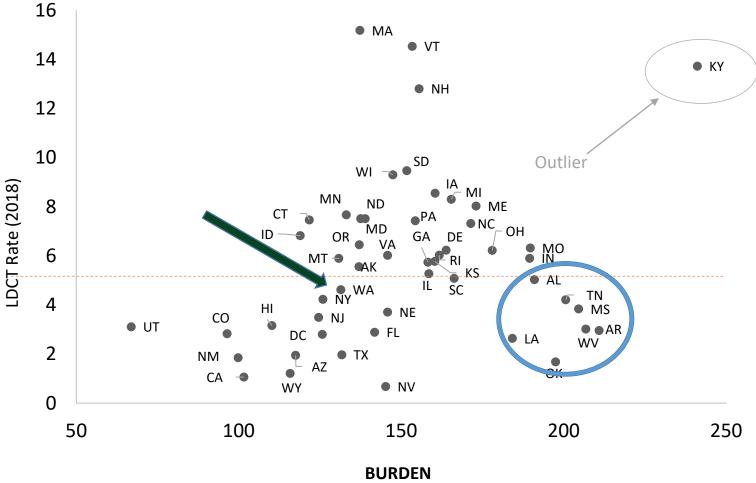
Lung Cancer Screening Saves Lives! But...

Lung Cancer Screening USA 2023: Population-Level Access and Effectiveness Challenges!



Osarogiagbon, Yang, Sequist. ASCO Educational Book 2023





Lung Cancer Mortality Rate Per 100,000 Adults 55-80 years (2013-2017)

Fedewa SA, et al. J Natl Cancer Inst. 2020. PMID: 33176362.

Avoid this... save lives!



February, 2020 June, 2020 April, 2021



Guideline-Concordant Management of Incidentally Detected Lung Nodules^{1,2}

• Pros:

- Starts from the point of detection of potentially malignant lung lesion
- LDCT eligibility criteria less relevant
- Bypasses LDCT implementation barriers
- Leverages existing clinical material, infrastructure
- Expands the reach of early detection to hard-to-reach populations
- Alleviates a medico-legal quandry

Cons:

- Requires some infrastructure for identifying, tracking, oversight
- Optimally requires transparent, interdisciplinary decision-making

¹Gould MK, Donington J, Lynch WR, et al. ACCP evidence-based clinical practice guidelines. Chest. 2013 PMID: 23649456,

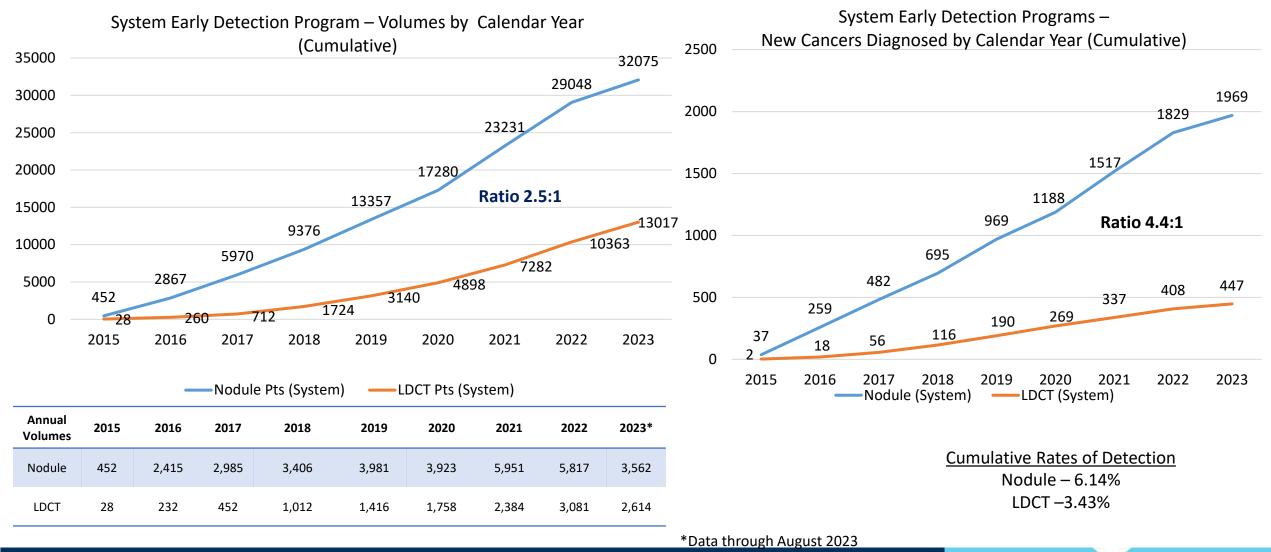
²MacMahon H, Naidich DP, Goo JM, et al. From the Fleischner Society 2017. Radiology. 2017 PMID: 28240562.



Get Better.

Detecting Early Lung Cancer (DELUGE) in MS Delta

Program Volumes





Get Better.

ILNP: Complementary Pathway to Early Lung Cancer Detection?

Patient Group	LDCT	LNP	MDC	P
Proportion eligible for LDCT by USPSTF 2013 Criteria, No. (%)				
All patients	4,513 (79.75)	1,756 (11.36)	570 (32.28)	< .0001
Patients with lung cancer	133 (88.67)	298 (42.69)	430 (42.57)	< .0001
Proportion eligible for LDCT by USPSTF 2021 Criteria, No. (%)				
All patients	4,720 (83.41)	2,280 (14.75)	718 (40.66)	< .0001
Patients with lung cancer	137 (91.33)	344 (49.28)	529 (52.38)	< .0001

Abbreviations: LDCT, Low-Dose Computed Tomography Lung Cancer Screening Program; LNP, Lung Nodule Program; MDC, Multidisciplinary Care Program; USPSTF, US Preventive Services Task Force.

