

Quality of life assessments as health outcomes: Lung cancer as an exemplar

Linda Sarna, RN, DNSc

Professor, UCLA School of Nursing

March, 2003

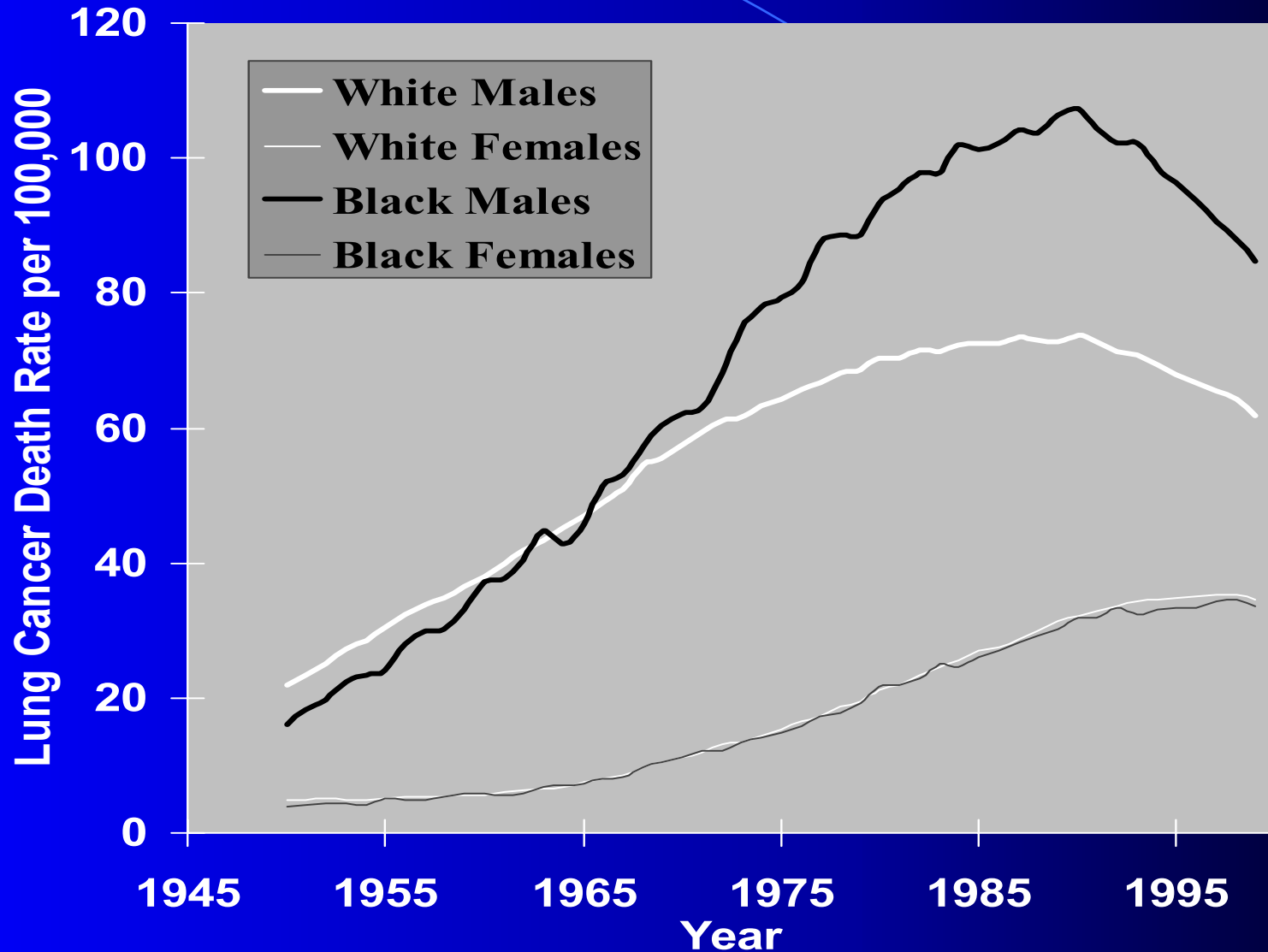
What is it?

