

**PATIENT CENTERED CARE**

Gita Mody, MD, MPH

**ePROs Monitoring in Thoracic Surgery and Oncology Patients**

July 12

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11:55

**Start Time**  
12:00

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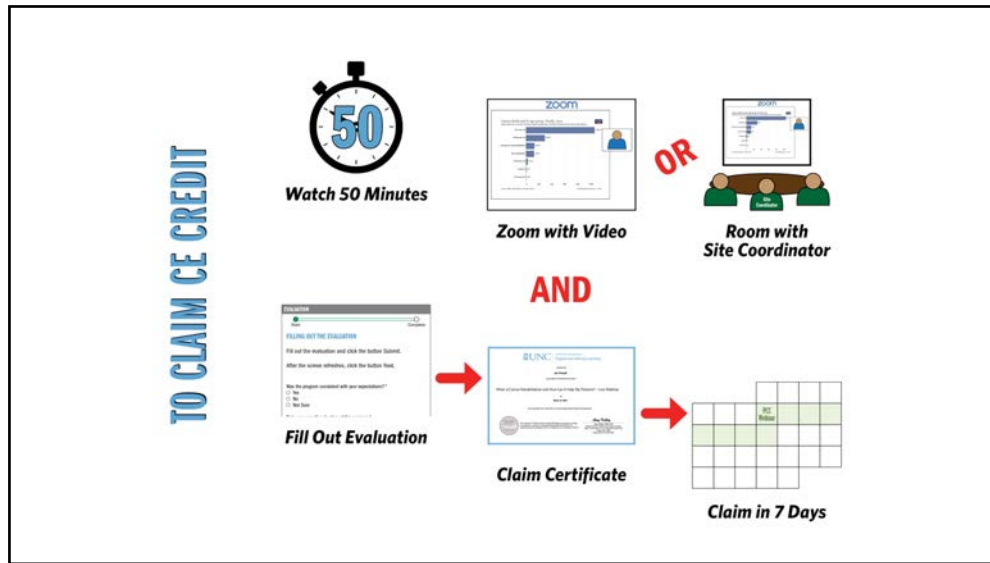
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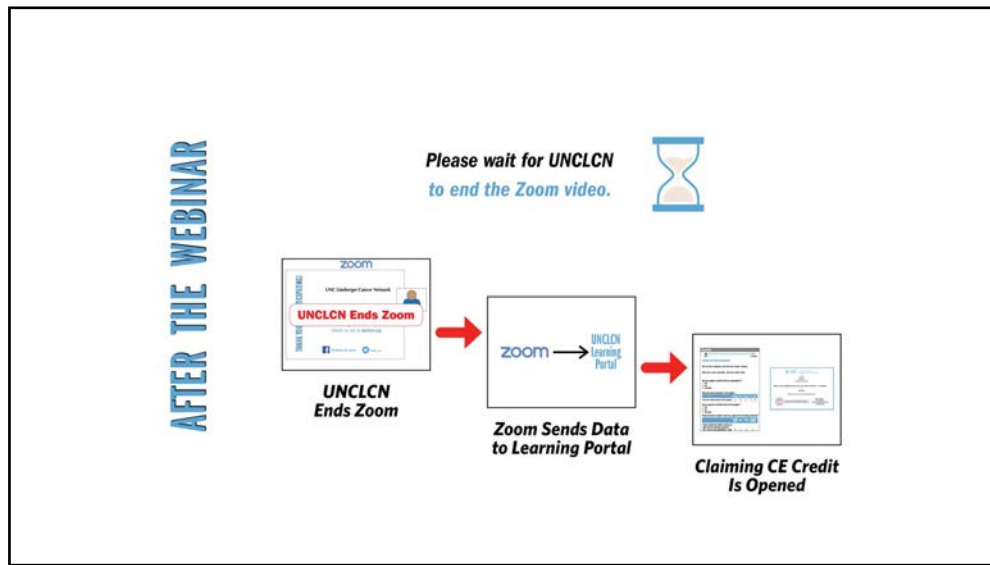
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UNC Lineberger Cancer Network  
**PATIENT CENTERED CARE**  
Live Webinar

Gita Mody, MD, MPH

**ePROs Monitoring in Thoracic Surgery and Oncology Patients**

July 12

6

**OUR PRESENTER**



**Gita Mody, MD, MPH**

Dr. Gita Mody is an Adjunct Assistant Professor at the UNC Gillings School of Global Public Health with the Public Health Leadership Program. She received her M.D. at Washington University School of Medicine in St. Louis and received her M.P.H. in Clinical Effectiveness from the Harvard School of Public Health. As an Assistant Professor in the UNC Department of Surgery and Director of Thoracic Surgical Oncology, her clinical expertise is in caring for lung cancer patients, who are amongst the most vulnerable and underserved groups in North Carolina. Her major research interest is in optimizing quality of life and other patient-centered outcomes in patients with chronic illness through studying the implementation of digital health and other complex interventions. Her training in comparative effectiveness research, patient-reported outcomes measurement, and implementation science are synergistic, and she is well-versed with experimental and pragmatic study designs. Her current and prior work is funded through grants from the National Heart, Lung and Blood Institute (NHLBI), American College of Surgeons (ACS), and the Thoracic Surgery Foundation (TSF). She is passionate about global equity in health and actively engages in training the next generation of clinical-scientists from low-resourced settings through her work in the Malawi Cancer Outcomes Research Program.

7

**OUR PRESENTER**

8

**OUR PRESENTER**

5. Dr. Gita Mody is an Adjunct Assistant Professor at the UNC Gillings School of Global Public Health with the Public Health Leadership Program.

9

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10

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11

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12

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13

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**ePRO is the abbreviation for "electronic Patient-Reported Outcome".**

Response	Percentage
True	0%
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**DISCLOSURES**

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UNC Lineberger Cancer Network ePRO is the abbreviation for "electronic Patient-Reported Outcome".

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0%	0	False	<input type="checkbox"/>

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16



# ePROs Monitoring in Thoracic Surgery and Oncology Patients

UNC Lineberger Cancer Network Webinar | July 12, 2023



**Gita N. Mody, MD MPH**  
Assistant Professor of Surgery  
Director of Thoracic Surgical Oncology  
UNC Department of Surgery  
Lineberger Comprehensive Cancer Center



17

## Disclosures

Research funding and advisor for Sivan Ltd.

18

## Objectives

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1. Describe symptom burden of thoracic surgical and oncologic conditions and treatments
2. Review reasons and methods for patient-reported outcomes monitoring
3. Discuss implementation of PRO monitoring in thoracic patients' survivorship care

19

## Thoracic surgery

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- Thoracic surgery includes the esophagus, mediastinum, trachea and chest wall.

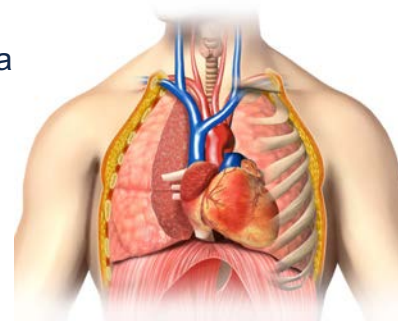


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## Chest diseases treated with surgery

- Emphysema
- Dysphagia
- Gastroesophageal reflux disease
- Tumors of the lung, esophagus, chest wall, mediastinum
- Tracheal anomalies
- Diaphragm disease
- End-stage lung disease requiring transplantation
- Benign chest wall abnormalities



21

## Types of thoracic surgery

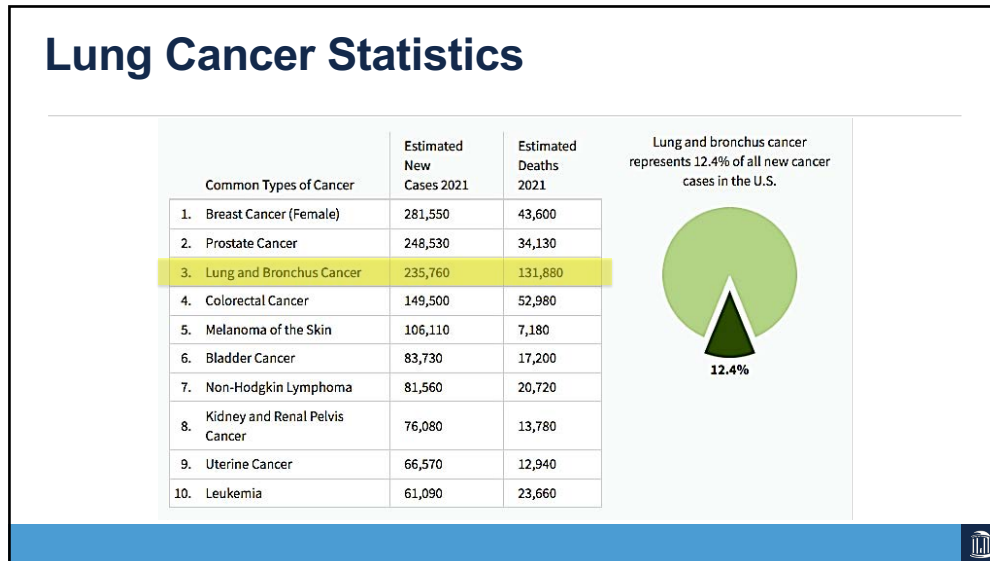
- Approaches
  - Open
  - Minimally invasive
    - Video Assisted Thoracoscopic Surgery (VATS)
    - Robotic Assisted Thoracoscopic Surgery (RATS)
    - Uniportal thoracoscopic surgery
- Procedures
  - Pulmonary resection
    - Wedge resection
    - Segmentectomy
    - Lobectomy
    - Pneumonectomy
  - Thymectomy
  - Diaphragm plication and repair
  - Chest wall resection
  - Lymph node biopsy
  - Decortication and Pleurodesis
  - Esophagectomy
  - Paraesophageal hernia repair



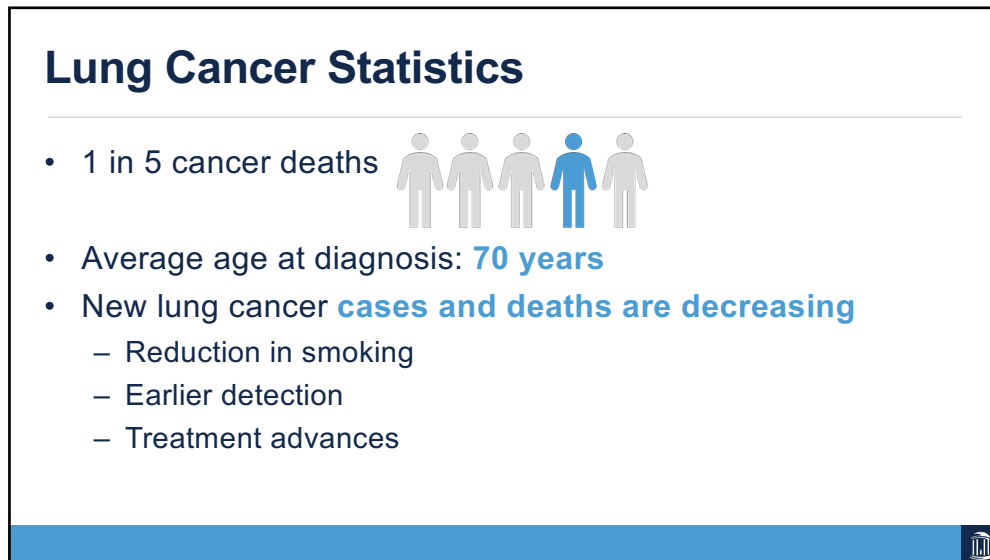
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22



23



24

## Stages of Lung Cancer

Of new cases, **17%** are diagnosed with local disease, **22%** at regional state, and **56%** with distant disease.

I stage      II stage      III stage      IV stage

Image credit: Adobe Stock (licensed)

25

### What is the most common treatment for early-stage lung cancer?

0%	0	Surgery
0%	0	Radiation
0%	0	Observation

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26

## Majority of Early-Stage Lung Cancer Patients Undergo Surgical Therapy

**76.7%** of those with Stage I disease

**83.8%** of those with Stage II disease

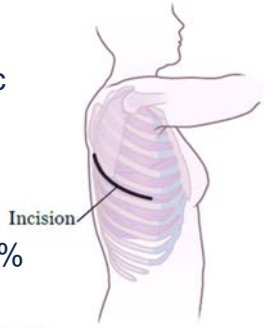


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## Lung resection

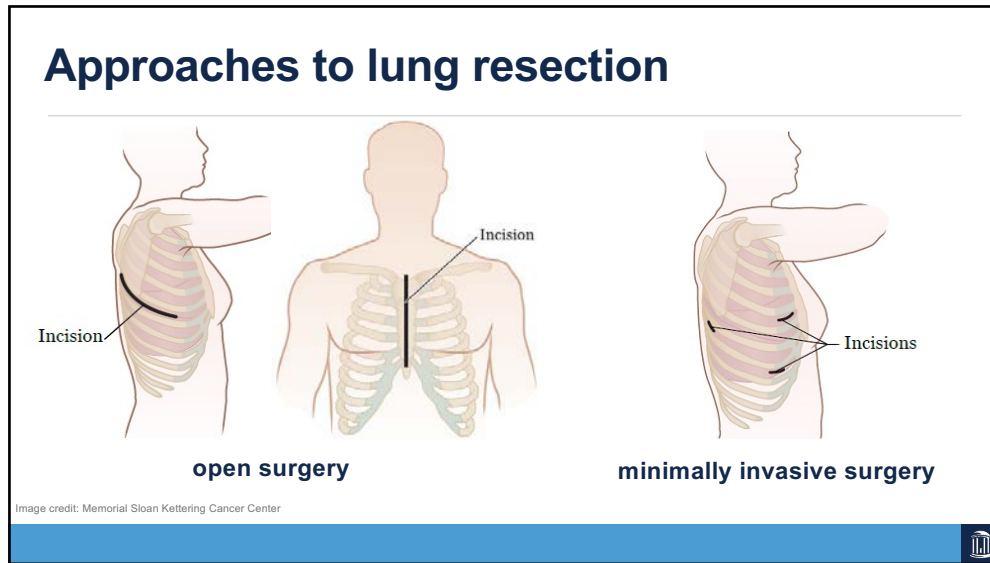
- Employed for diagnosis, treatment, and palliation of lung cancer and other thoracic conditions.
- >80,000 lung resection procedures are performed annually in the United States.
- Pulmonary lobectomy is increasing by 1.7% per year.