Even if 100% of eligible persons by USPSTF 2021 criteria had been enrolled into LDCT screening, ILNP would have detected 20% of all stage I/II patients in the entire cohort.

Osarogiagbon, et al. Epub J Clin Oncol.
PMID: 35258994
DOI: 10.1200/JCO.21.02496



METHODS A prospective observational study enrolled pa compared them with patients managed in a Multidisc distribution, surgical resection rates, 3- and 5-year survi diagnosed with lung cancer.

RESULTS From 2015 to May 2021, 22,886 patients were 1,766 in Multidisciplinary Care. Of 150, 698, and 1,010 programs, 61%, 60%, and 44% were diagnosed at clinical IV (P = .0005): 47%, 42%, and 32% had curative-intent rates were 80% (95% CI, 73 to 88) versus 64% (60 to 6 were 76% (67 to 87) versus 60% (56 to 65) versus 44% (4 lung cancer would have been deemed eligible for LDCT criteria, and 54% by 2021 criteria. Even if all eligible pat LDCT, the Nodule Program would have detected 20%

CONCLUSION LDCT and Lung Nodule Programs are cor detection and curative treatment to different-risk popula leviate emerging disparities in access to early lung can-

J Clin Oncol OO. © 2022 by American Society of Clinical Oncology

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Although aggregate US lung cancer incidence and mortality statistics have improved in recent years, they mask great geographic heterogeneity. 1-3 States and counties in the Southeastern and Midwestern United States lag behind in the emerging improvement. 1,3 The aggregate 5-year lung cancer survival barely reaches 21%, largely because 79% of patients present with regional and distant metastatic disease, when the 5-year survival is 32% and 6%, respectively.1 Only 15% present with localized disease when the 5-year survival is 59%.1

Low-dose computed tomographic screening for lung cancer (LDCT) saves lives. 4,5 Annual LDCT was recommended by the US Preventive Services Task Force

ASCO

ASSOCIATED

CONTENT

Appendix

Author affiliations

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and support

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ORIGINAL ARTICLE

Potential Impact of Criteria Modi and Sex Disparities in Eligibility f Screening

Matthew P. Smeltzer, PhD. Wei Liao, PhD. Nicho Carrie Fehnel, BBA, Dordan Goss, MA, Catherine Rodolfo Ramos, BA, Talat Qureshi, BS, Ayesha M Meredith A. Ray, PhD, a Raymond Uyiosa Osarogias

^aDivision of Epidemiology, Biostatistics, and Environmental Healtl Memphis, Tennessee

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Received 18 August 2022; revised 20 September 2022; accepted 2 Available online - 5 October 2022

ARSTRACT

Introduction: Low-dose computed tomography (LDCT) screening reduces lung cancer mortality, but current eligibility criteria underestimate risk in women and racial minorities. We evaluated the impact of screening criteria modifications on LDCT eligibility and lung cancer detection.

Methods: Using data from a Lung Nodule Program, we compared persons eligible for LDCT by the following: U.S. Preventive Services Task Force (USPSTF) 2013 criteria (55-80 y, \geq 30 pack-years of smoking, and \leq 15 y since cessation); USPSTF2021 criteria (50-80 y, ≥20 pack-years of smoking, and <15 y since cessation); quit duration expanded to less than or equal to 25 years (USPSTF2021-QD25); reducing the pack-years of smoking to more than or equal to 10 years (USPSTF2021-PY10); and both (USPSTF2021-QD25-PY10). We compare across groups using the chi-square test or analysis of variance.

Results: The 17,421 individuals analyzed were of 56% female sex, 69% white, 28% black; 13% met USPSTF2013 criteria; 17% USPSTF2021; 18% USPSTF2021-QD25; 19% USPSTF2021-PY10; and 21% USPSTF2021-QD25-PY10. Additional eligible individuals by USPSTF2021 (n = 682) and USPSTF2021-QD25-PY10 (n = 1402) were 27% and 29% black, both significantly higher than USPSTF2013 (17%, p < 0.0001). These additional eligible individuals were 55% (USPSTF2021) and 55% (USPSTF2021-QD25-PY10) of female sex, compared with 48% by USPSTF2013 (p < 0.05). Of 1243 persons (7.1%) with lung cancer, 22% were screening eligible by USPSTF13. USPSTF2021-QD25-PY10 increased the total number of persons with lung cancer by 37%. These additional individuals with lung cancer were of 57% female sex (versus 48% with USPSTF2013, p = 0.0476) and 24% black (versus 20% with USPSTF2013, p = 0.3367).

Journal of Thoracic Oncology Vol. 18 No. 2: 158-168

Network Open.

Original Investigation | Oncology **Evaluation of Lung Cancer Ri** or Guideline-Concordant Mo

Raymond U. Osarogiagbon, MBBS; Wei Liao, PhD; Nicholas Anberitha T. Matthews, PhD: Matthew P. Smeltzer, PhD: Pa

Abstract

Co

IMPORTANCE Guideline-concordant management diagnosis, but the lung cancer risk profile of persons from that of screening-eligible persons.