- Many definitions
- WHO (1948) “state of complete physical, mental, and social well-being, and not merely the absence of disease.”
- No gold standard
- Means different things to different people
- Different instruments measure different things
- Health-related QOL

Assessment of Quality of Life & Symptom Distress

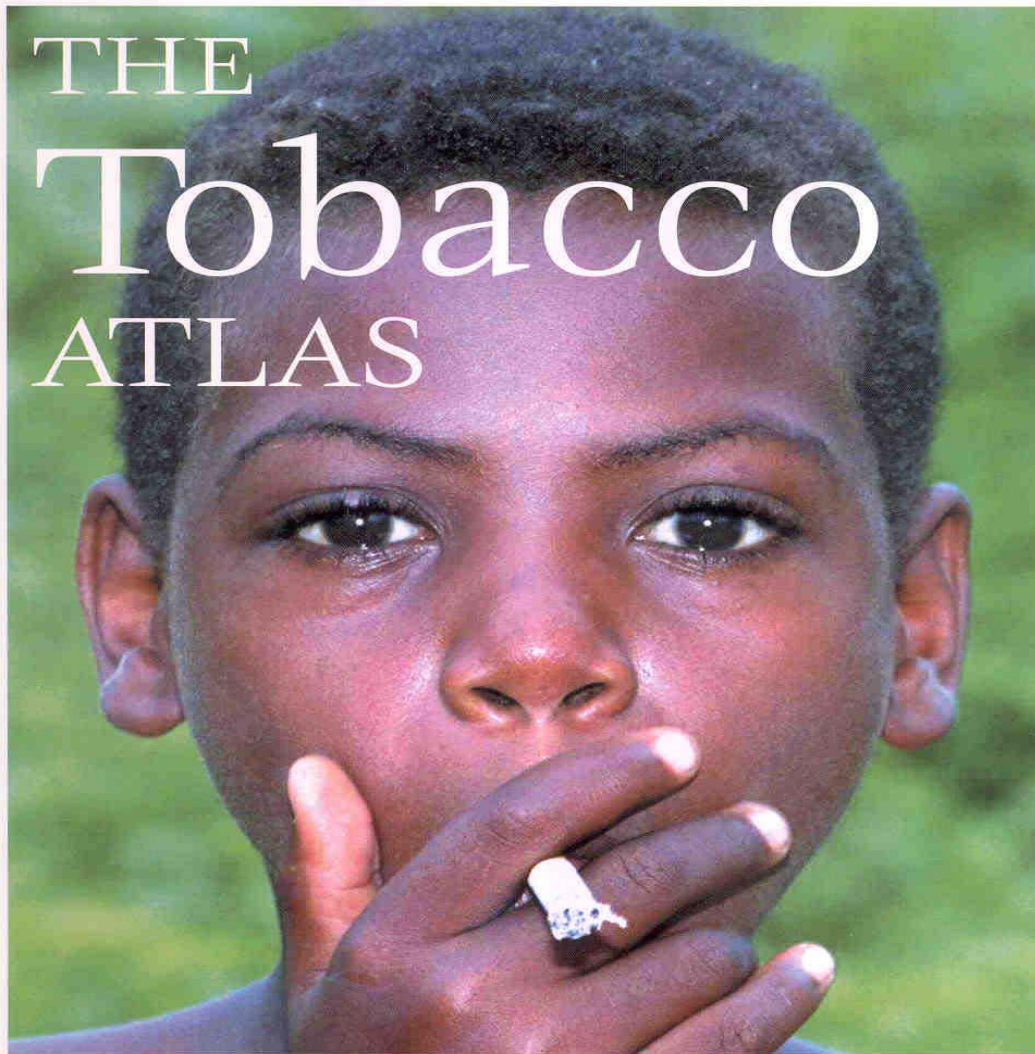
- Useful information for clinicians as an indicator of clinical benefit beyond survival
- Comparisons across treatments (risk/benefit)
- Toxicities/symptoms of new treatments
- Assist patients in making decisions about treatment options especially for palliation
- Useful in evaluating needs for supportive care services

US Lung Cancer Death Rates 1950-1999



Fourth most preventable cause of death (WHO, 2003)

THE
Tobacco
ATLAS



DR JUDITH MACKAY & DR MICHAEL ERIKSEN



WORLD HEALTH ORGANIZATION

Global Impact (WHO, 2002)

- 1/3 world's population currently smokes (1.1 billion smokers)
 - 3.5 million die every year
- 10 million annual deaths projected by 2030
 - 100 million deaths in 20th century
 - 900 million deaths projected for the 21st century
 - 70% in developing countries