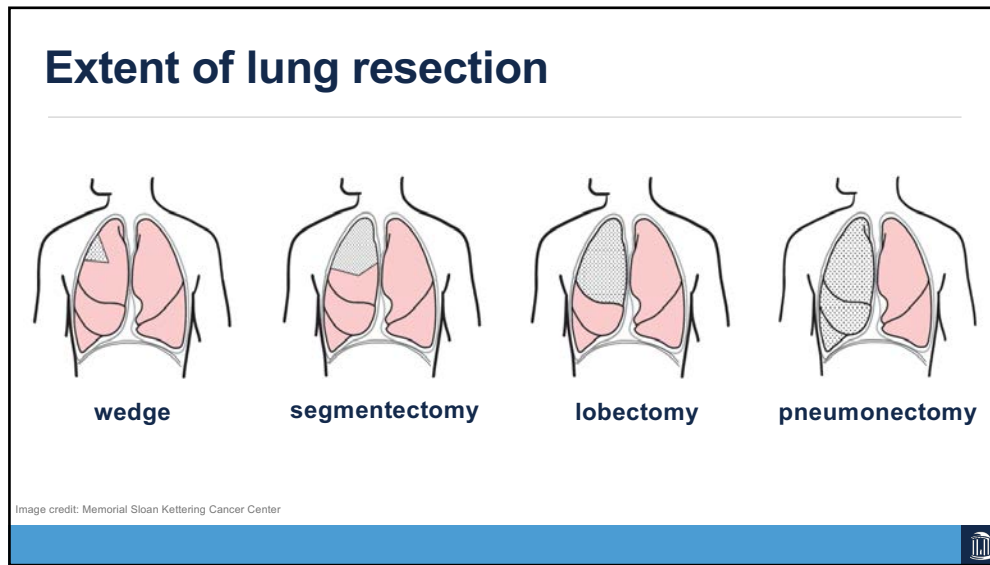
Incision

Image credit: Memorial Sloan Kettering Cancer Center

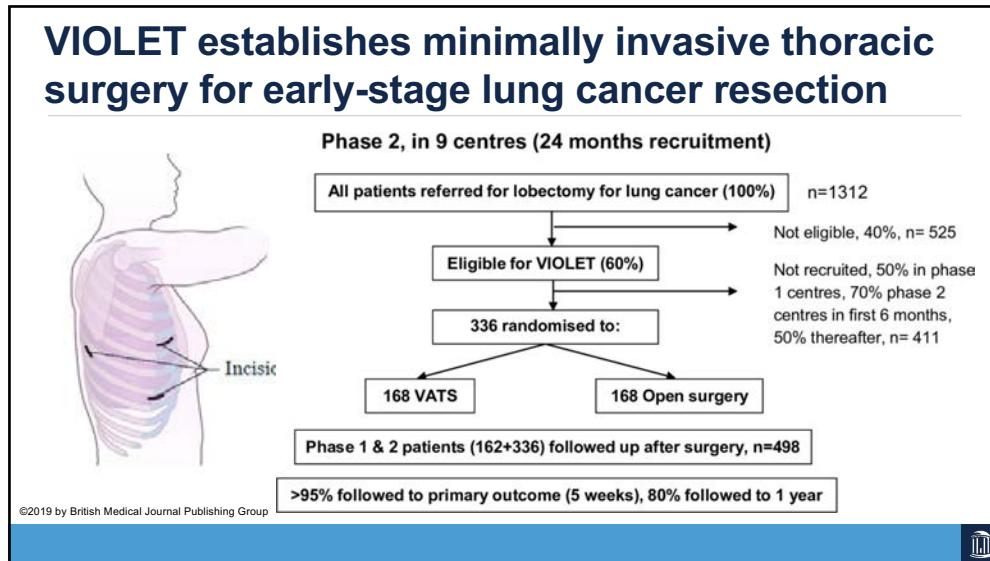
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29



30



31

### VIOLET demonstrates improved QOL for patients with VATS

<p><b>Study design:</b></p> <ul style="list-style-type: none"> <li>- cT1-3, N0-1 and M0 lung cancer</li> <li>- 56 months, 503 participants</li> </ul>	<p><b>Clinical results:</b></p> <ul style="list-style-type: none"> <li>- fewer complications</li> <li>- no difference in serious adverse events</li> <li>- hospital stay was shorter (4 vs 5 days)</li> <li>- lower 1 year readmission rates (29.0% vs. 35.9%)</li> <li>- Similar PFS (HR 0.74, 0.43 to 1.27; p=0.27)</li> <li>- Similar OS (HR 0.67, 0.32 to 1.40; p=0.282)</li> </ul>
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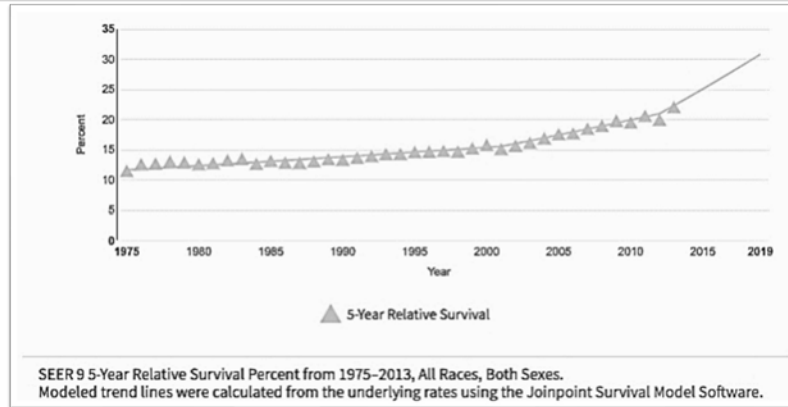
**QOL results:**

- less pain on VAS
- less analgesic consumption
- better physical function (EORTC QLQ-C30)
- improved global health status

32

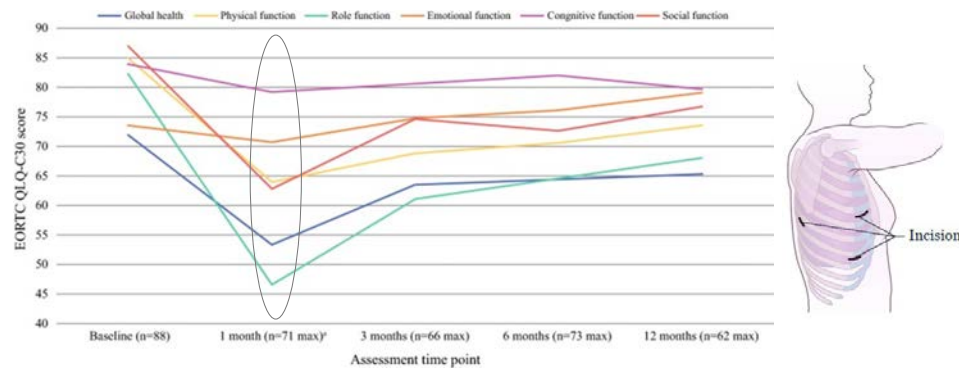


## Survival among patients with lung cancer is improving

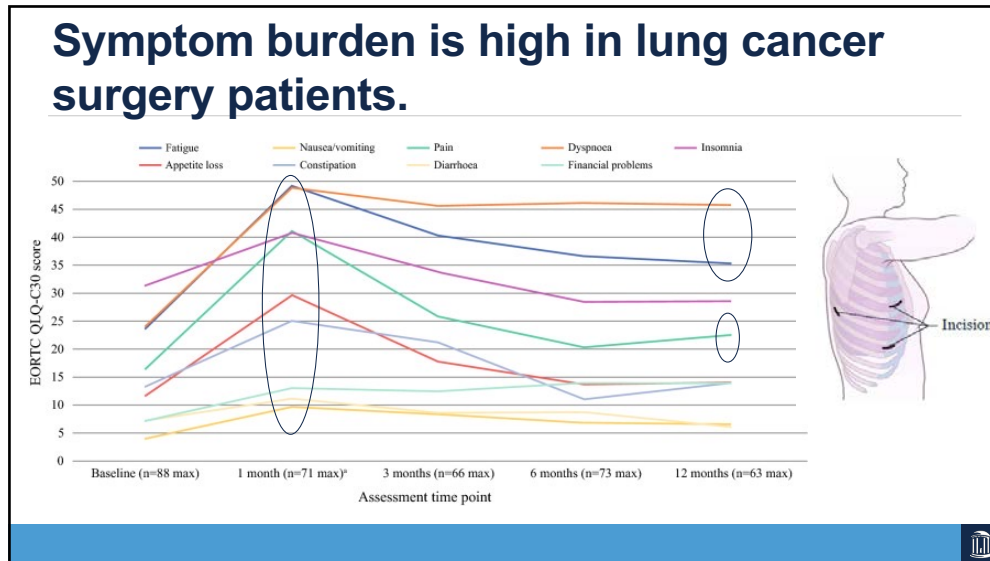


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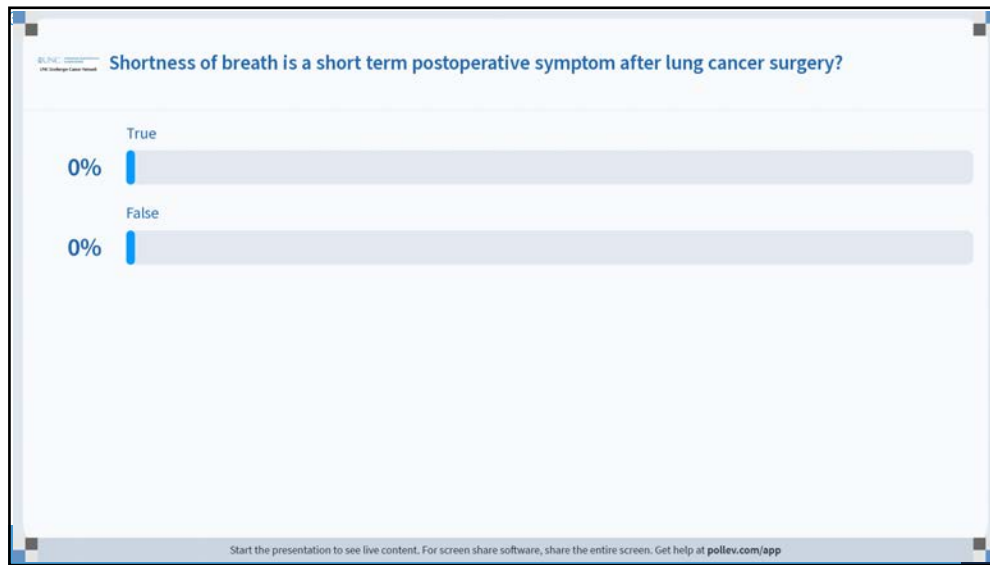
## Lung cancer surgery patients experience deficits in Health-Related Quality of Life



34



35



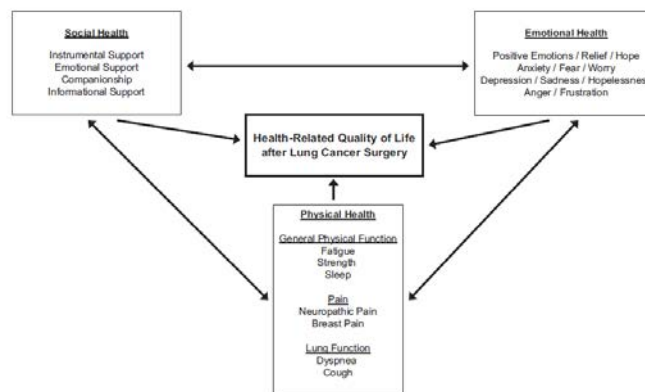
36

## Audience question

- Shortness of breath is a short term postoperative symptom after lung cancer surgery?
  - A. True
  - B. False

37

## Lung cancer surgery patients' HRQOL priorities



38

### When should HRQOL be measured?

The diagram illustrates the continuum of perioperative care with four icons in circles: 1. A person with a stethoscope (preoperative). 2. A person in a hospital bed with medical equipment (intraoperative). 3. A person with a cane (postoperative). 4. A person sitting in a chair with a doctor (long-term recovery). A large double-headed arrow below the icons spans the width of the diagram, with the text "across the continuum of perioperative care" centered within it.