OBJECTIVE To compare lung cancer diagnosis haza computed tomography screening (LDCT cohort) and

DESIGN, SETTING, AND PARTICIPANTS This pros enrollees from January 1, 2015, to December 31, 202 system. Participants were prospectively identified, o survival was updated at 6-month intervals. The LDC Reporting and Data System as having no potentially those with potentially malignant lesions (Lung-RAD! by smoking history into screening-eligible vs screeni cancer, younger than 50 years or older than 80 years cohort only) were excluded. Participants were follow

MAIN OUTCOMES AND MEASURES Comparative patient, nodule, and lung cancer characteristics bety

RESULTS There were 6684 participants in the LDC men [50.49%]; 5774 [86.39%] in the Lung-RADS 1-2 and 12 645 in the LNP cohort (mean [SD] age, 65.42 [19.75%] screening eligible and 10 148 [80.25%] scr 1244 (18.61%) of the LDCT cohort, 492 (19.70%) of (28.72%) of the screening-ineligible LNP cohort (P < mm for the LDCT cohort (3 [IQR, 2-4] mm for Lung-F cohorts), 9 (IQR, 6-16) mm for the screening-eligible screening-ineligible LNP cohort. In the LDCT cohort (1.44%) in the Lung-RADS 1-2 cohort and 162 (17.80 cohort, it was diagnosed in 531 (21.27%) in the scree screening-ineligible cohort. Compared with Lung-R/ were 16.2 (95% CI, 12.7-20.6) for the screening-eligi screening-ineligible cohort: compared with Lung-RA 0.3 (95% CI, 0.2-0.4), respectively. The stage of lun (64.46%) in the LDCT cohort, 276 of 531 (52.00%) 447 (56.60%) in the screening-ineligible LNP cohor

JAMA Network Open. 2023;6(2):x230787. doi:10.1001/jamanet

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Thoracic Oncology Origina

Pulmonary Nod Screening, and 1 Medicare Popul

Paul Pinsky, PhD; Eric Miller, PhD; 1

BACKGROU may reduce RESEARCH

lung cance diagnosed

STUDY DES gram-Med of Medicar with a dia month per nying code R91.1 (ICI classified b diagnosis of cancer stas

RESULTS: (of 5.0 year nosis were 2.9%, and in the PN disease of a the PN an rates were

INTERPRET PNs tender had PNs tl LDCT scar lung cance

KEY WORDS

ABBREVIATIONS: HMO = health mainter hazard ratio; ICD = International Classifica low-dose CT; PN = pulmonary nodule; SE miology and End Results

AFFILIATIONS: From the Division of Cance M.), National Cancer Institute, Bethesda, MD

1304 Original Research

Received: 27 February 2023 | Revised: 11 April 2023 | Accepted: 24 April 2023

DOI: 10.1002/cncr.34844

ORIGINAL ARTICLE

Diagnostic follow-up of indeterminate pulmonary nodules in the Medicare population

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²Multidisciplinary Thoracic Oncology Program Baptist Cancer Center, Memphis, Tennessee,

Correspondence

Paul F. Pinsky, 9609 Medical Center Dr. Bethesda, MD 20892, USA. Email: pp4f@nih.gov

Abstract

Background: Management of indeterminate pulmonary nodules (IPNs) is associated with redistribution of lung cancer to earlier stages, but most subjects with IPNs do not have lung cancer. The burden of IPN management in Medicare recipients was assessed.

Methods: Surveillance, Epidemiology, and End Results-Medicare data were analyzed for IPNs, diagnostic procedures, and lung cancer status. IPNs were defined as chest computed tomography (CT) scans with accompanying International Classification of Diseases (ICD) codes of 793.11 (ICD-9) or R91.1 (ICD-10). Two cohorts were defined: persons with IPNs during 2014-2017 comprised the IPN cohort, whereas those with chest CT scans without IPNs during 2014-2017 comprised the control cohort. Excess rates of various procedures due to reported IPNs over 2 years of follow-up (chest CT, positron emission tomography [PET]/PET-CT, bronchoscopy, needle biopsy, and surgical procedures) were estimated using multivariable Poisson regression models comparing the cohorts adjusted for covariates. Prior data on stage redistribution associated with IPN management were then used to define a metric of excess procedures per latestage case avoided

Results: Totals of 19,009 and 60,985 subjects were included in the IPN and control cohorts. respectively; 3.6% and 0.8% had lung cancer during follow-up. Excess procedures per 100 persons with IPNs over a 2-year follow-up were 63, 8.2, 1.4, 1.9, and 0.9 for chest CT, PET/PET-CT, bronchoscopy, needle biopsy, and surgery, respectively. Corresponding excess procedures per late-stage case avoided were 48, 6.3, 1.1, 1.5, and 0.7 based on an estimated 1.3 late-stage cases avoided per 100 IPN cohort subjects.

Conclusions: The metric of excess procedures per late-stage case avoided can be used to measure the benefits-to-harms tradeoff of IPN management.

KEVWORDS

diagnostic imaging, lung neoplasms, Medicare, pulmonary nodule, surgical procedures

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Cancer. 2023;1-9 wileyonlinelibrary.com/journal/cncr 1

Osarogiagbon RU. 'The Mid-South Miracle.' Fred Hutch Cancer Center Value in Cancer Care Summit 2023. November 2, 2023.

Structured Multidisciplinary Decision-Making

Lung Cancer Care is Complex!

Anatomy

Patient characteristics

Widening array of options

Provider factors

Care-delivery systems

Lesion detection Outcome Diagnostic biopsy **Staging tests Treatment** evaluation PET-CTa Surgerydb CT-guided needleab Clinicalcdeg CXRa Brain CT or MRIa XRTf Bronchoscopy^{cb} CT^a CT scan^a VATS/RATSdb Bone scana Chemod PET-CTa Mediastinoscopydb Thoracentesis acdeb Targeted therapy^d Surgery + chemo^{dbe} Chamberlain^{db} Pericardiocentesis^{adb} Open surgical^{db} **EBUS**cdb Surgery + XRT^{dbg} EUScdfb Surgery + chemo + XRT^{dbeg} CT-guided biopsyab Chemo + surgery^{edb} Mediastinoscopydb ChemoXRT + surgery^{egdb} Palliative care cdegh Chamberlaindb Hospice carehi VATS/RATSdb VAMLAdb TEMLA^{db} Open surgical^{db}

INVOLVED PHYSICIAN SPECIALIST

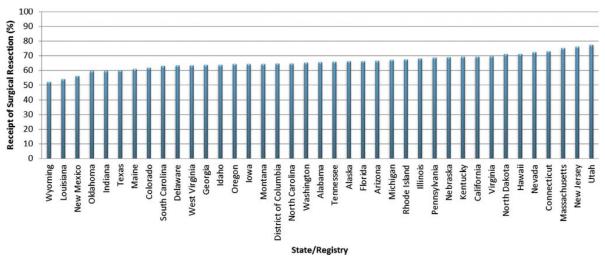
a Radiologist; b Pathologist; c Pulmonologist; d Surgeon; e Medical Oncologist; f Gastroenterologist; g Radiation Oncologist; h Palliative care specialist; i Hospice care specialist.