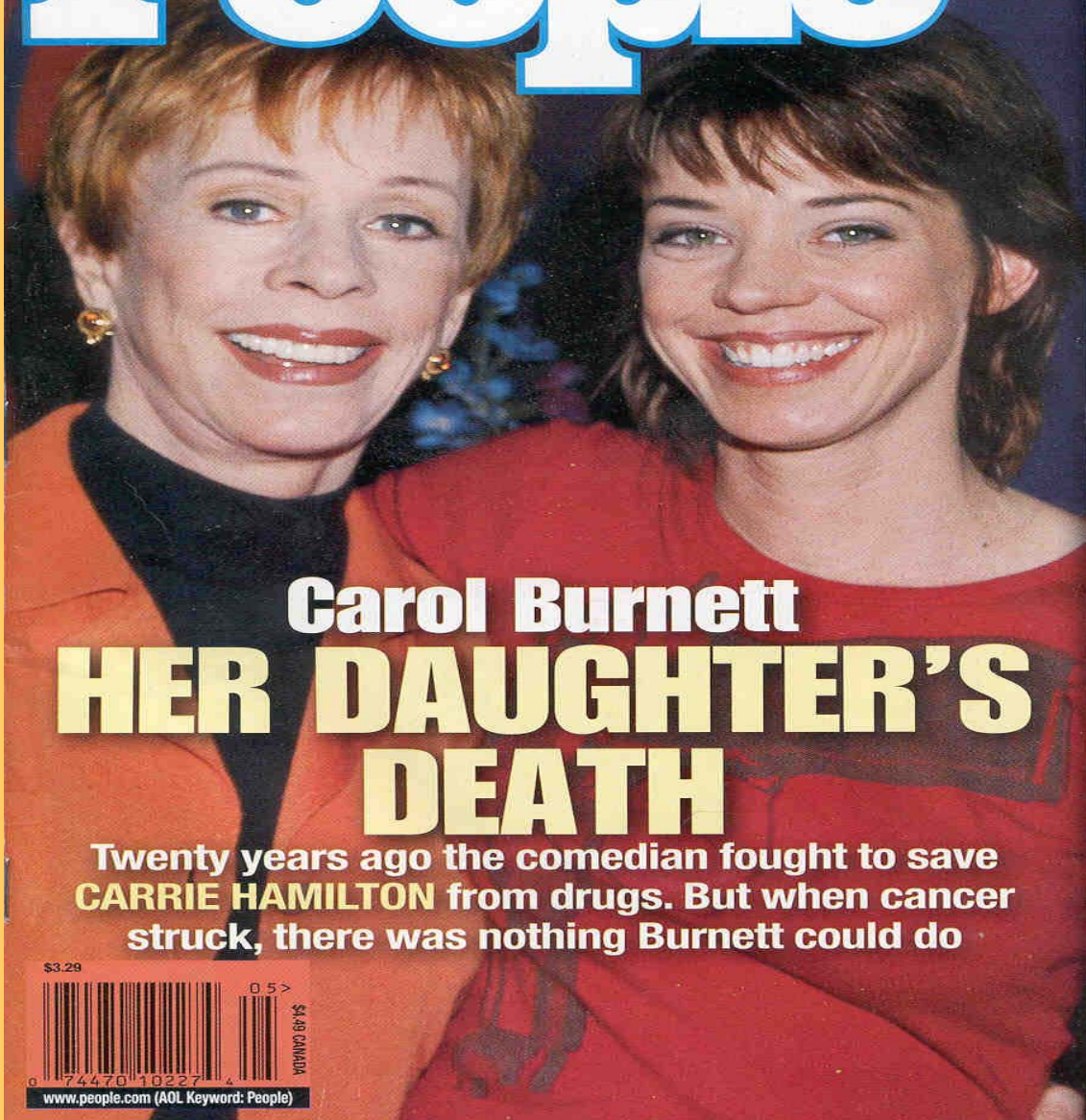
Prevalence of lung cancer cases by state: estimates for 2003

- California, 14,400
- Florida, 13,200
- Texas, 10,900
- New York, 10,000
- Pennsylvania, 8,700
- Indiana, 7,400
- Michigan, 6,100

FEBRUARY 4, 2002

People

weekly



Carol Burnett **HER DAUGHTER'S DEATH**

Twenty years ago the comedian fought to save **CARRIE HAMILTON** from drugs. But when cancer struck, there was nothing Burnett could do

\$3.29



0 5 >

\$4.99 CANADA

0 74470 10227 4

www.people.com (AOL Keyword: People)

Women & Smoking

A Report of the Surgeon General 2001

- Since 1980, 3 million women have died prematurely from tobacco
- Lung cancer surpassed breast cancer as leading cause of cancer death in 1987
- More deaths (68,800) than breast, ovarian, cervical & endometrial cancers combined
 - Legacy Survey: 13% of American women aware of this fact

Why QOL as an endpoint for Lung Cancer care?

- Overall five-year survival 14%
- Lack of good methods for early detection
- Majority diagnosed at advanced disease
- Minimally effective treatment for advanced disease
- Some treatments may help symptoms but not prolong life
- 45 million smokers in the US will make lung cancer a continued concern.