39

### Thoracic surgery patients report gaps between preop expectations and postop HRQOL

**10** semi-structured interviews with elderly patients

**1** year after thoracic surgery

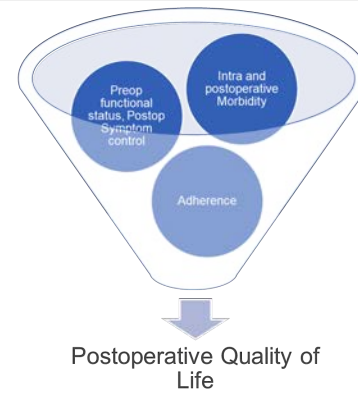
- Unexpected duration of physical recovery time
- Eventual return to baseline physical function
- Improvement in emotional HRQOL

Mody GN, Bennett A, Irani M, Kerwin C, Jaklitsch M, Frain L. Geriatric patient experience after thoracic surgery- how to help older patients expect the unexpected. Presented by Mody G at ISOQOL 27th Annual Conference, October 2020.

40

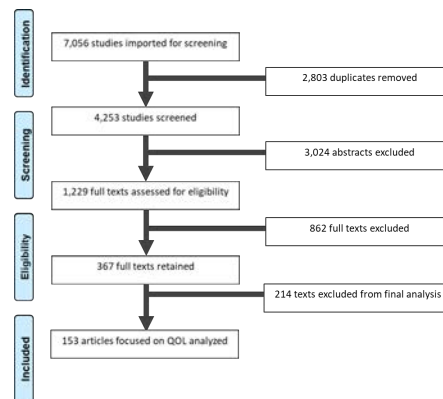
## Quality of Life experiences after thoracic surgery are multifactorial

- How do the outcomes thoracic surgery patients experience contribute to their postoperative quality of life?
- How do the expectations of patients contribute to their postoperative quality of life?



41

## Systematic review on HRQOL after lung cancer surgery identified numerous publications



Dr. Aurelie Merlo, PGY 6

42

## Postoperative Symptom Burden in Patients Undergoing Lung Cancer Surgery

153 texts - Long-term quality of life further categorized by theme

- 34 texts - Longitudinal trajectory of QOL. How does QOL change over time after lung cancer surgery?
- 49 texts - Risk factors for poor QOL. What are the risk factors that predict poor QOL after lung cancer surgery?
- 4 texts - Relationship of poor perioperative QOL to outcomes. How does poor perioperative QOL impact outcomes after lung cancer surgery?
- 12 - texts. Articles validating QOL instruments and cross-sectional studies that do not classify elsewhere
- 54 texts - Symptom burden. What is the symptom burden after lung cancer surgery?

*Journal of Pain and Symptom Management* Vol. 64 No. 3 September 2022

**Original Article**

**Postoperative Symptom Burden in Patients Undergoing Lung Cancer Surgery**

Avantia Merks, MD, Rebecca Carlson, MEd, AHP, John Espes III MD, Britney M. Williams, MD, MPH, Prasad Balakrishnan, MD, Sarah Chen, MD, Lauren Dawson, BS, Daniel Johnson, BS, Julia Bricker, BS, Cecilia Pasquini, MD, PhD, and Gita N. Moyle, MD, MPH

Department of Surgery (A.M., J.E., B.M.W., G.N.M.), University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, USA; University Libraries (R.C.), University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, USA; Marshall University (P.B.), Huntington, West Virginia, USA; Department of Surgery (S.C.), Medical University of South Carolina, South Carolina, USA; University of North Carolina at Chapel Hill School of Medicine (L.D., D.J., J.B.), Chapel Hill, North Carolina, USA; Section of Patient-Centered Outcomes Research (C.P.), Leeds Institute for Medical Research at St James's, University of Leeds, Leeds, UK; Lineberger Comprehensive Cancer Center (G.N.M.), University of North Carolina, Chapel Hill, North Carolina, USA

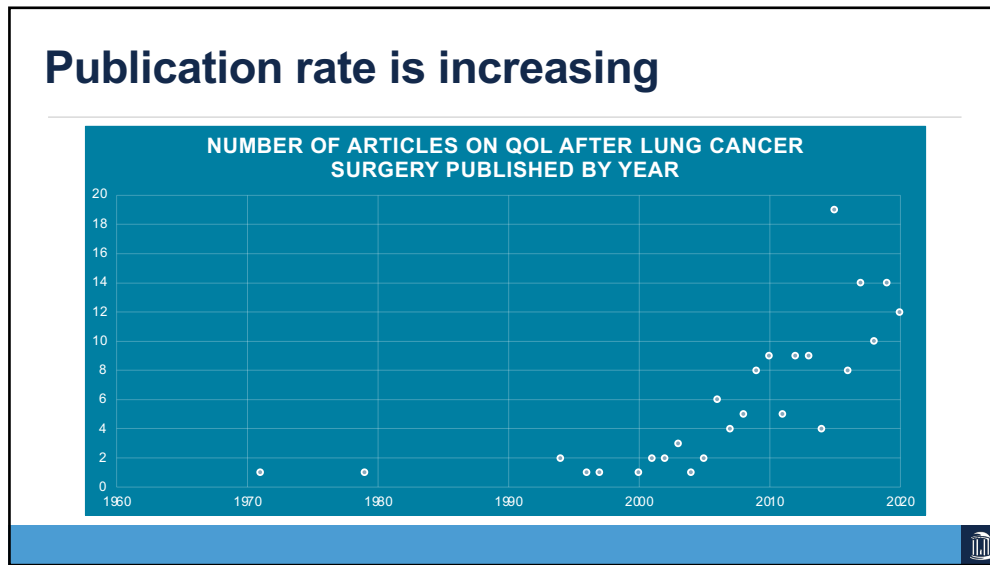
**Abstract**

**Context.** Previous studies on quality of life (QOL) after lung cancer surgery have identified a long duration of symptoms postoperatively. We first performed a systematic review of QOL in patients undergoing surgery for lung cancer. A subgroup analysis was conducted focusing on symptom burden and its relationship with QOL.

**Objective.** To perform a qualitative review of articles addressing symptom burden in patients undergoing surgical resection for lung cancer.

**Methods.** The present systematic review utilized search terms for symptoms, functional status, and well-being as well as instruments commonly used to evaluate global QOL and symptom experiences after lung cancer surgery. The articles examining symptom burden (n = 54) were analyzed through thematic analysis of their findings and graded according to the Oxford Centre for Evidence-based Medicine rating scale.

43



44

## Measurement approaches vary

Quality of Life Outcome Measures and Frequency Used in the 54 Included Articles

SF-36 or SF-12	12
EORTC QLQ-C30 or LC-13	11
Hospital Anxiety and Depression Score	11
Subjective data	6
Acceptance of Illness Scale; American Thoracic Society Questionnaire; Athens Insomnia Scale; Baseline Dyspnea Index; Breathlessness Questionnaire; Brief Fatigue Inventory; Brief Pain Inventory; Center for Epidemiologic Studies – Depression Scale; Control Preferences Scale; Coping Inventory; Decisional Conflict Scale; Douleur Neuropathique 2 or 4; Experiences in Close Relationships Scale II; Functional Assessment of Cancer Therapy – Lung; General Sleep Disturbance Scale; Godin Leisure Time Exercise Questionnaire; Herth Hope Questionnaire; Impact of Event Scale; Karnofsky Performance Scale; Lee Fatigue Scale; Leeds Assessment of Neuropathic Symptoms and Signs; Leicester Cough Questionnaire; Lung Cancer Symptom Questionnaire; MD Anderson Symptom Inventory; Medical Coping Modes Questionnaire; Medical Outcomes Study Social Activity Limitations Scale and Symptom Assessment Scale; Mental Adjustment to Care Scale; Mini-Mental State Examination; Multidimensional Scale of Perceived Social Support; Multidimensional Fatigue Symptom Inventory–Short Form; Numeric Rating Scale; Patient-Reported Outcomes Measurement Information System Tools; Perceived Family Support Scale; Physical Activity Questionnaire; Picker Patient Experience; Pittsburg Sleep Quality Index; Posttraumatic Growth Inventory; Post Traumatic Stress Disorder Checklist Civilian Version; Profile of Moods Questionnaire; Self-Administered Comorbidity Questionnaire-19; Self-Efficacy Scale; Stress Thermometer; Social Support Scale; State-Trait Anxiety Inventory; Symptom Distress Scale; Toronto Mindfulness Scale; Veterans RAND 12-Item Health Survey; Visual Analogue Scale; 12-item World Health Organization Disability Assessment Schedule 2.0	<5

45

## Key findings

1. Symptom burden is high before and after surgery.
2. Pain, dyspnea, cough, fatigue, depression, anxiety are most studied symptoms.
3. Pre-surgery symptoms are a risk factor for symptom acuity and persistence after surgery.
4. Symptom burden is a predictor of postoperative QOL.



46

## Objectives

1. Describe symptom burden of thoracic surgical and oncologic conditions and treatments
2. **Review reasons and methods for patient-reported outcomes monitoring**
3. Discuss implementation of PRO monitoring in thoracic patients' survivorship care

47

## Who should report on HRQOL?

- Patients at risk for lung cancer
- Comparison of Health Utility Scores for common postoperative conditions

**Table 2—Patients' Perception of Possible Outcomes of Lung Surgery as Represented by Utility Scores**

Outcomes	Utility Score* (95% CI)
Pneumonia requiring 2 wk of hospitalization	0.81 (0.74-0.88)
Atelectasis requiring bronchoscopic therapy	0.80 (0.72-0.88)
Ventilator dependence for 3 d	0.76 (0.68-0.84)
Ventilator dependence for 7 d	0.74 (0.66-0.82)
Ventilator dependence for 15 d	0.66 (0.57-0.75)
Ventilator dependence for 30 d	0.59 (0.49-0.69)
Permanent ventilator dependence with estimated survival of 6 mo	0.10 (0.04-0.16)
Acute myocardial infarction	0.49 (0.40-0.59)
Can walk only two city blocks without stopping	0.48 (0.40-0.56)
Current activity level reduced by half	0.44 (0.37-0.51)
Oxygen dependence	0.33 (0.26-0.40)
1 mo of nursing home placement followed by a one-block walking limitation (because of dyspnea)	0.30 (0.23-0.37)
Need assistance with activities of daily living	0.19 (0.13-0.25)
Limited to bed to chair existence	0.17 (0.11-0.23)
Progressive lung cancer	0.17 (0.10-0.24)
Permanent nursing home placement	0.16 (0.10-0.22)

\*Utility scores range from 0 representing death to 1 representing perfect health.

48



## Who should report on postoperative HRQOL?

### Clinician-reported Outcomes



### Patient-reported Outcomes



49

## Patient-Reported Outcome Measure (PROM)

- Measurement based on report that comes directly from patient about status of patient's health condition **without amendment or interpretation of patient's response**
  - New FDA guidance in 2020

### Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)  
Center for Devices and Radiological Health (CDRH)  
December 2020  
CDER/CDRH

50

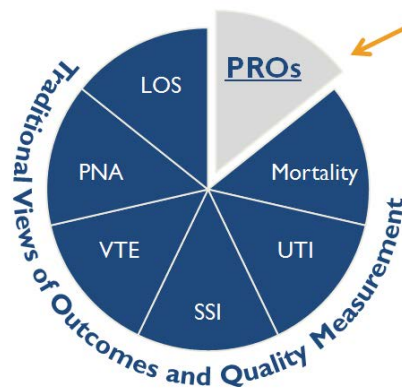
## What is a Patient-Reported Outcome (PRO)?

Based on a report that comes **directly from the patient** about the status of the patient's health condition without amendment or interpretation of the patient's response

- Developed with patient and clinician input
- Evidence of psychometric testing for validity and reliability

51

## PROs are a Significant Piece of the Pie



Complementing ACS NSQIP with PROs will give us the full picture of surgical quality improvement



52

## Is it a PROM? Questions to ask:

- **Low bar**

- Does it measure a health concept appropriate for direct patient report?
- Does it measure perceptions of how a patient feels or functions, beliefs about a health concept, or experience?

- **Higher Bar**

- Were items or instrument developed with patient and clinician input?
- Psychometric, validity, reliability evidence?



"Setting a low bar helps us to consistently exceed our expectations."

Image credit: Cartoonstock.com

53

## Why does measuring PROs matter?

"For patients, there is much more to success than alive or dead, complication, no complication.