Osarogiagbon RU. Achieving better quality of lung cancer care. In: Tanoue L, Detterbeck F, editors. Lung Cancer: A Practical Approach to Evidence-Based Clinical Evaluation and Management. St. Louis, MO: Elsevier; 2018:167-182.





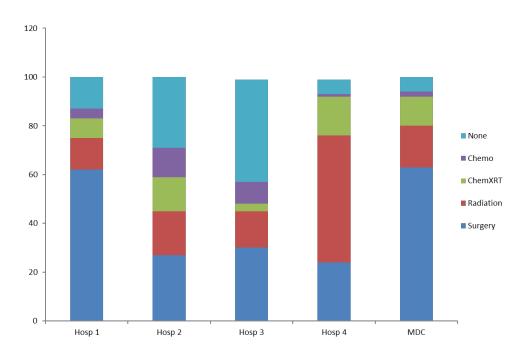
Problem: Guideline-Discordant Treatment



Sineshaw, Wu, Flanders, Osarogiagbon, Jemal. J Thorac Oncol 2016

County-level range: 12.8% to 91.7%!

Sineshaw, Sahar, Osarogiagbon, Flanders, Yabroff, Jemal. Chest. 2020;157:212-222.



Treatment of Stage I/II NSCLC- Single Healthcare System. Osarogiagbon, Unpublished

What is 'Multidisciplinary Care'?

- A title/brand/marketing opportunity?
- A program?
- Care by a group of individuals?
- A set of benchmarks or standards?
- A set of behaviors?
- A set of beliefs? A way of thinking? Conceptual model built around principles of care?





INTERNATIONAL ASSOCIATION FOR THE STUDY OF LUNG CANCER

Stakeholder Perspectives: Multidisciplinary Model

	er rerspectives.		Territor y Title ere r	
	Patients & Caregivers	Physicians	Hospital Admins.	Health Insurance
Benefits				
Physician collaboration	+	+	+	+
Coordinated care	+	+	+	+
Concordance with recommendations	+	+	+	+
Timeliness of care	+	+	+	+
Challenges				
Financial disincentives		+		
Scheduling conflicts		+		
Conflicting treatment opinions		+		
Lack of validated benchmarks			+	+

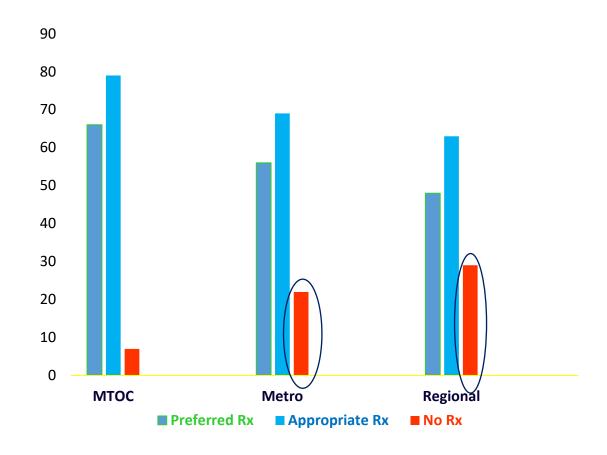
Multidisciplinary Care: A Definition

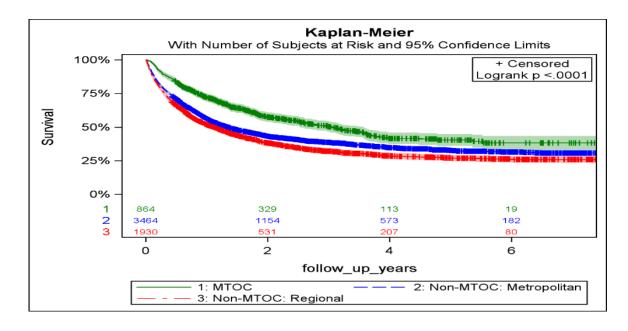
• Delivered by a <u>coordinated team</u> committed to <u>processes</u> that enhance certain group behaviors <u>demonstrated</u> to be necessary for high quality <u>outcomes</u>.

MultiD Care Saves Lives

'Building a multidisciplinary bridge across the quality chasm of thoracic oncology...'

Baptist Memorial Healthcare Corporation NSCLC patients 2011-2017





Ray MA, et al. JTO Clin Res Rep 2021. PMID: 34590046



Get Better.

The Immutable Core of Multidisciplinary Care

A coordinated team...

<u>Team</u>

- Anatomy
 - All physician specialties/skill sets (diagnosticians, tissue procurers, treatment specialists)
 - Central coordination through navigators
 - Must include the patient and their caregivers
- Physiology
 - 1. Recognition of the team by members and non-members
 - 2. <u>Commitment</u> to mutually agreed team-level objectives
 - 3. <u>Interdependent functionality</u> toward team objectives
 - 4. Regular <u>reflection</u> to regulate and adapt team objectives and processes

Team Science Principles

- 1. Shared mental models
 - What do we seek to achieve?
 - How do we achieve it?
 - How can we tell where we are in getting from here to there (benchmarking)?
- 2. Mutual trust
- 3. Mutual performance monitoring
 - Evidence-based care
 - Concordance between recommendations and care delivery
 - Quality and safety of care
- 4. Backup behavior
 - Program success independent of single individuals' availability: 'the show goes on.'
- 5. Psychological safety
 - Team members empowered to speak up.
- 6. Closed-loop communication
 - Content, structure and reliability of message.