Lung Cancer & QOL



- Clinical research
- Clinical practice
- Advanced disease
- Survivors

Quality of Life

- Multidimensional construct affected by lung cancer and its treatment
- Common Components
 - Physical
 - Emotional/Psychological
 - Social
 - Spiritual/existential
- Patient's perspective

Most commonly reported lung cancer symptoms included in QOL assessments

- Dyspnea
- Cough
- Hemoptysis
- Depression
- Pain
- Fatigue
- Anorexia
- Weight loss

Patient preferences

(Silvesteri et al, 1998)

Opinions of patients with NSCLC treated with cisplatin based chemo for advanced lung cancer (n = 81)

Findings: Wide variation

Only 22% chose chemotherapy over supportive care alone for 3 mo survival

68% chose chemotherapy if it substantially reduced symptoms even if it didn't prolong life

QOL Assessments

- KPS (1947)
- Generic (e.g SF-36)
 - Comparisons by age, gender, disease
- Cancer specific (e.g. EORTC)
 - Core questionnaire and modules
- Lung cancer specific (e.g. LCSS)
- Inclusion of side effects of treatment
- Inclusion of Symptoms

Three common instruments to assess Quality of Life in lung Cancer

- **Lung Cancer Symptom Scale**

- 9 items
- E.g appetite, fatigue, cough, dyspnea, pain
- Visual analogue
- Time frame: within the past day
- Symptomatic distress, individual items, global QOL

- **Fact-L**

- General & site specific module
- 34 core items
- 7 lung cancer items: e.g. dyspnea, cough, weight loss, cognition
- Time frame: within the past week
- Mean score, individual items

EORTC-QLQ- C30

- Core (30 items): physical, role, emotional, cognitive, social, global health status
- Disease-specific LC-13: 13 items
 - e.g Dyspnea, cough, sore mouth, hemoptysis, alopecia
- Different scaling for different questions
 - 4 pt Likert scale
 - 7-pt analogue scale
 - Subscale scores
- Time frame: within past week
- Many languages

Quality of Life scores

- LCSS: overall QOL, symptom severity, activity status
- EORTC: global score, functional scales (physical, role, emotional, cognitive, social), financial difficulty
- FACT-L: Physical, social/family, emotional, functional well-being

What is a clinically meaningful change in QOL?

- EORTC
 - 10% difference from baseline score
 - Sustained symptom control
- FACT_L: trial-outcome index (combination of physical and functional well-being)
 - 8 points, 5 points
 - Improved, stable, progressed
- LCSS
 - 2 pt change

Factors affecting appraisals of QOL

- Age
- Gender
- Race/Culture
- Marital status
- Comorbid conditions
- SES
- Tobacco use? Cessation???

Positive and Negative aspects

- Short term toxicities and side effects of treatment
- Longer term side effects of treatment
- Recovery to pre-existing levels of function
- Existential issues: wiser & blessed because of experience
- Reframing: retrospective appraisals of the experience

QOL and Advanced Lung Cancer

- Patients with lung cancer have more symptoms, greater emotional distress than other people with cancer
- QOL independent prognostic indicator
- Strongly tied to symptom distress
 - For patients
 - For families

QOL and Clinical Trials

- Review of 151 QOL reports on patients with lung cancer over a 25-year period (1970-1995) (Montazeri et al)
 - 42 studies focused on NSCLC
 - All except one focused on patients with advanced stage disease
 - 50 different instruments

Recent Review of Phase III trials

- Phase II trials (1998-2002, July)
- 39 randomized phase III trials identified
 - Only 14 (36%) included information about QOL
 - Some mentioned QOL in methods but did not report data
 - 7 different measures of QOL
 - A variety of definitions for improvement

Issues in comparing QOL data across clinical trials

- Frequency of measurement
- Scores for interpretation (Global vs details)
 - Lack of detail for intervention
 - Parts less than the sum of the whole
- Lack of normative data for comparison
 - Differences by age, gender
- Floor vs ceiling effects
- Attrition
- missing data
- Control for comorbid conditions
- Language and cultural barriers

QOL & Lung Cancer Survivors

(Sarna et al, 2002)

- Cross-sectional study of 142 NSCLC survivors
- QOL issues varied widely
 - 71% “hopeful”
 - 50% “positive life changes”
 - 22% distressed mood (CES-D)
 - 60% >1 comorbid condition
 - >50% < 70% FEV₁ % predicted
 - 13% continued to smoke