Image credit: Adobe Stock (licensed)

How often have we heard 'They said my hip replacement went well, **but I am now housebound,**' or 'He says I have a good flow rate in my bypass graft, **but I still get pain after 10 metres.**'

*Vallance-Owen, BMJ 2008*

54

## How to measure PROs?

PRO (tool):	PROM (instrument)
Symptoms:	St. George's Respiratory Questionnaire (SGRQ)
Functional status:	Patient-Reported Functional Status (PRFS)
Health-Related Quality of Life:	EORTC QLQ-C30
Self-efficacy for managing condition:	PROMIS Self-Efficacy



55

### Patient-Reported Outcomes version Of The Common Terminology Criteria For Adverse Events (PRO-CTCAE™)

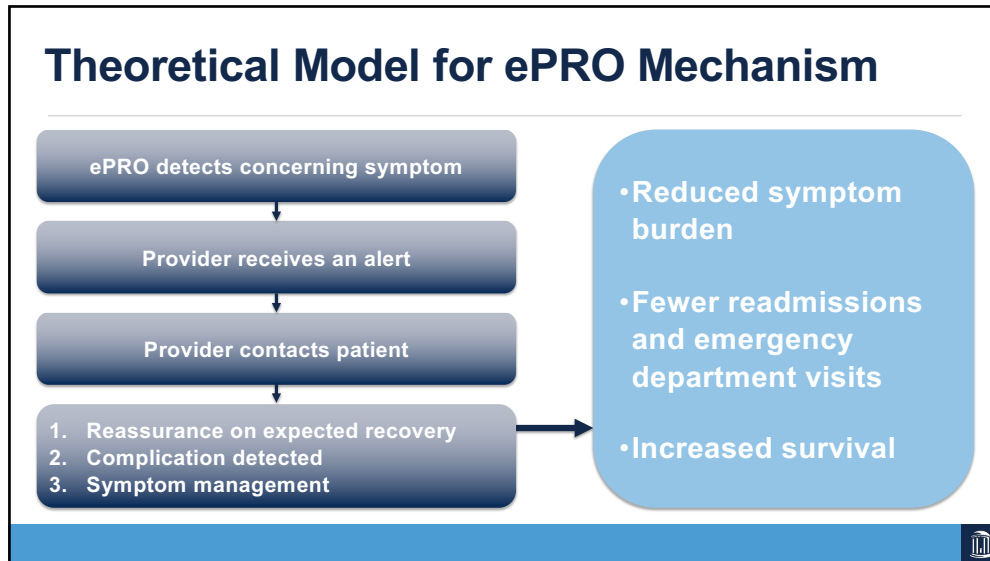
QUICK GUIDE TO THE ITEM LIBRARY\*

Oral	Respiratory	Neurological	Sleep/Wake	Sexual
Dry mouth S	Shortness of breath SI	Numbness & tingling SI	Insomnia SI	Achieve and maintain erection S
Difficulty swallowing S	Cough SI	Dizziness SI	Fatigue SI	Ejaculation F
Mouth/throat sores SI	Wheezing S			Decreased libido S
Cracking at the corners of the mouth (cheilosis/cheilitis) S		<b>Visual/Perceptual</b>	<b>Mood</b>	Delayed orgasm P
Voice quality changes P	<b>Cardio/Circulatory</b>	Blurred vision SI	Anxious FSI	Unable to have orgasm P
Hoarseness S	Swelling FSI	Flashing lights P	Discouraged FSI	Pain w/sexual intercourse S
	Heart palpitations FS	Visual floaters P	Sad FSI	
	<b>Cutaneous</b>	Watery eyes SI		
<b>Gastrointestinal</b>	Rash P	Ring in ears S	<b>Genitourinary</b>	<b>Miscellaneous</b>
Taste changes S	Skin dryness S		Irregular periods/vaginal bleeding P	Breast swelling and tenderness S
Decreased appetite SI	Acne S	<b>Attention/Memory</b>	Missed expected menstrual period P	Bruising P
Nausea FS	Hair loss A	Concentration SI	Vaginal discharge A	Chills FS
Vomiting FS	Itching S	Memory SI	Vaginal dryness S	Increased sweating FS
Heartburn FS	Hives P		Painful urination S	Decreased sweating P
Gas P	Hand-foot syndrome S	<b>Pain</b>	Urinary urgency FI	Hot flashes FS
Bloating FS	Nail loss P	General pain FSI	Urinary frequency FI	Nosebleed FS
Hiccups FS	Nail ridging P	Headache FSI	Change in usual urine color P	Pain and swelling at injection site P
Constipation S	Nail discoloration P	Muscle pain FSI	Urinary incontinence FI	Body odor S
Diarrhea F	Sensitivity to sunlight P	Joint pain FSI		
Abdominal pain FSI	Bed/pressure sores P			
Fecal incontinence FI	Radiation skin reaction S			
	Skin darkening P			
	Stretch marks P			

\*Complete library of items available at: <https://healthcaredelivery.cancer.gov/pro-ctcae>

Version date: 3/31/2020

56



57

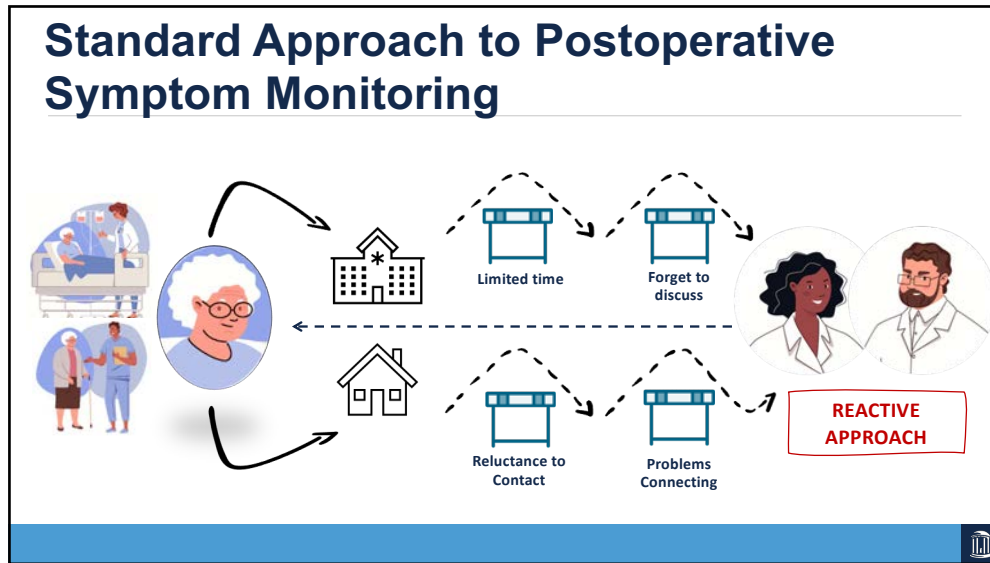
### What is a electronic PRO monitoring?

Collects PROs on repeated intervals via:

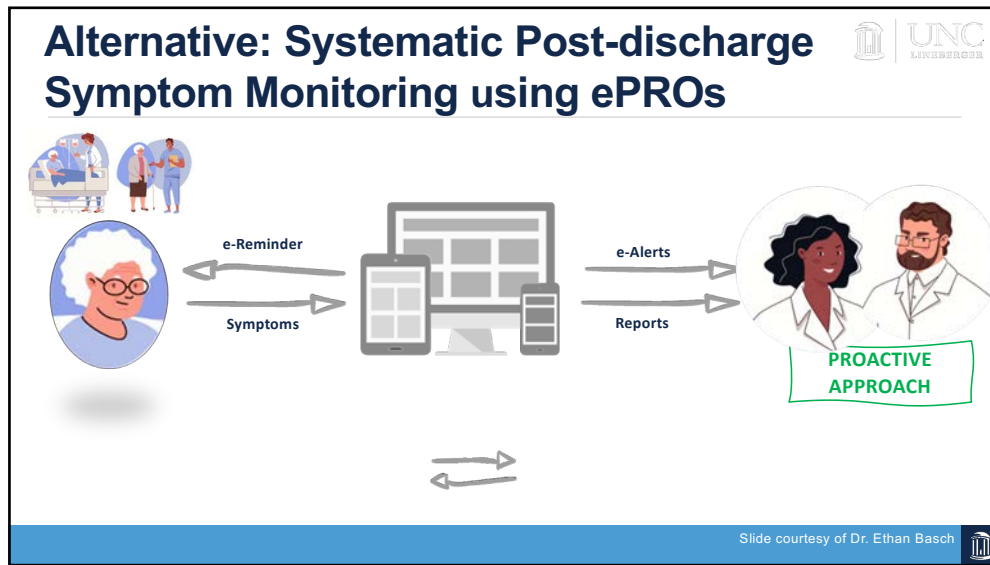
- Paper
- Kiosk
- Tablet
- Home phone (IVR)
- Phone call

- Delivers PROs to clinicians
  - Alerts (email, Epic, text message)
  - Symptom reports

58



59




60


## Collection of Patient-Reported Outcomes (PROs) can be done remotely and in real-time.



Web



Mobile



Automated Telephone Systems

61

## Evidence for PRO effectiveness in advanced oncology

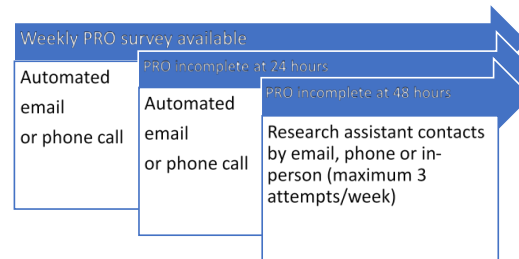
- PROTECT was a multicenter cluster randomized trial.
- To evaluate ePRO symptom monitoring vs. a usual care control group
- Community oncology practices in the US national network of the Alliance for Clinical Trials in Oncology were invited to participate.
  - Consecutively approach and enroll up to 50 adults with any type metastatic cancer receiving treatment with chemotherapy, targeted oral therapy, and/or immunotherapy if they understood English, Spanish, or Mandarin.
    - Patients with indolent lymphoma or acute leukemia or who were receiving hormonal monotherapy were excluded.

62

## Lung cancer patients undergoing PRO monitoring within the PROTECT study

- Adults  $\geq 18$  years old
- Advanced/metastatic disease
- Systemic therapy at community oncology sites
- Weekly PRO-CTCAE survey
- Opportunity for write-in symptoms
- Automated system (+reminders)
- Alerts for severe, very severe or increasing symptoms
- 3-month satisfaction survey

Weekly electronic PRO survey delivery and reminder schedule.



63

## Baseline characteristics of patients with lung cancer v. patients with other cancer types

	Lung cancer (n=118)	Other cancers (n=475)	p value
Age (mean, sd)	64.4 (9.9)	61.9 (11.9)	0.03
ECOG score (n, %)			0.002
0	41 (34.7%)	211 (44.5%)	
1	59 (50.0%)	218 (46.0%)	
2	14 (11.9%)	44 (9.3%)	
3	4 (3.4%)	1 (0.2%)	
Comorbidities <sup>a</sup> (n,%)			0.02
0-1	67 (56.8%)	323 (68.0%)	
2-4	51 (43.2%)	152 (32.0%)	
Education			0.06
Up to 8th	2 (2%)	8 (1.7%)	
9th to 11th	12 (10%)	23 (4.9%)	
High School/GED	39 (33%)	134 (28.8%)	
Some College	39 (33%)	131 (28.2%)	
Associates Degree	5 (4%)	34 (7.3%)	
College Degree	12 (10%)	79 (17.0%)	
Advanced Degree	8 (7%)	56 (12.0%)	

64



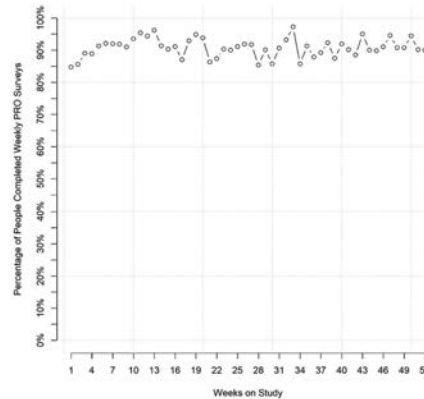
## Demographics of lung cancer patients choosing IVR for PRO monitoring

	IVR (n=47)	Web-based (n=71)	p value
Age (mean, sd)	65.28 (9.59)	63.87 (10.13)	0.45
Gender (n, %)			0.563
Male	18 (38.3%)	31 (43.7%)	
Female	29 (61.7%)	40 (56.3%)	
Education*			0.009
Up to 8th	1 (2.2%)	1 (1.4%)	
9th to 11th	8 (17.4%)	4 (5.6%)	
High School/GED	21 (45.7%)	18 (25.4%)	
Some College	12 (26.1%)	27 (38.0%)	
Associates Degree	2 (4.3%)	3 (4.2%)	
College Degree	0 (0.0%)	12 (16.9%)	
Advanced Degree	2 (4.3%)	6 (8.5%)	
Prior computer/device use			< 0.001
Never	17 (36.2%)	2 (2.8%)	
Ever (once a week to daily)	30 (63.8%)	69 (97.2%)	
Prior email use			< 0.001
Never	26 (55.3%)	5 (7.0%)	
Ever (once a week to daily)	21 (44.7%)	66 (93.0%)	
Prior internet use			< 0.001
Never	21 (44.7%)	2 (2.8%)	
Ever (once a week to daily)	26 (55.3%)	69 (97.2%)	