Continuous data collection, analysis and interpretation CORE PRINCIPLE!

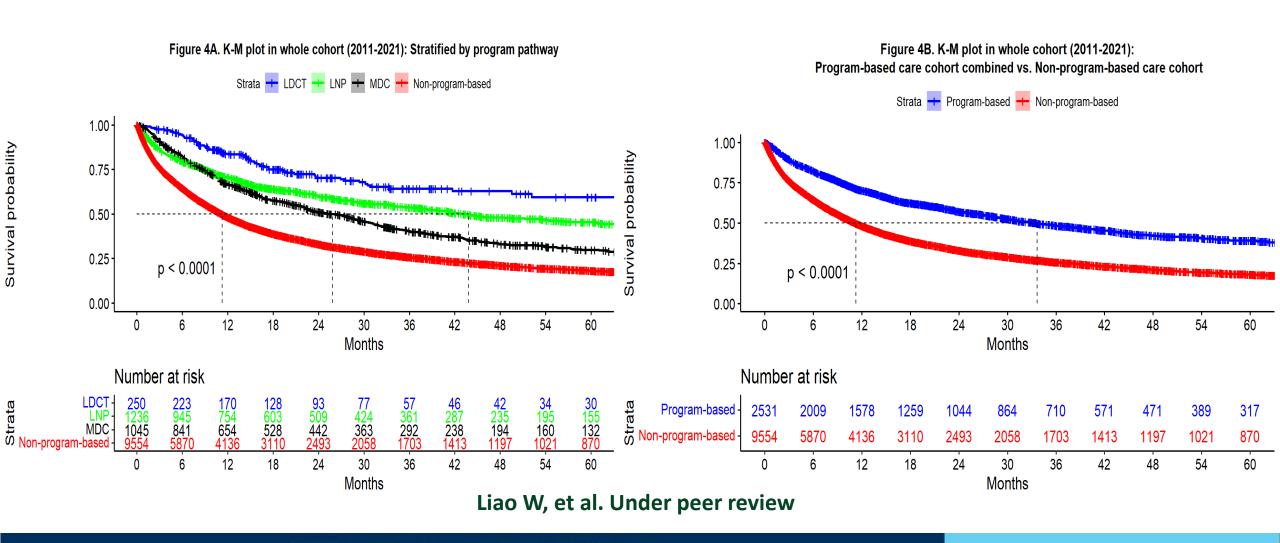


Applied Team Science: Multidisciplinary Team-Based Care

Team Principles	Team Behaviors	Team Benchmarks	Team Targets
Shared Mental Models	Commitment to pre-agreed conference and meeting logistics	 Attendance at regular conference Attendance at monthly program meeting(s) 	 Team members are present at all team meetings At least one of each specialty present at all conferences (med onc, rad onc, surgery, pulm, pathology, radiology, navigation) All conference cases are presented by the referring provider or their pre-specified delegate
Mutual Trust	Systematic, prospectively coordinated case selection: eg.	- % of cases presentations that are prospective	- 100% prospective presentations
	all new cases	- % of institutional cases presented at conference	- 50% in Y1, 70% in Y2, 90% all subsequent years
Mutual Performance Monitoring Backup Behavior Psychological Safety Closed-Loop Communication	Commitment to standard, evidence-based care (evaluation and treatment) pathways Consideration of all relevant clinical information/perspectives Multi-level incorporation of patient/caregiver perspectives	 Concordance between consensus recommendations and care delivered Guideline concordant staging practice Stage-appropriate treatment rate 	 80% concordance rate All discordant care documented with reason(s) why 80% guideline concordant staging practice 80% stage appropriate treatment rate
	Team meeting results in precise, strategic, evidence-based consensus plan. The consensus plan is documented, quickly and verifiably communicated to all team members	 % of patients with a conference note completed % of conference notes routed to entire care team % of case presentations for which stage is articulated and documented Verifiable/timely communication of recommendations 	 100% of presentations have a conference note completed, including attributed stage and detailed recommendations with justifications 100% of conference notes are routed to care team within 48 hours



Red Bar Challenge: BMHCC 2015 - 2021

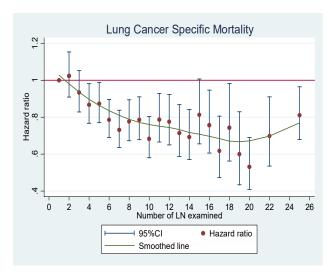




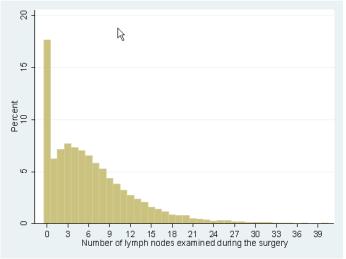
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Surgical Quality Improvement: The Mid-South Quality of Surgical Resection (MS-QSR) Project

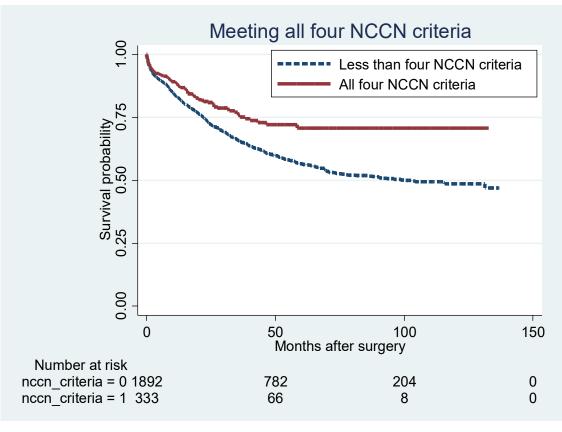
The Problem: Poor Surgical Quality Begets Poor Outcomes The main component of the problem: poor pathologic nodal evaluation