Figure 1. Physical and Mental Quality of life Score Comparisons

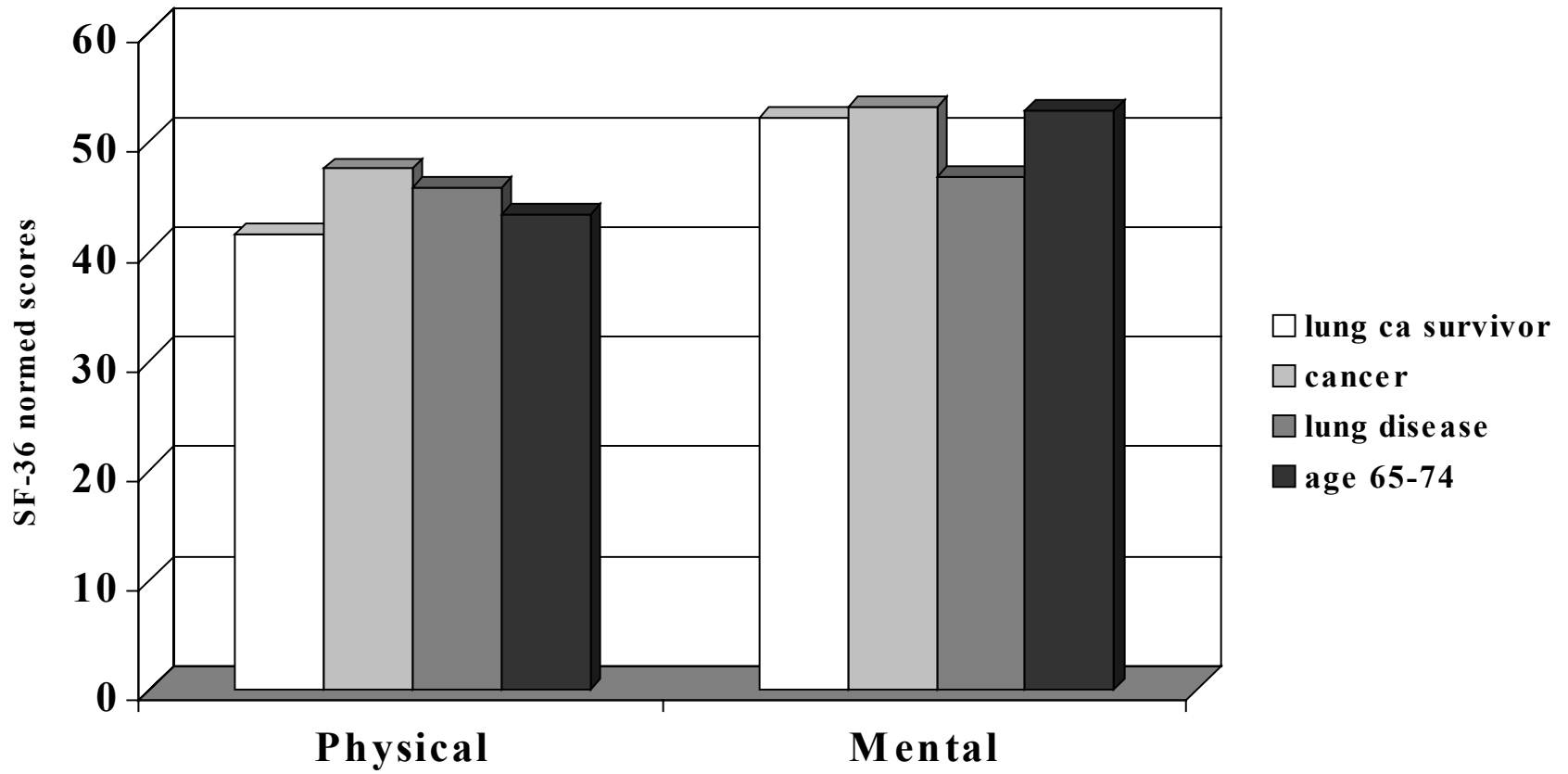
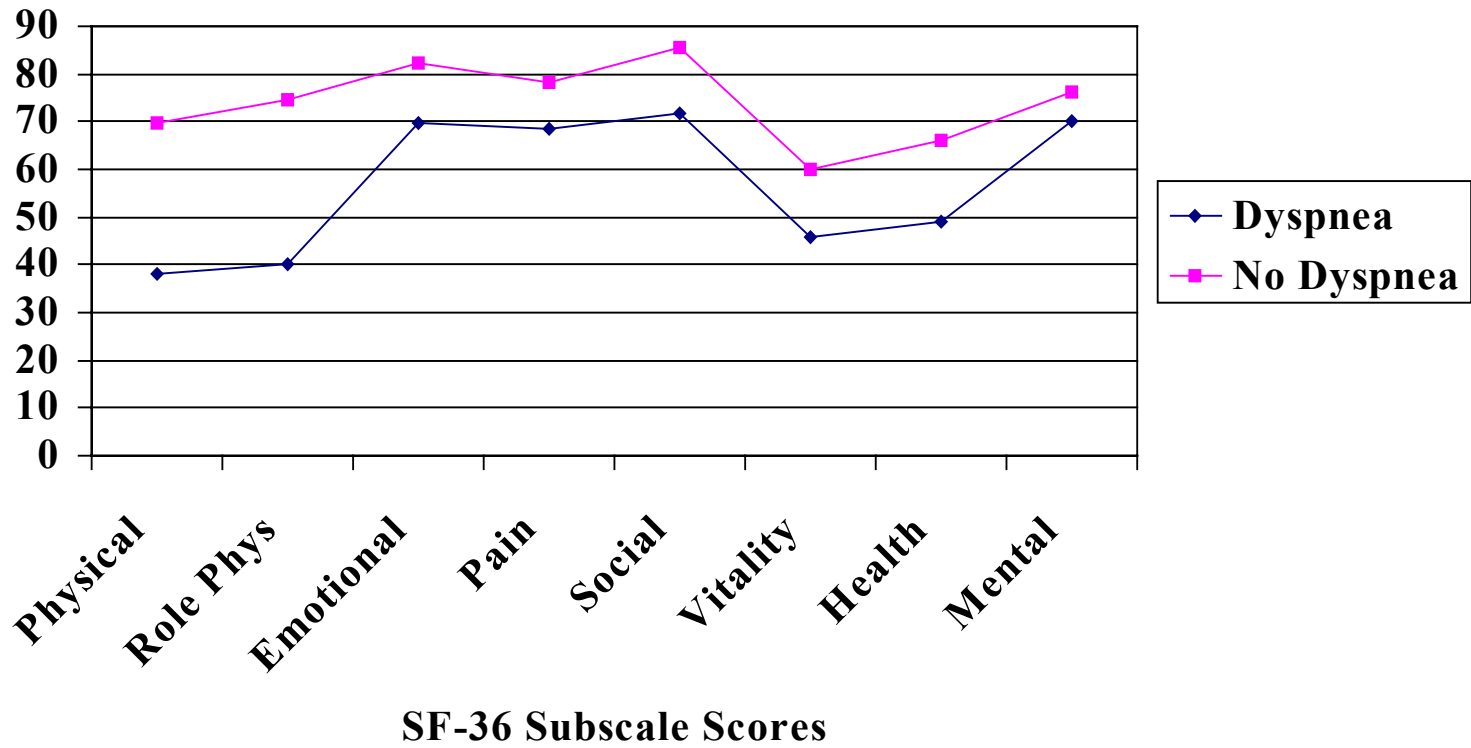