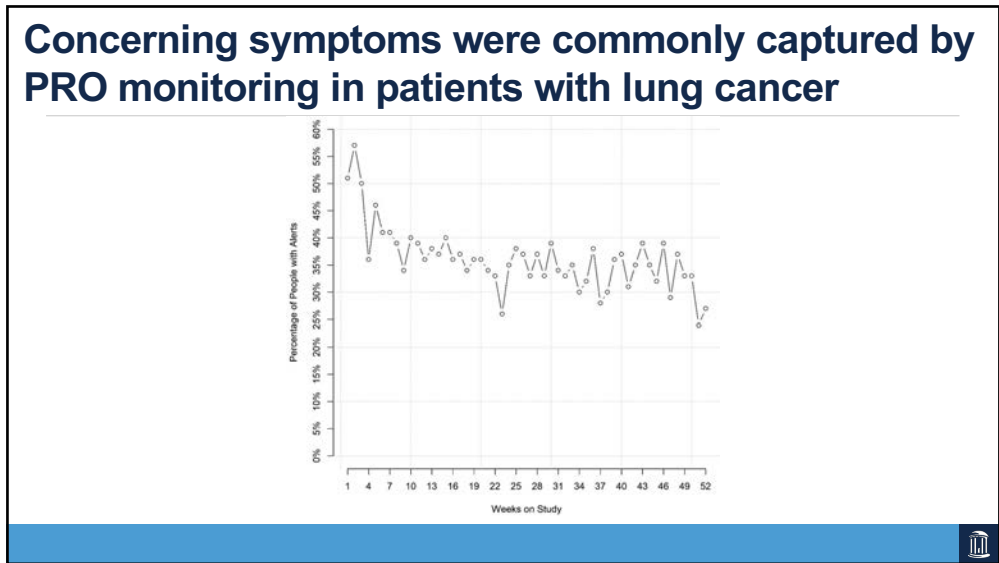
\*1 missing response

65

## Weekly PRO survey completion for long-term monitoring between visits



66



67

### Concerning symptoms were commonly captured by PRO monitoring in patients with lung cancer

Symptom Type	% (n = 118)	Mean continuous duration (weeks)*	Mean reported weeks**
Pain	83.1%	2.87	8.3
Reduced Activity	58.5%	1.98	4.99
Diarrhea	51.7%	1.34	3.51
Reduced Appetite	51.7%	1.16	2.28
Dyspnea	50.8%	2.02	5.28
Constipation	47.5%	1.07	2.20
Nausea	48.3%	1.28	3.65
Fallen	43.2%	1.23	2.55
Insomnia	39.0%	1.29	3.89
Depression	37.3%	1.58	4.93
Vomiting	22.0%	1.06	2.27
Financial Toxicity***	15.3%	n/a	n/a

\*Mean continuous duration is calculated as the average number of consecutive weeks a concerning symptom was reported, per patient.  
 \*\*Mean reported weeks is calculated as the total number of weekly records a concerning symptom was reported, averaged over the number of patients who reported such a symptom.  
 \*\*\* Financial Toxicity was collected every 4 weeks

68

## Weekly PRO survey write-in symptoms by lung cancer patients.



69

## Alerts to providers for concerning symptoms led to intervention

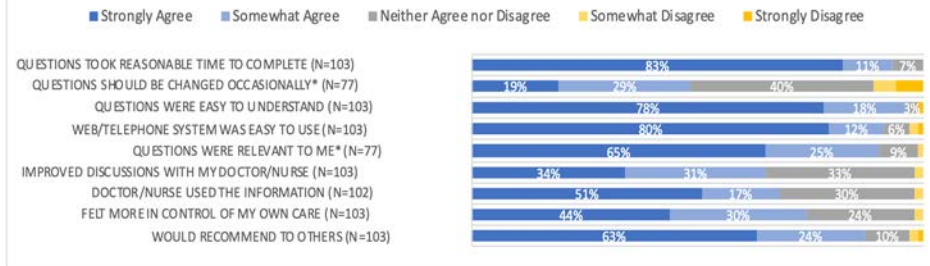
Intervention	n	% (n=1470)*
Coached patient to self-manage or treat symptoms	270	18.4%
Prescribed or changed medications (supportive drugs and/or cancer treatment)	162	11%
Expedited a clinic appointment	68	4.6%
Ordered imaging and/or laboratory test(s)	28	1.9%
Referred to the emergency department	11	0.7%
Planned to address concern at next clinic visit	281	19.1%

\*More than one intervention may have been taken per alert.

70

## Lung cancer patients would recommend using remote PRO monitoring

Figure 5. Lung cancer patient feedback on weekly PRO survey use.



71

## PRO-TECT Lung Conclusions

1. Remote PRO monitoring was feasible in lung cancer patients in the setting of a pragmatic trial.
2. Lung cancer patients on treatment experience a high-symptom burden, which can be detected by PRO surveys.
3. Practice nurses and providers were able to respond to PRO alerts with various management strategies.
4. Real-world experience and best implementation strategies are needed going forward.

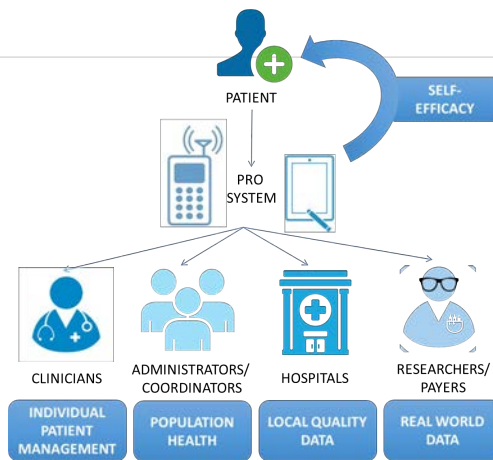
72

## Objectives

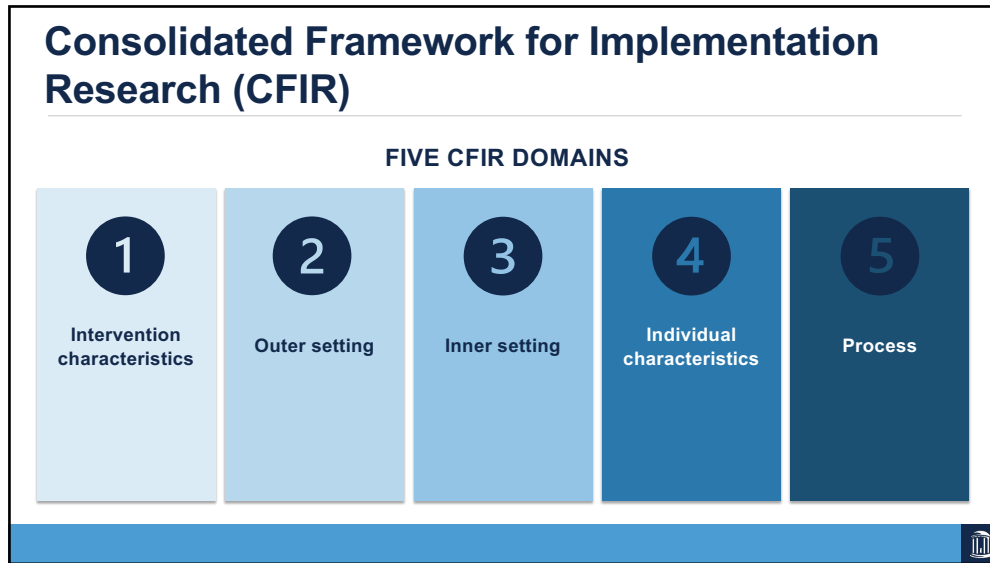
1. Describe symptom burden of thoracic surgical and oncologic conditions and treatments
2. Review reasons and methods for patient-reported outcomes monitoring
3. **Discuss implementation of PRO monitoring in thoracic patients' survivorship care**

73

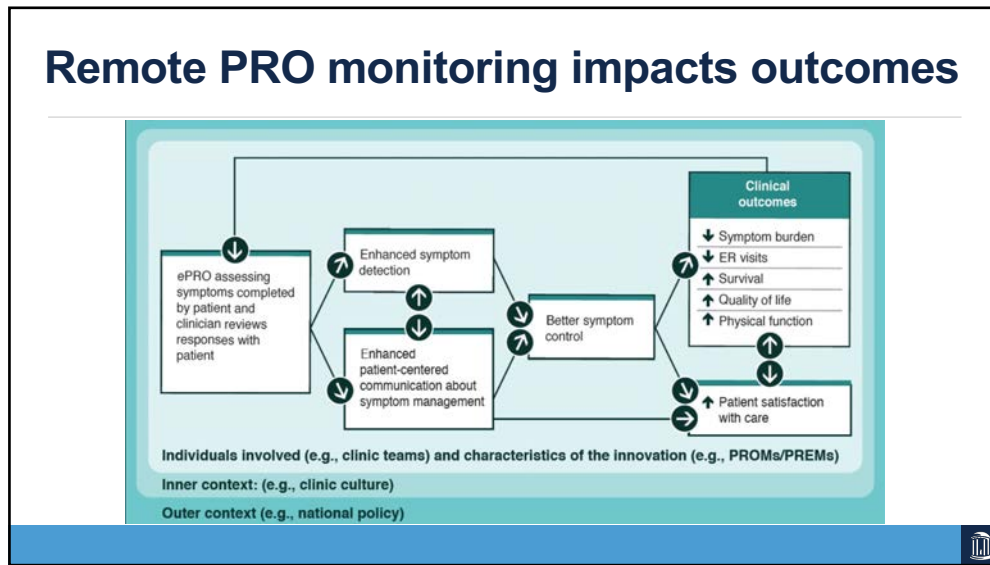
## Value of PRO Data in the Electronic Medical Record



74



75



76

## Organizations increasingly advocate for PRO integration

- Center for Medicare and Medicaid Services (CMS)
- National Quality Forum (NQF)
- National Institutes of Health (NIH)
- National Cancer Institute (NCI)
- US Food and Drug Administration (FDA)
- American College of Surgeons (ACS)
- American College of Chest Physicians (ACCP)
- Center for Medical Technology Policy (CMTF)
- Patient-Centered Outcomes Research Institute (PCORI) created by Affordable Care Act



77

## UNC Health Care System & UNC Hospitals

- State-owned, not-for-profit medical system
- Affiliated with UNC-Chapel Hill School of Medicine
  - Academic teaching hospital
  - Tradition of public health & service within the community and beyond



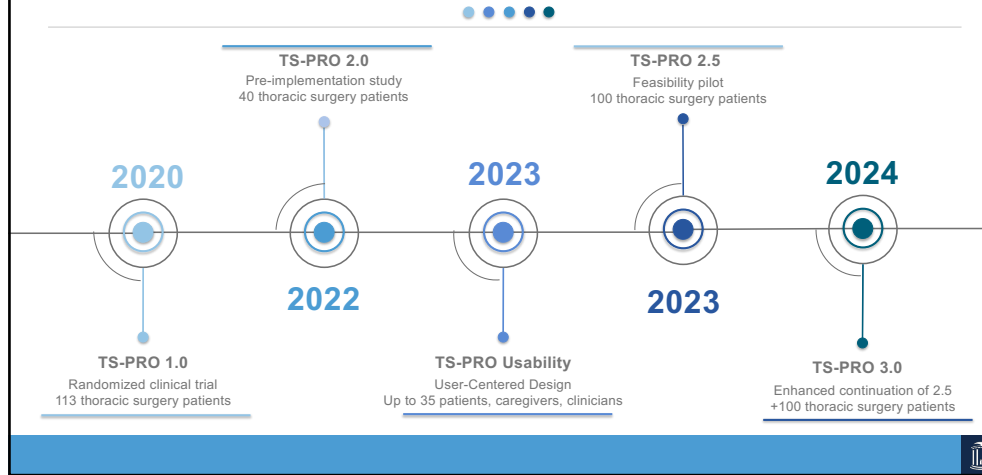
78

## Multidisciplinary Thoracic Oncology Program

- MTOP at UNC Hospitals organized in 1993
- Patients who need testing for - or have been diagnosed with - lung cancer, mesothelioma, and other thoracic malignancies
- Care team includes:
  - surgery
  - pulmonary medicine
  - medical and radiation oncology
  - thoracic radiology
  - pathology
  - oncology nursing

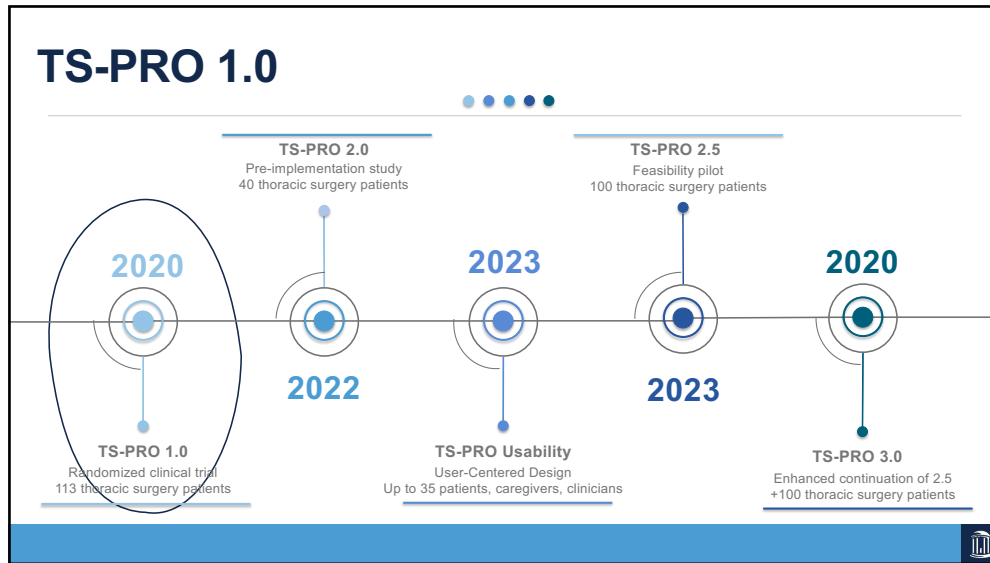
79

## A Timeline of TS-PRO Studies at UNC



80





81

**TSPRO 1.0 enrollment**

- Recruited **preoperatively** from the UNC MTOP
- April 2020-February 2022
- Eligibility criteria
  - 18 years of age or older
  - **English-speaking**
  - Presenting for elective inpatient thoracic surgery
  - Able and willing to complete **web-based** symptom survey