Osarogiagbon RU, et al. Ann Thorac Surg. 2014 PMID: 24266949



Osarogiagbon RU, et al Ann Thorac Surg. 2016 PMID: 27262908

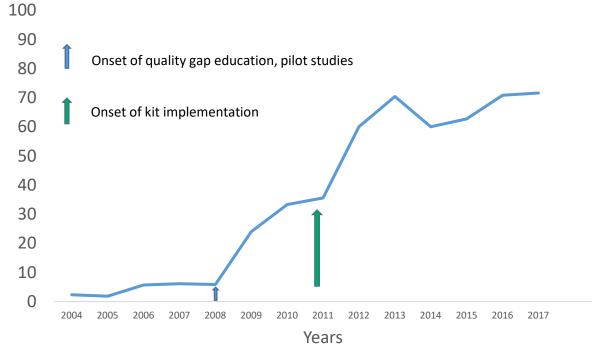


Osarogiagbon RU, et al. Ann Thorac Surg. 2017

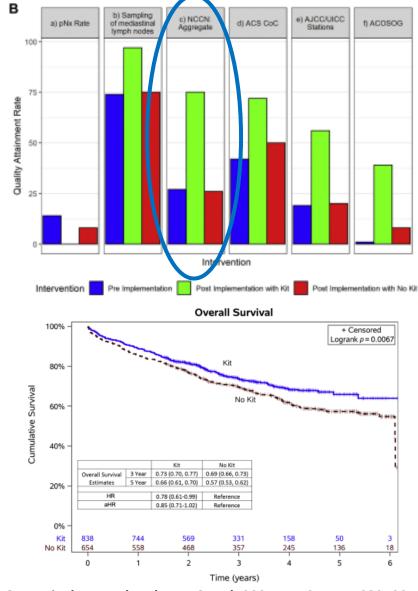
PMID: 28366464



Attainment of National Comprehensive Cancer Network (NCCN) Surgical Quality Benchmark*



^{*}NCCN: Anatomic resection + negative margins + hilar/intrapulmonary node sampling + ≥ 3 mediastinal nodal station sampling



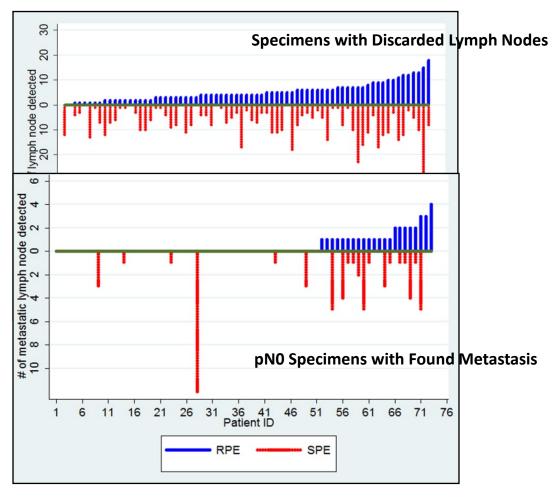
Osarogiagbon et al. J Thorac Oncol. 2021. PMCID: PMC8012255.



Get Better.

Takes Two to Tango: Pathology Interventions





- Discarded lymph nodes were found in 90% of lobectomy specimens
- 60% of intrapulmonary lymph nodes were discarded without examination
- 29% of discarded lymph nodes had metastasis, including 12% of pNO specimens

Raymond U. Osarogiagbon, M. Nicholas R. Faris, MDiv, a,b Mei Phillip Oieabulu, M.B.B.S... O Meghan Meadows-Taylor, MPH Paul Levy, MD, Vishal Sachde Xiao-Ou Shu, PhD, Yu Shyr, Pl

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ABSTRACT

Introduction: Suboptimal patholog prevails after curative-intent resecti We evaluated the impact of a lym collection kit on lung cancer surge prospective, population-based, stag tion study.

Methods: From January 1, 2014, to A implemented the kit in three homog cohorts involving 11 eligible hospitals f hospital referral regions. Our primary logic nodal staging quality, defined evidence-based measures: the number stations examined, proportions with p such as nonexamination of lymph no quality benchmarks including the Nati Cancer Network criteria. Additional perioperative complications, health c overall survival.

Results: Of 1492 participants, 56% ha kit and 44% without, Pathologic nodal significantly higher in the kit cases: 0.29

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Surgeon Quality and Patient S Non-Small-Cell Lung Cancer

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ABSTRACT

PURPOSE The quality and outcomes of curative-intent populations. Surgeons are key drivers of surg association between surgeon-level intermediat survival differences, and potential mitigation b

PATIENTS AND Using a baseline population-based surgical METHODS surgeon-level cut points for rates of positive lymph nodes, nonexamination of mediastinal sections. Applying the baseline cut points to a su population-based data set, we assign surgeon gories in reference to each metric: 1 (<25th per tile), and 3 (>75th percentile). The sum of per surgeon quality tiers: 1 (4-6, low), 2 (7-9, intern used chi-squared, Wilcoxon-Mann-Whitney, compare patient characteristics between the ba and across surgeon tiers. We applied Cox prop amine the association between patient survival sequentially adjusting for clinical stage, patien cific processes.

RESULTS From 2009 to 2021, 39 surgeons performed 4,08 and subsequent cohorts. Among 31 subsequent c five were tier 2, and 21 were tier 3. Tier 1 and 2 s outcomes than tier 3 surgeons (hazard ratio [H] 1.19; 95% CI, 1.00 to 1.43, respectively). Adju mitigated the surgeon-tiered survival differen (95% CI, 0.8 to 1.3) and 0.93 (95% CI, 0.7 to 1.