Figure 1. Quality of life Scores of Lung Cancer Survivors with and without Dyspnea



Predictors of QOL: SF-36

- Mental well being ($R^2 = 34\%$)
 - Distressed mood
 - Being “White”
- Physical well being ($R^2 = .28$)
 - Older age
 - Living alone
 - $FEV_1 < 70\%$ predicted
 - Distressed mood
 - Time since diagnosis
 - More comorbid conditions

QOL and Women with Lung Cancer

Impact of study findings on nursing care

- **Information about QOL and symptom management assists nurses in:**
 - identifying risk factors for decreased QOL and increased distress
 - identifying protective factors
 - anticipating changes in QOL and symptoms
 - providing support for family members
 - selecting outcome measures

Most Distressing* QOL Items Ranked by >25% of Women

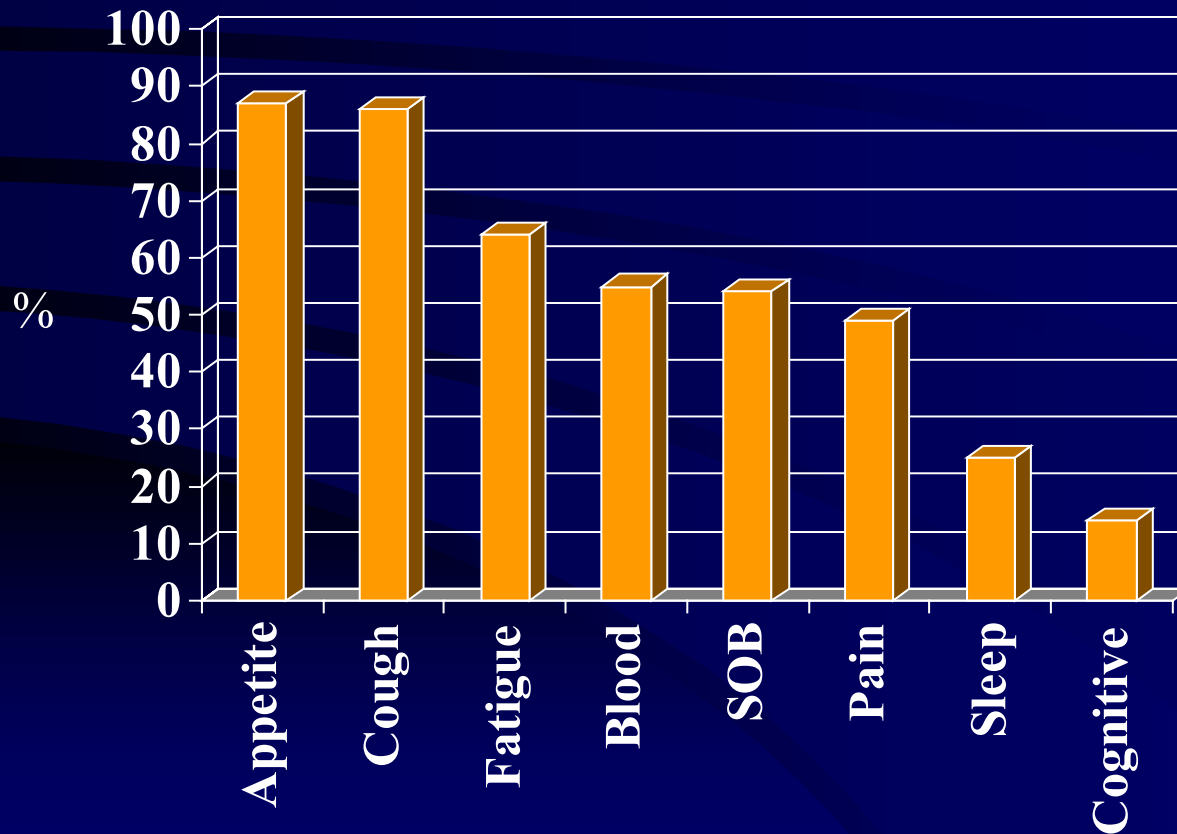
- **Physical**
 - Fatigue (28%)
- **Psychological**
 - Distress with dx (75%)
 - Distress with rx (60%)
 - Anxiety (52%)
 - Self-concept (41%)
 - Appearance (40%)
- **Psychological: Fears**
 - Metastasis (69%)
 - Diagnostic tests (63%)
 - Recurrence (53%)
- **Social**
 - Sexual function 77%
 - Family 76%
 - Activities at home (30%)
 - Financial burden (28%)
 - Employment (26%)
- **Spiritual**
 - Uncertainty (54%)
 - No positive changes (35%)