The **TS-PRO** Study  
Improving Quality of Life after Thoracic Surgery Using Patient-Reported Outcomes

82

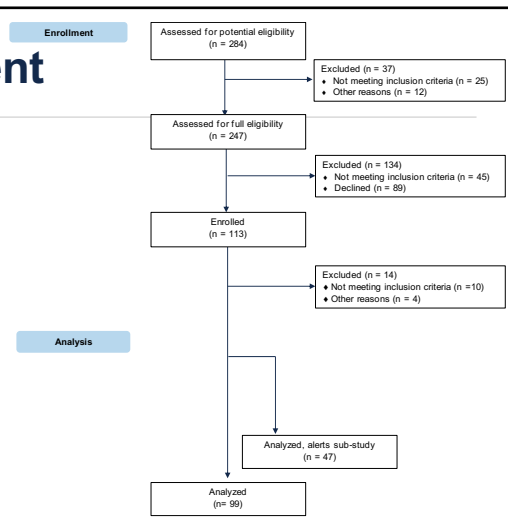
## TS-PRO 1.0 Symptom Reporting via automated ePROs

- Via UNC PRO-Core
- Web-based
- Email invitations to complete surveys sent per schedule
  - Automated email reminders
  - Study-team reminders by telephone as needed

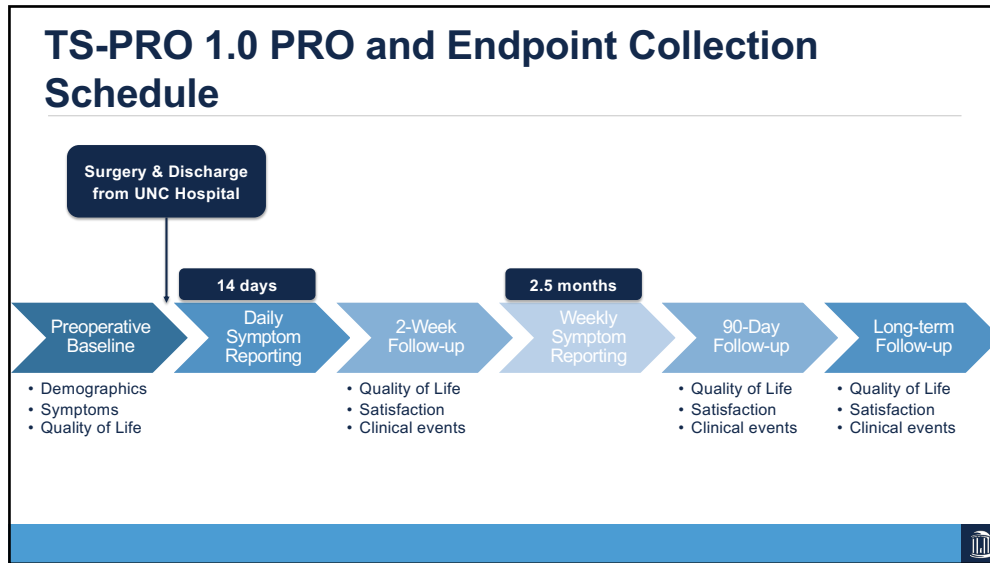
83

## TS-PRO 1.0 Enrollment

- 56% agreed to participate
- 113 enrolled and randomized
  - 57 passive monitoring
  - 56 active monitoring
- 99 participants began ePRO monitoring



84



85

### TS-PRO 1.0 Demographic Characteristics

	Active Arm (n=56)	Passive Arm (n=57)	Combined (n=113)
Male gender, n (%)	24 (42.9)	18 (32.7)	42 (37.8)
Age, mean ± sd	56.6 ± 13.6	63.1 ± 13.7	60.0 ± 14.0
Race, n (%)			
White	37 (67.2)	42 (77.8)	79 (72.5)
Black or African American	11 (20.0)	8 (14.8)	19 (17.4)
Native American or Alaskan Native	4 (7.3)	1 (1.9)	5 (4.6)
Native Hawaiian or Pacific Islander	0 (0.0)	0 (0.0)	0 (0.0)
Asian	0 (0.0)	2 (3.70)	2 (1.8)
Other	2 (3.6)	1 (1.9)	3 (2.8)
Prefer not to answer	1 (1.8)	0 (0.0)	1 (0.9)

86

## No demographic differences (refused vs. agreed)

	Approached (n=202)	Agreed (n=113)	Refused (n=89)	p-value
Age (years), mean (SD)	61.1 (14.1)	60.0 (14.0)	62.4 (14.3)	0.113
Male, n (%)	83 (41.5)	42 (37.8)	41 (46.1)	0.252
Ethnicity, n (%)				
Hispanic	3 (1.5)	2 (1.9)	1 (1.1)	1.00
Race, n (%)				0.287
White	146 (73.7)	79 (72.5)	67 (75.3)	0.336
Black or African-American	38 (19.2)	19 (17.4)	19 (21.4)	
Native American/Alaska Native	6 (3)	5 (4.6)	1 (1.1)	
Native Hawaiian/Pacific Islander	1 (0.5)	-	1 (1.1)	
Asian	3 (1.5)	2 (1.8)	1 (1.1)	
Other	3 (1.5)	3 (2.7)	-	
Prefer not to answer	1 (0.5)	1 (0.9)	-	

87

## TS-PRO 1.0 Clinical Characteristics

	Active Arm (n=56)	Passive Arm (n=57)	Combined (n=113)
BMI	30.15 ± 7.8	28.44 ± 6.5	29.30 ± 7.2
FEV1, mean±sd	87.05 ± 20.5	79.14 ± 23.2	83.06 ± 22.1
DLCO, mean±sd	83.25 ± 21.5	73.93 ± 21.2	78.37 ± 21.7
CAD, n (%)	53 (94.6)	47 (85.4)	100 (90.1)
Diabetes, n (%)	10 (17.9)	5 (9.1)	15 (13.5)
HTN, n (%)	30 (53.6)	33 (60.0)	63 (56.8)
PVD/PE/DVT, n (%)	6 (10.7)	4 (7.3)	10 (9.0)
Smoking, current, n (%)	5 (8.9)	9 (16.4)	14 (12.6)
Smoking, ever, n (%)	31 (58.9)	38 (69)	71 (64.0)
Lung cancer, n (%)	13 (23.6)	25 (45.5)	38 (34.5)
Malignancy, n (%)	28 (50.0)	37 (68.5)	65 (59.1)

88

## TS-PRO 1.0 Surgery Types

	Active Arm (n=56)	Passive Arm (n=57)	Combined (n=113)
Wedge, n (%)	19 (38.0)	16 (32.6)	35 (35.4)
Segmentectomy, n (%)	1 (2.0)	1 (2.0)	2 (2.0)
Lobectomy, n (%)	10 (20.0)	16 (32.7)	26 (26.3)
Pneumonectomy, n (%)	1 (2.0)	2 (4.1)	3 (3.0)
Chest wall repair, n (%)	3 (6.0)	3 (6.1)	6 (6.1)
Diaphragm repair, n (%)	4 (8.0)	2 (4.1)	6 (6.1)
Thymectomy, n (%)	2 (4.0)	3 (6.1)	5 (5.1)
Biopsy, n (%)	7 (14.0)	4 (8.2)	11 (11.1)
Other, n (%)	5 (5.05%)	3 (6.00%)	2 (4.08%)

89

## TS-PRO 1.0 ePRO Participation Levels

Post-discharge timing	High (>80%*)	Moderate (50-80%*)	Low (1-49%*)	None (0%*)	Total
<b>Daily survey delivery (14 surveys)</b>					
Day 1-7	34%	27%	17%	22%	100%
Days 8-14	37%	28%	13%	22%	100%
<b>Weekly survey delivery (11 surveys)</b>					
Weeks 3-4	64%	10%	0%	26%	100%
Weeks 5-8	51%	25%	6%	18%	100%
Weeks 9-12	49%	20%	7%	24%	100%

\*% of post-discharge ePRO surveys completed

90

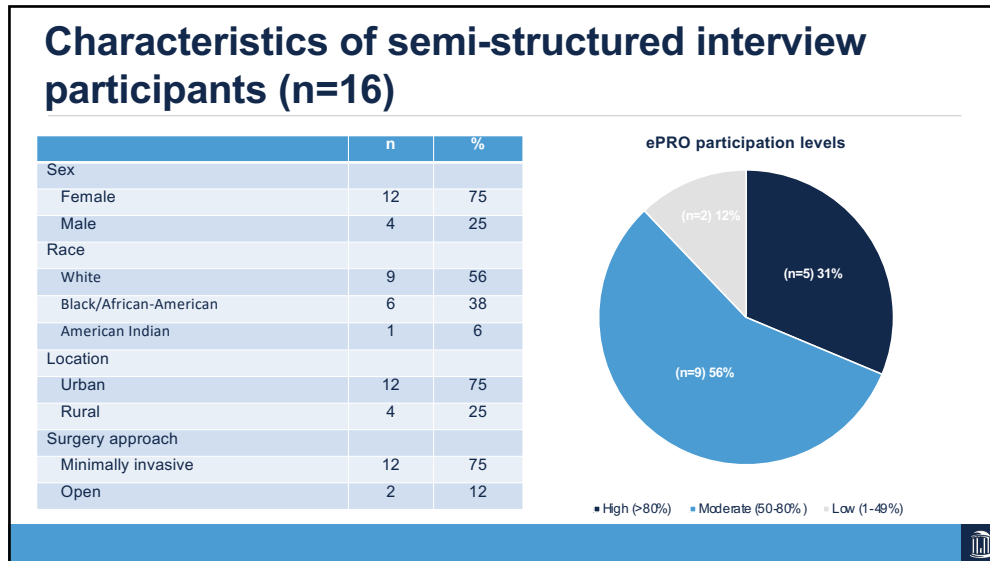
### Predictors of ePRO Participation Level

	None	Low (0-50% survey completed)	Medium (50-80% completed)	High (>80% completed)	p-value
<b>Overall</b>	12 (12.1)	27 (27.3)	18 (18.2)	42 (42.4)	0.155
Active monitoring	4 (33.3)	12 (44.4)	13 (72.2)	21 (50.0)	
Passive monitoring	8 (66.7)	15 (55.6)	5 (27.8)	21 (50.0)	
<b>Gender</b>					0.179
Male	6 (50.0)	13 (50.0)	7 (38.9)	11 (26.2)	
Female	6 (50.0)	13 (50.0)	11 (61.1)	31 (73.8)	
<b>Race</b>					0.339
White	7 (58.3)	15 (55.6)	13 (72.2)	32 (76.2)	
Black	3 (25.0)	8 (29.6)	4 (22.2)	4 (9.5)	
Other	2 (16.7)	4 (14.8)	1 (5.6)	6 (14.3)	
<b>Education</b>					0.064
No college degree	9 (90.0)	15 (71.4)	5 (35.7)	19 (55.9)	
College degree or more	1 (10.0)	6 (28.6)	9 (64.3)	14 (41.2)	
Other	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	
<b>Marital Status</b>					0.009
Not married or partnered	8 (72.7)	4 (19.0)	7 (50.0)	9 (25.7)	
Married or partnered	3 (27.3)	17 (81.0)	7 (50.0)	26 (74.3)	
<b>Computer Frequency</b>					0.148
Seldom or never	2 (18.2)	2 (10.0)	0 (0.0)	1 (2.9)	
Daily or often	9 (81.8)	18 (90.0)	14 (100.0)	34 (97.1)	
<b>Smoke</b>					0.015
Never	1 (8.3)	6 (22.2)	8 (44.4)	21 (50.0)	
Smoking ever	11 (91.7)	21 (77.8)	10 (55.6)	21 (50.0)	

91

- ### TS-PRO 1.0 Patient Interview Methods
- 30–60-minute audio-taped telephone interview
  - Semi-structured interview guide:
    - Section 1. Barriers and Facilitators Encountered During Study
    - Section 2. Enrollment Experience
    - Section 3. Experience with Clinician Contacts due to Alerts (*Active Monitoring Arm only*)
    - Section 4. Closing

92



93

### Qualitative analysis by COM-B domains

**Capability**

Theme 1. **Symptoms** and physical functioning during surgical recovery were **barriers** to ePRO assessment completion.

"There was days where I was feeling awful and I didn't complete the survey, but it was because of how I was physically feeling, not because of I didn't wanna do the survey, if that makes sense."

"I think I was just mainly exhausted, and it was that [the surveys] were helpful and

"... a couple of weeks that I didn't complete [the surveys] ... was at the beginning because I was still going through a little bit of, I guess, side effects from the surgery, so I really wasn't doing a lot of things on the computer or on the internet at that time. That was the only time."

Is daily too often?

Doing assessments when feeling better?

94

## Qualitative analysis by COM-B domains

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**Opportunity**


Offer telephonic even if have internet?

Theme 2. Adequate access to the required technology was a barrier to completing web-based ePROs for a few participants.