CONCLUSION Readily accessible intermediate outcomes metr geon performance for targeted process impr patient survival disparities.

INTRODUCTION

Although improving in recent years, the aggregate 5-year survival of all patients diagnosed with lung cancer in the United States is still only approximately 23%.1 Most 5-year survivors have had curative-intent surgery for non-smallcell lung cancer (NSCLC). However, fewer than 50% of recipients of surgical resection survive 5 years.2,3 In CALGB/Alliance 140503, patients with stage IA NSCLC had a 5-year disease-free survival of 64% and two thirds of deaths were attributed to lung cancer.4 Long-term survival disparities after curative-intent resection of NSCLC are welldescribed at the patient and institution levels.5-8 Older

Resection Quality With Implementation Node Specimen Collection Kit Olawale Akinbobola, MPH. Meredith A. Ray, PhD. Carrie I Andrea Saulsberry, MBA, a Kourtney Dortch, BS, a Matthew S Nicholas R. Faris, M. Div. a,c Raymond U. Osarogiagbon, M. &

Institution-Level Evolution of Lung Can

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ABSTRACT

Introduction: Lung cancer surgery with a lymph node kit improves patient-level outcomes, but institution-level impact is unproven.

Methods: Using an institutional stepped-wedge implementation study design, we compared lung cancer resection quality between institutions in preimplementation and postimplementation phases of kit deployment and, within implementing institutions, resections without versus with the kit. Benchmarks included rates of nonexamination of lymph nodes, nonexamination of mediastinal lymph nodes, and attainment of American College of Surgeons Operative Standard 5.8. We report institution-level adjusted ORs (aORs) for attaining quality benchmarks.

Results: From 2009 to 2020, three preimplementing hospitals had 953 resections; 11 implementing hospitals had 4013 resections, 58% without and 42% with the kit. Quality was better in implementing institutions and with kit cases. Compared with preimplementing institutions, the aOR for nonexamination of lymph nodes was 0.62 (0.49-0.8, p = 0.002), nonexamination of mediastinal lymph nodes was 0.56 (0.47-0.68, p < 0.0001), and attainment of Operative Standard 5.8 was 7.3 (5.6-9.4, p < 0.0001); aORs for kit cases were 0.01 (0.001-0.06), 0.08 (0.06-0.11), and 11.6 (9.9-13.7), respectively (p < 0.0001 for all). Surgical quality was persistently poor in preimplementing institutions but sequentially improved in implementing institutions in parallel with kit adoption. In implementing institutions, resections with the kit had a uniformly high level of quality, whereas nonkit cases had a low level of quality, approximating that of preimplementing institutions. Within implementing institutions, 5-year overall survival was 61% versus 51% after surgery with versus without the kit (p < 0.001).

Conclusions: 5 tion kit improv lung cancer res

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Keywords: Lun collection; Pati

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Disclosure: Dr. specimen collect Eli Lilly; serving Society, the Ass Roche, Biodesix Tryptych Health founder of Once consultant for remaining autho Address for cor FACE Multidiscl

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Lung: Research

Two Interventions on Pathologic Nodal Staging in a Population-Based Lung Cancer Resection Cohort

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ABSTRACT

BACKGROUND Despite its prognostic importance, poor pathologic nodal staging of lung cancer prevails. We evaluated the impact of 2 interventions to improve pathologic nodal staging.

METHODS We implemented a lymph node specimen collection kit to improve intraoperative lymph node collection (surgical intervention) and a novel gross dissection method for intrapulmonary node retrieval (pathology intervention) in nonrandomized stepped-wedge fashion, involving 12 hospitals and 7-pathology groups. We used standard statistical methods to compare surgical quality and survival of patients who had neither intervention (group 1), pathology intervention only (group 2), surgical intervention only (group 3), and both interventions (group 4).

RESULTS Of 4019 patients from 2009 to 2021, 50%, 5%, 21%, and 24%, respectively, were in groups 1 to 4. Rates of nonexamination of lymph nodes were 11%, 9%, 0%, and 0% and rates of nonexamination of mediastinal lymph nodes were 29%, 35%, 2%, and 2%, respectively, in groups 1 to 4 (P < .0001). Rates of attainment of American College of Surgeons Operative Standard 5.8 were 19%, 22%, 70%, and 83%; and rates of International Association for the Study of Lung Cancer complete resection were 14%, 21%, 53%, and 61% (P < .0001).

Compared with group 1, adjusted hazard ratios for death were as follows: group 2, 0.93 (95% CI, 0.76-1.15); group 3, 0.91 (0.78-1.03); and group 4, 0.75 (0.64-0.87). Compared with group 2, group 4 adjusted hazard ratio was 0.72 (0.57-0.91); compared with group 3, it was 0.83 (0.69-0.99). These relationships remained after exclusion of wedge resections.

CONCLUSIONS Combining a lymph node collection kit with a novel gross dissection method significantly improved pathologic nodal evaluation and survival

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or patients who undergo curative-intent surgery for non-small cell lung cancer, the pathologic nodal stage is a major determinant of subsequent management and prognosis, 1-3 Lymph node involvement connotes a worse prognosis and eligibility for adjuvant therapy.2-5 Accurate pathologic nodal staging is increasingly important as more effective adjuvant therapy options become available. It depends on the combination of retrieval of hilar, mediastinal, and intrapulmonary

nodes; thorough examination of all specimens; and complete, accurate reporting of the final pathologic findings.6

Deficits in these processes have been widely reported, with adverse impact on patient survival. For example,

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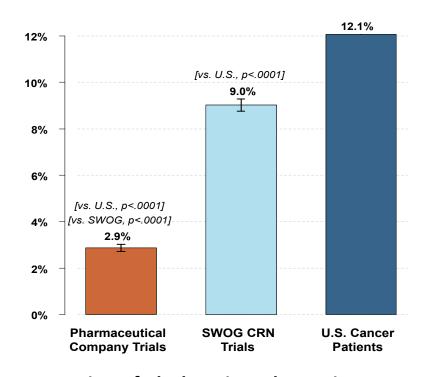
Building clinical trials infrastructure in research deserts...