(N=230)

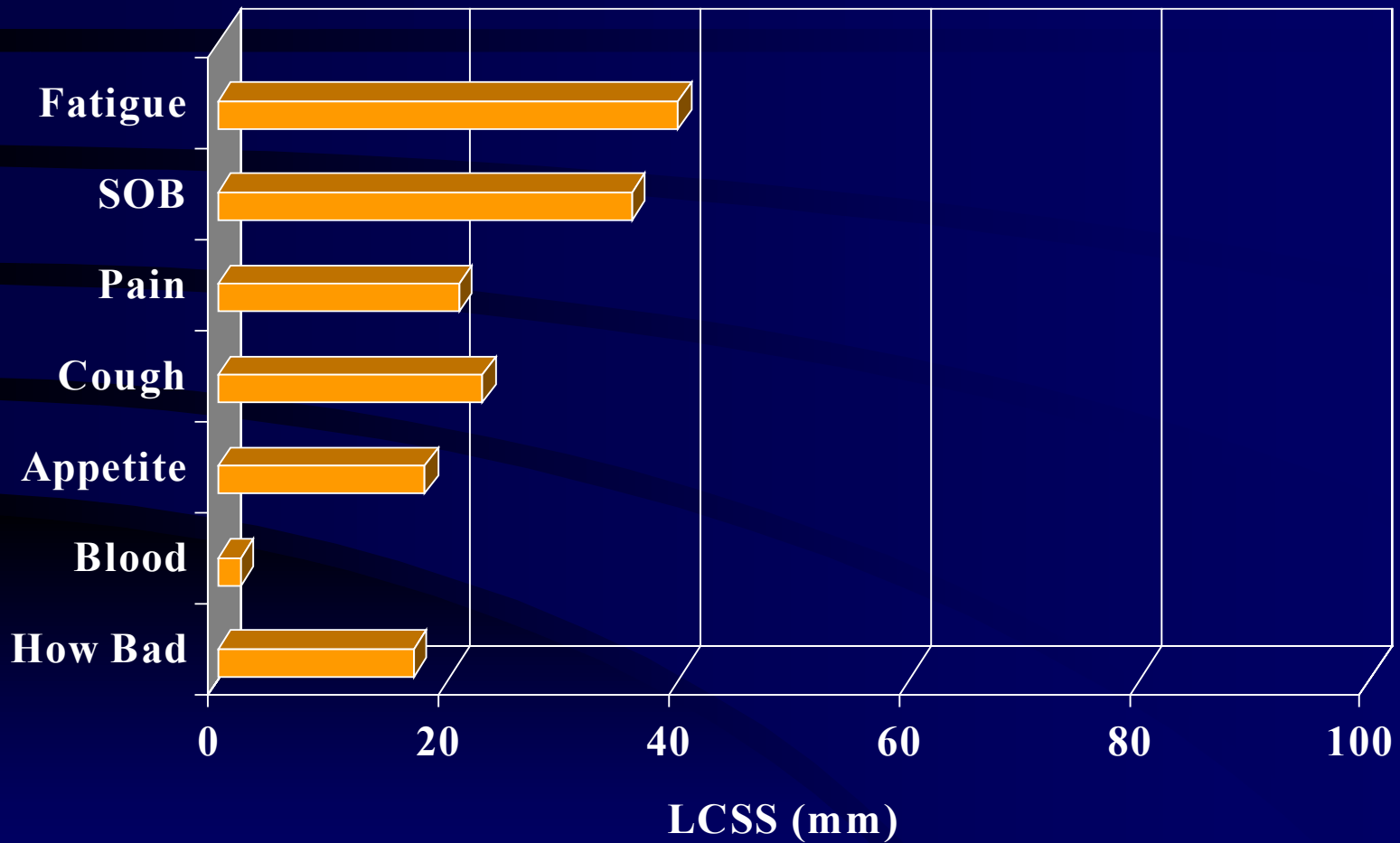
Rated <4 with 0 being worst possible

Women with Lung Cancer (n=230)

Frequency of Symptoms



Mean Symptom Severity



Symptom Correlates of QOL

Symptom	Phys	Psych	Social	Spirit	Global
Appetite	-.32	-.90	-.25	ns	-.25
Fatigue	-.52	-.32	-.39	ns	-.41
Pain	-.50	-.30	-.34	ns	-.36
Cough	-.34	-.15	-.23	ns	-.20
SOB	-.40	-.29	-.35	ns	-.36
Blood	ns	ns	ns	ns	ns
How bad	-.44	-.39	-.49	ns	-.46

Frequency of Symptom Clusters

Pain Model

Symptom Cluster	Percent
Pain & fatigue	79
Pain & SOB	77
Pain, fatigue, & SOB	76
Pain, fatigue, SOB, & cough	67
Pain, fatigue, SOB, cough, & blood	48
Pain, fatigue, SOB, cough, blood, & appetite	46

Women with Lung Cancer (n = 230)
Frequency of Ascriptions of Meaning of Illness

Meaning	N	%
<u>Positive</u>	141	61.3
challenge	118	51.3
value	23	10.0
<u>Negative</u>	79	34.3
enemy	41	17.8
loss	16	6.5
punishment	15	6.5
weakness	7	3.0
<u>Other</u>	10	4.3

Qualitative & Mixed Methods Approaches

The Aftermath of Lung Cancer

- Adjustment: integrating change
 - “adjusting to not be able to exert myself”
- Physical ability: slowing down
 - “not able to do what I used to do”
- Health and self-care: Taking control
 - Appreciation for health, stopping smoking
- Support: giving and receiving
 - “being an inspiration to others”
- Existential: A changed life
 - “Everyday a gift”

Different strategies for assessing QOL responses

- Patient preferences: Weighting of items that reflect the importance by patients of different aspects of QOL or survival
- Standard gamble, time trade off
- QALY: quality adjusted life year
 - May facilitate comparisons across studies
 - Calculate social costs
- Q-Twist (quality adjusted time without symptoms of disease and toxicity of treatment)
 - Time spent with symptoms is important
 - Benefits vs tolerance for toxicity