"Well, my daughter, I was usin' her email, and it wouldn't let her login... see, my daughter do that, and she live [elsewhere], so I'd rather be called on the phone to answer any survey."

"...I live in the country. If anything, the service is a little slow, but as far as loggin' in and answerin' the questions and stuff it was no problem."

"It's just I tried to log in on my phone, and it wouldn't—you know, it just wouldn't go to that website..."



95

## Qualitative analysis by COM-B domains

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**Opportunity**

Theme 3. Participants reported ease of completing the ePRO assessments.


"[The surveys] weren't that long, so they weren't time consuming at all."

"The questions and the answers were self-explanatory. It was pretty simple, pre the questions. "

Busy clinicians?

Theme 4. Patients preferred engagement on ePRO participation with the surgical care team.

"Yeah, [the surgeon] told me when we were in office, they asked me and then sent the person in...I did it more for the surgeon than if you would've hit me blind, I probably would've questioned it more... I guess it gave it legitimacy, with the surgeon [telling me]."



96




## Qualitative analysis by COM-B domains

**Motivation** Shorten or tailor ePRO?

Theme 5. Participants reported **irrelevant or repeated** ePRO monitoring questions.

"I think also because the surgery didn't really turn out the way that it was expected, that I think a lot of the questions didn't really apply to me because, like I said, [surgery] didn't really do what it was supposed to do."

"I think it was aimed [at someone with more extreme symptoms]—I came back negative for cancer... and I'm in overall good health. I don't want to say [the surveys were] monotonous because you—I can see where the questions need to be asked and in the time frame that they're asked. It was just for me, it was just asking a lot of questions that I wasn't running into..."



97


## Qualitative analysis by COM-B domains

**Motivation** Tie to perioperative teaching or discharge process?

Theme 6. Participants reported a lack of clarity on ePRO assessment **integration with routine clinical care**.

"I don't know. I don't know if [my care team] see the survey, if they don't see the survey. I don't know."

"Well, I think, to begin with, I thought it was all part of the care there at UNC. I guess after talking to them, I realized that it was a study that was bein' done separate."



98

## Qualitative analysis by COM-B domains

### Motivation

Theme 7. Participants reported increased awareness of their symptoms and recovery with ePRO use.

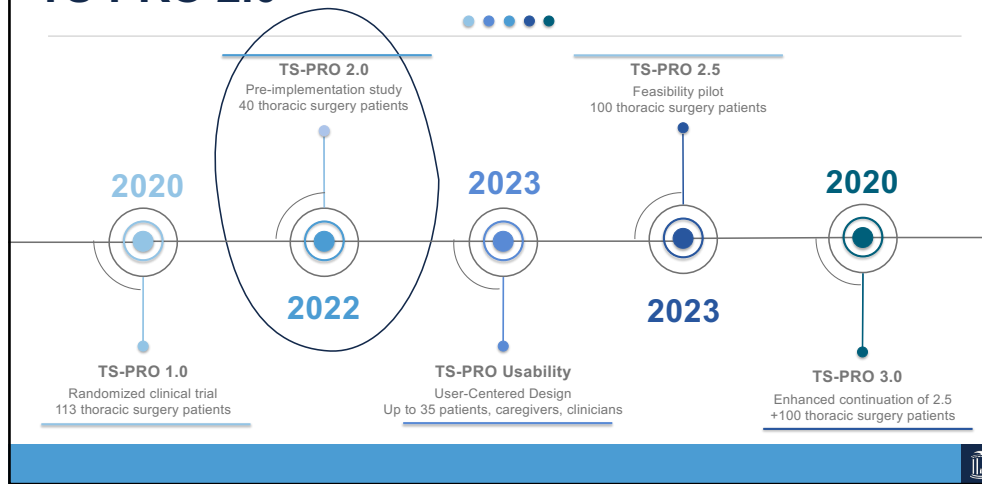
"I think it's beneficial because it makes you think about how you're feelin'. Again, I was goin' through so much that I think it was crucial, really, to make sure there wasn't major problems with me."

"[The questions] gives the patient time to really think about what symptoms that they may be having. They may not think about it at the moment, but when they're filling out the survey, they have a chance to think about how they're feeling... it was good [the surveys] continue to come so that if [symptoms] do come, I can write 'em down, and then hopefully someone from the team would reach out and ask me, "When did they start? How are you feeling? Do you feel like you need to come in?" Follow-up questions like that."

"[The surveys help] you keep up with yourself, plus you feel like you have support from another ... source."

99

## TS-PRO 2.0



100

## Revised Recruitment Materials



**Your At-Home Recovery Monitor**  
HELP US IMPROVE SURGICAL CARE FOR YOU AND OTHER PATIENTS

We want to learn how monitoring your recovery and symptoms after you leave the hospital can help improve your care after chest surgery.

Share your symptoms directly with us through an online survey throughout your recovery period.

TSPRO2@UNC.EDU

**UNC Thoracic Surgery Recovery Monitoring Study**

**How do we monitor your recovery after you are sent home from the hospital?**

Recovery monitoring is done by automatically sending you questions about your symptoms. These questions are also known as "Patient Reported Outcomes" (PROs). PROs are information about how you feel that you share directly with us. The information you provide can help us to improve your care.

**What happens in this study?**

- There are 1-2 study visits that can be completed in-person or by phone. At these visits, we will ask you some questions and go over how to use the Recovery Monitor platform.
- We will then send you the symptom assessment questions automatically. You will do your assessment twice a week for 2 weeks and then once a week for 4 weeks. Each assessment takes about 3 minutes. They can be completed online or by automated phone call.
- Overall, your participation in the study will last approximately 6 weeks. Afterwards, you will be asked to participate in an interview about your experiences using the Recovery Monitor during that time.

**UNC Thoracic Surgery Recovery Monitoring Study**

**FAQ**

**How do I fill out the Recovery Monitor symptom assessments?**  
Your first assessment will be sent to you automatically by email or phone a few days after you get home. You will then get reminders to fill out your assessments. You can do each assessment whenever you feel ready by logging in or calling back the Recovery Monitor phone line: 919-828-8848.

**Who can use my Recovery Monitor symptom assessments?**  
Only UNC providers with access to your medical record can view a graph with your latest symptoms, usually within 24-48 hours of completing your assessment. Your surgery team will use these reports to monitor you while you are at home and prepare for your follow-up appointments.

**I am tired and have pain after my surgery. I know it's important to do my symptom assessment, but can't do it now. What should I do?**  
If a family member or friend can help you when your assessment is due. It is important for you to complete all the symptom assessments so the providers can see how your symptoms are changing over time. This will also help you understand your recovery time.

**I filled out my assessment, but I did not hear back from my surgery team.**  
If you're doing well, the team may not reach out to you. If you are worried about anything, call the clinic to check in with your nurse navigator at 919-843-8808 or to schedule a call with your nurse practitioner/physician at 919-843-2803. If something seems serious, go to your closest emergency room or call 911 as it is possible the team has not seen your assessment report yet.


**I am confused how these Recovery Monitor symptom assessments are being used or will help me.**  
The symptom assessment report goes into your medical record. Any serious symptoms get sent directly to your surgery team. There are many people involved in your recovery after you are sent home from the hospital. Symptom assessments let your important recovery issues get directly to your surgery team.

**The symptom assessment items do not seem to be relevant to me. Should I keep filling them out?**  
Sometimes symptoms like tingling at your incision do not show up right after surgery. By doing your assessments, you will be more aware of what to watch out for. We can prescribe medications to help with these issues when they do come up.

**My computer crashed during my survey? What should I do now?**  
Do not worry, you can call the study team at 919-888-8888 and we will help you get back on track.

101

## TS-PRO 2.0 Enrollment

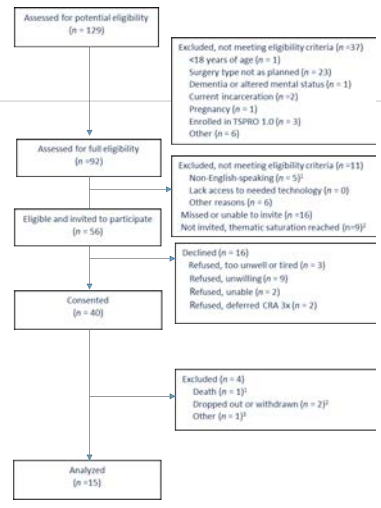


**Your At-Home Recovery Monitor**  
HELP US IMPROVE SURGICAL CARE FOR YOU AND OTHER PATIENTS

We want to learn how monitoring your recovery and symptoms after you leave the hospital can help improve your care after chest surgery.

Share your symptoms directly with us through an online survey throughout your recovery period.

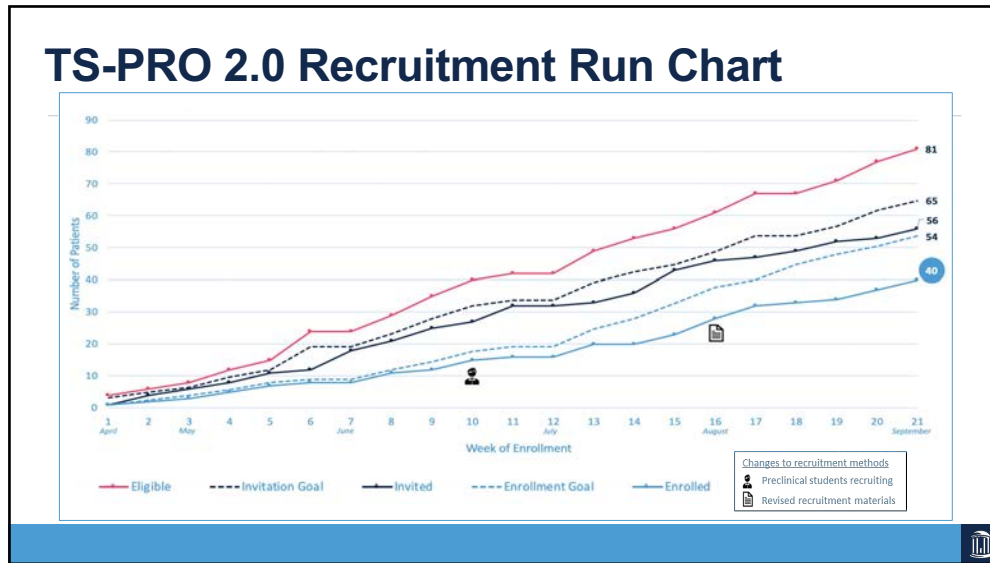
TSPRO2@UNC.EDU



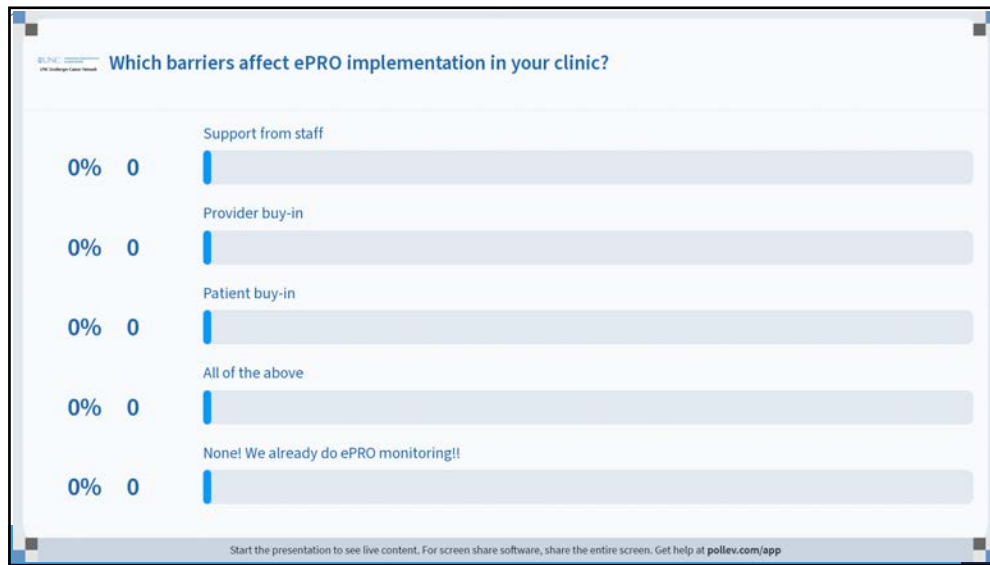
```

graph TD
    A[Assessed for potential eligibility  
(n = 129)] --> B[Assessed for full eligibility  
(n = 92)]
    A --> E1[Excluded, not meeting eligibility criteria (n = 37)  
<18 years of age (n = 1)  
Surgery type not as planned (n = 23)  
Dementia or altered mental status (n = 1)  
Current incarceration (n = 2)  
Pregnancy (n = 1)  
Enrolled in TSPRO 1.0 (n = 3)  
Other (n = 6)]
    B --> C[Eligible and invited to participate  
(n = 56)]
    B --> E2[Excluded, not meeting eligibility criteria (n = 11)  
Non-English speaking (n = 5)1  
Lack access to needed technology (n = 0)  
Other reasons (n = 6)]
    C --> D[Consented  
(n = 40)]
    C --> E3[Missed or unable to invite (n = 16)  
Not invited, thematic saturation reached (n=9)2]
    D --> F[Analyzed  
(n = 15)]
    D --> E4[Declined (n = 16)  
Refused, too unwell or tired (n = 3)  
Refused, unwilling (n = 9)  
Refused, unable (n = 2)  
Refused, deferred CRA 3x (n = 2)]
    F --> E5[Excluded (n = 4)  
Death (n = 1)3  
Dropped out or withdrawn (n = 2)4  
Other (n = 1)5]
    
```

102



103



104

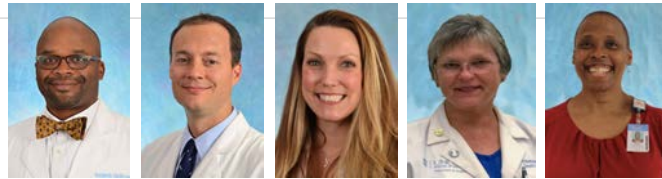
## Audience question

- Which barriers affect ePRO implementation in your clinic?
  - A. Support from staff
  - B. Provider buy-in
  - C. Patient buy-in
  - D. All of the above
  - E. None! We already do ePRO monitoring!!