Clinical Trials Matter Because....

- 'The best treatment is a clinical trial.'
- 'Tomorrow's treatment, today.'
- 'Shooting fish in a barrel': biology-driven experimentation.

- Equitable access to clinical trials matters because...
 - Extrapolation of benefit/harms in unstudied populations
 - Timely accrual, completion, interpretation, implementation...
 - Yes,..... lives matter!

In this age of rapid-fire discovery, 'the best treatment is a clinical trial...'



15% swog CRN vs. U.S. for colorectal cancer (p=.37)

10% 3% 7.4% 11.1% 2.2% 11.8% 12.4% 2.1% 8.4% 11.5% 3.9% 12.1% 14.9%

Breast Cancer Colorectal Cancer (NSCLC)

Pharma Trials SWOG CRN U.S. Cancer Pts

Proportion of Black patients by setting

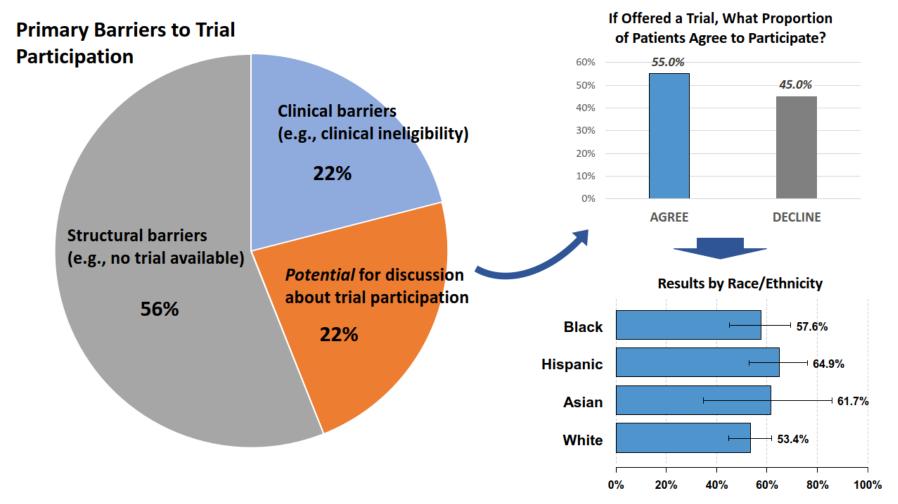
Proportion of Black patients by setting for common cancers

Unger JM, Hershman DL, Osarogiagbon RU, Gothwal A, Anand S, Dasari A, Overman M, Loree JM, Raghav K. Representativeness of Black Patients in Cancer Clinical Trials Sponsored by the National Cancer Institute Compared With Pharmaceutical Companies. JNCI Cancer Spectr. 2020. <u>PMID: 32704619</u>



Get Better.

The *Real* Barriers to Clinical Trials Participation



Unger JM, Vaidya R, Hershman DL, Minasian LM, Fleury ME. Systematic Review and Meta-Analysis of the Magnitude of Structural, Clinical, and Physician and Patient Barriers to Cancer Clinical Trial Participation. J Natl Cancer Inst. 2019;111:245-255. PMID: 30856272

Unger JM, Hershman DL, Till C, Minasian LM, Osarogiagbon RU, Fleury ME, Vaidya R. "When Offered to Participate": A Systematic Review and Meta-Analysis of Patient Agreement to Participate in Cancer Clinical Trials. J Natl Cancer Inst. 2021;113:244-257. **PMID: 33022716**

Framework for Solutions

- Understand where the true barriers are.
- Identify stakeholders:
 - Policymakers, organizations
 - Care delivery institutional leadership
 - Clinicians
 - Funders/sponsors
 - Patients/caregivers
 - Advocacy groups
 - Clinical trialists
- Make the stakeholder-centered case to each!
- Build infrastructure... meet the people where they are.
- Set goals, benchmark, measure, measure, measure....





Benchmarking, data collection, analysis and feedback

- Organizational
 - Institutional case-volumes
 - Clinical trials portfolio
- Physician
 - Credentialed
 - Participating
 - Accruing

- Research staff
 - Recruitment
 - Training
 - Retention
- Cultural:
 - 'We are not a university, why are we doing this?'
 - 'Time is money, this is a waste of time...'

Finding Enduring Solutions....!

- Build infrastructure where they population of interest resides: 'meet people where they are...'
- Data centricity: 'you can't improve what you don't measure...'
- Game out progress, set expectations: 'fail to plan, plan to fail...'
- Team-building: 'shared mental models, closed loop communication, mutual performance monitoring, mutual trust, back-up behavior, etc.'
- Financial models for sustainability: 'no margin, no mission'
- Leverage technology



Take-Home Messages

- Lung Nodule Programs provide a robust, complementary, epidemiologically sound pathway to early lung cancer detection.
 - Provides access to early detection to a non-overlapping, high-risk population.
 - Concurrent deployment alleviates looming disparities inadvertently induced by LDCT.
 - Can be implemented even when LDCT unavailable.
- Multidisciplinary decision-making saves lives, synthesizes decision-making.
- Close attention to surgical quality a vital component for population impact.
- Program-based care creates the shortest pathway to population-level lung cancer outcomes improvement.
- The best treatment is a clinical trial; build clinical trials infrastructure where the population is.



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DELUGE

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