Recommendations

- QOL data provide a critical information about benefits & impact of treatment and should be a primary endpoint in many studies
- Individual QOL assessments can be included in routine clinical care
 - Screen for potential problems
 - Further assessment
- Valid and reliable tools are available

Selected References

- Bergman B et al (1994). The EORTC QLQ-LC13: a modular supplement to the EORTC Core Quality of Life Questionnaire (QLQ-C30) for use in lung cancer clinical trials. EORTC Study Group on Quality of Life. Eur J Cancer. 30A:635-642.
- Cella DF et al (1995). Reliability and validity of the Functional Assessment of Cancer Therapy – Lung (FACT-L) quality of life instruments. Lung Cancer. 12:199-220.
- Cooley Me. (2000) Symptoms in adults with lung cancer. A systematic research review. J Pain Symptom Manage. 19:137-153.
- Hollen PJ et al. (1994) Quality of life during clinical trials: conceptual model for the lung cancer symptom scale (LCSS). Support Care Cancer. 2:213-222.
- Ganz PA et al. (1991) Quality of life assessment: an independent prognostic variable for survival in lung cancer. Cancer. 67: 3131-3135.
- Kurz ME et al. (2000) Symptomatology and loss of physical functioning among geriatric patients with lung cancer. J Pain Symptom Manage. 19:249-256
- Montazeri A et al. (1998). Quality of life in patients with lung cancer: a review of literature from 1970-1995. 26:23-30.
- Sarna L et al (2002). Quality of life of long-term survivors of non-small cell lung cancer. JCO. 20; 2920-2929.
- Silvestri G et al (1998). Preferences for chemotherapy in patients with advanced non-small cell lung cancer: descriptive study based on scripted interviews. BMJ. 317, 771-775.
- Steer CB et al. (2001). Is there quality in clinical benefit. Ann Oncol. 12: 1191-1193