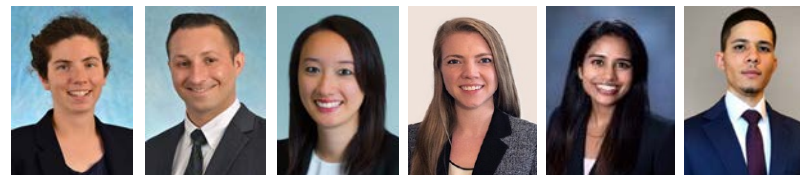


105

## Acknowledgements: clinical care team



Ben Haithcock   Jason Long   Lauren Hill   Bernice Newsome   Julia Coleman



16 CT Residents



106

## Acknowledgements: funding

- NIH National Heart, Lung, and Blood Institute (K23HL157765)
- American College of Surgeons Foundation
- Sivan Innovation



107

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1. Slide contributions: Ethan Basch, Angela Smith, Amanda Gentry
2. UNC Pro Core

108

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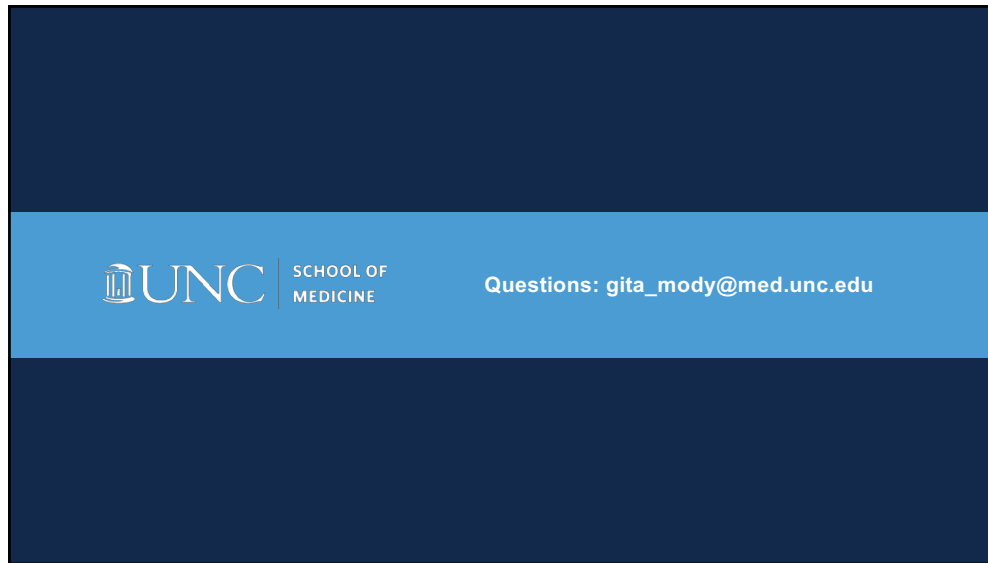
109

*For more information, please visit our website:*

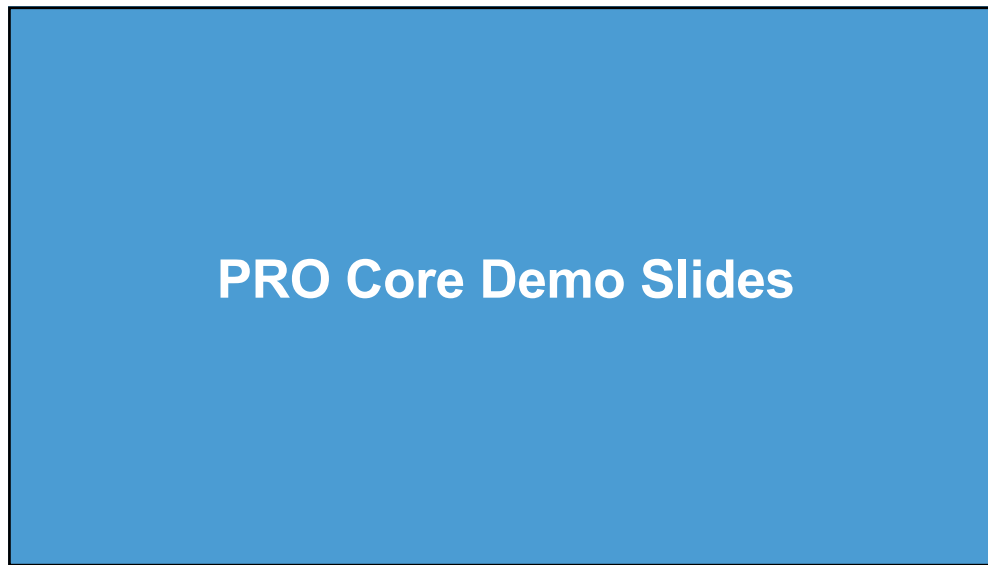
## Patient-Centered Perioperative Care Research Laboratory at UNC



110

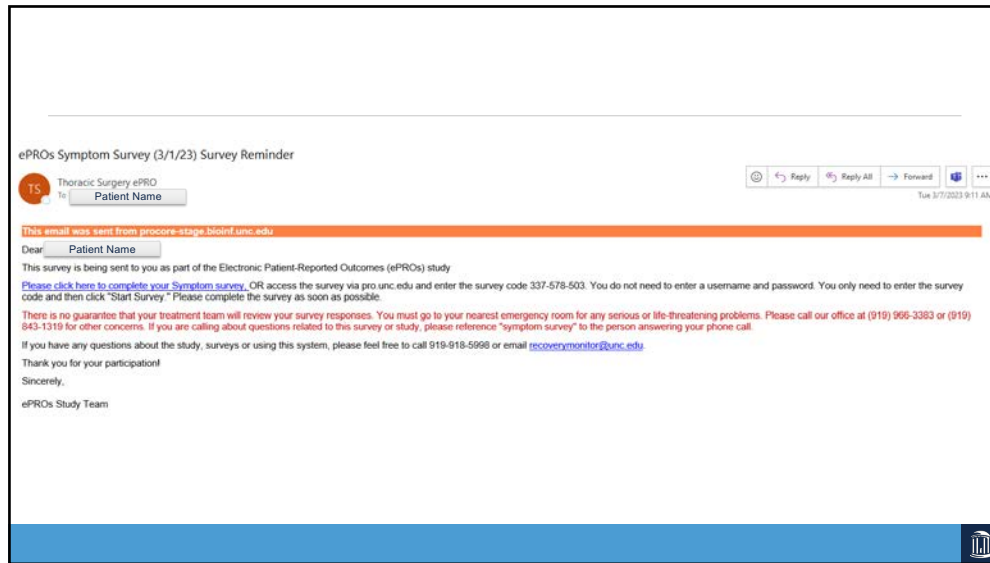


111

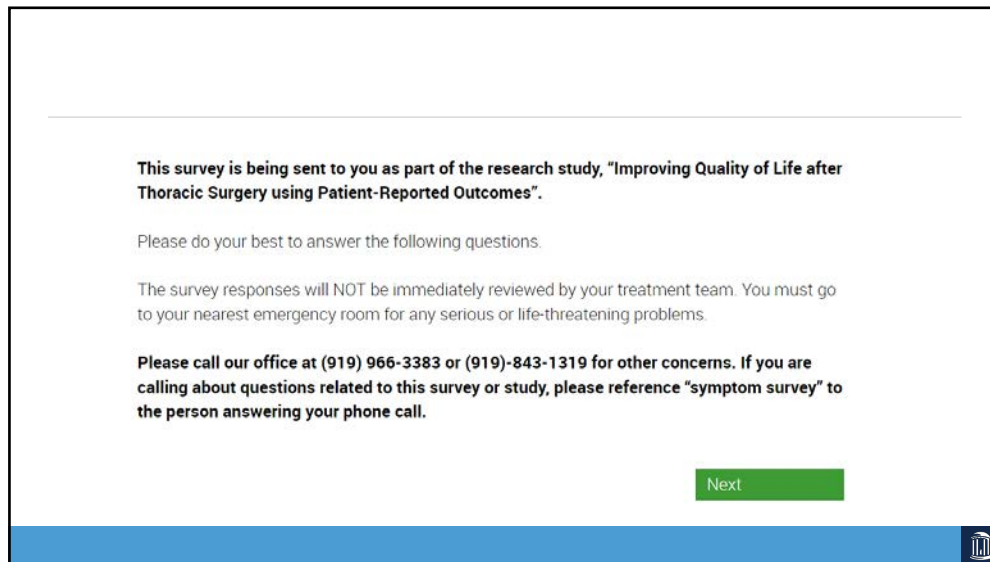


112





113




114

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### Your Quality of Life

We are interested in some things about you and your health. Please answer all of the questions yourself by selecting the option that best applies to you. There are no right or wrong answers. The information that you provide will remain strictly confidential.

Next




115

---

Do you have any trouble taking a short walk outside the house?

- Not at all
- A little
- Quite a bit
- Very much

Next



116

---

**During the past week**, were you limited in doing either your work or other daily activities?


Not at all

A little

Quite a bit

Very much

Next



117


---

How would you rate your overall health during the past week?

1 2 3 4 5 6 7

Very Poor Excellent

Next




118

---

As you recover from your thoracic surgery, you may experience various symptoms and/or side effects. For each question, please select the ONE box that best describes your experiences over the past **24 hours**, so we can understand your preoperative symptoms.

Next

Department of Surgery 

119

---

In the last **24 hours**, what was the SEVERITY of your CONSTIPATION at its WORST?

None


Mild

Moderate

Severe

Very severe

Next




120

---

In the last **24 hours**, how **OFTEN** did you feel a **POUNDING OR RACING HEARTBEAT** (PALPITATIONS)?

- Never
- Rarely
- Occasionally
- Frequently
- Almost constantly



121


---

Do you have any other symptoms that you wish to report?

No

Yes

If yes, please describe:



122


---

This survey is complete. Thank you!

**Note: This survey is used for research. If you have severe symptoms or health issues that you think need medical attention, it is important you contact your doctor directly.**

You must go to your nearest emergency room for any serious or life-threatening problems.

Please call our office at (919) 966-3383 or (919)-843-1319 for other concerns. If you are calling about questions related to this survey or study, please reference "symptom survey" to the person answering your phone call.



123



### Questions/Comments?


Nobody has responded yet.  
Hang tight! Responses are coming in.

Start the presentation to see live content. For screen share software, share the entire screen. Get help at [pollev.com/app](https://pollev.com/app)

124

**THANK YOU!**

**University Cancer  
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**The Telehealth Team**

**Tim Poe, Director**

**Veneranda Obure, Technology Support Specialist**      **Andrew Dodgson, DPT, Continuing Education Specialist**


**Jon Powell, PhD, Continuing Education Specialist**      **Nadja Brown, Interim Administrative Support Specialist**

**Oliver Marth, Technology Support Technician**      **Patrick Muscarella, Technology Support Technician**

**Lauren Lowe, Intern**

125

**UPCOMING LIVE WEBINARS**




**ADVANCED PRACTICE PROVIDER**

Overview of Clinical Trials for the APP

**July 19**  
**4:00 PM**

**Overview of Clinical Trials for the APP**  
**Clarissa Urban, PA-C**

---




**RESEARCH TO PRACTICE**

Therapeutic Approaches for Soft Tissue Sarcomas: 2023 Update

**July 26**  
**12:00 PM**

**Therapeutic Approaches for Soft Tissue Sarcomas: 2023 Update**  
**Mark Woodcock, MD**

---



**PATIENT CENTERED CARE**

Cognitive Impairment in Cancer: Updates in Understanding Causes and Effective Treatments

**August 9**  
**12:00 PM**

**Cognitive Impairment in Cancer: Updates in Understanding Causes and Effective Treatments**  
**Zev Nakamura, MD**

Complete details on upcoming Live Webinars:  
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126

**SELF-PACED, ONLINE COURSES**



**ADVANCED PRACTICE PROVIDER**  
Self-Paced Online Course

**Parenting with Cancer**  
**Justin Yopp, PhD**

---



**RESEARCH TO PRACTICE**  
Self-Paced Online Course

**The Ketogenic Diet for Brain Tumor Patients: A Phase 1 Trial and Beyond**  
**Jethro L. Hu, MD**

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**PATIENT CENTERED CARE**  
Self-Paced Online Course

**Cancer Pathology: How Diagnosis Drives Treatment**  
**Yuri Fedoriw, MD**

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127

**THANK YOU FOR PARTICIPATING!**

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128