Status Report: Cancer Care Outcomes Research and Surveillance Consortium (CanCORS)

NCI Board of Scientific Advisors
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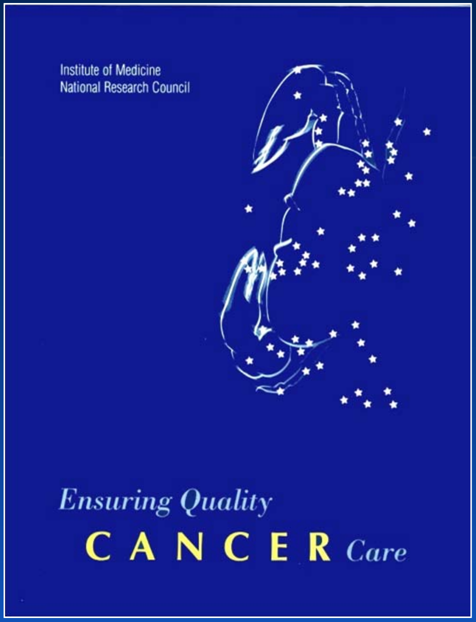
Disparities in quality of care

“For many Americans with cancer, there is a wide gulf between what could be construed as the ideal and the reality of their experience with cancer care.” (IOM, 1999)



Institute of Medicine
National Research Council

Ensuring Quality
CANCER Care

Studies have repeatedly shown quality of cancer care varies by:

- **Age**
- **Race/ethnicity**
- **Education/income**
- **Geography**

But we don’t really know *why* disparities occur

Possible explanations

- Patients
  - lack of information
  - Preferences

- Physicians
  - inadequate knowledge base
  - Biases

- “The System”
  - inadequate facilities/access
  - poor coordination of care
  - inadequate reimbursement

Need for data on “real-world” outcomes

How do cancer and cancer treatments affect patients and their families?

- **Short-term effects, e.g. treatment toxicity**
- **Long-term effects, e.g. employment**

CanCORS

- Scientific Goals
  - Examine treatment choice with a special focus on *why* certain groups receive lower quality care
  - Characterize the outcomes of treatment in the “real world”
  - Develop state-of-the art methods for outcomes research

CanCORS

Prospective collection of data from:

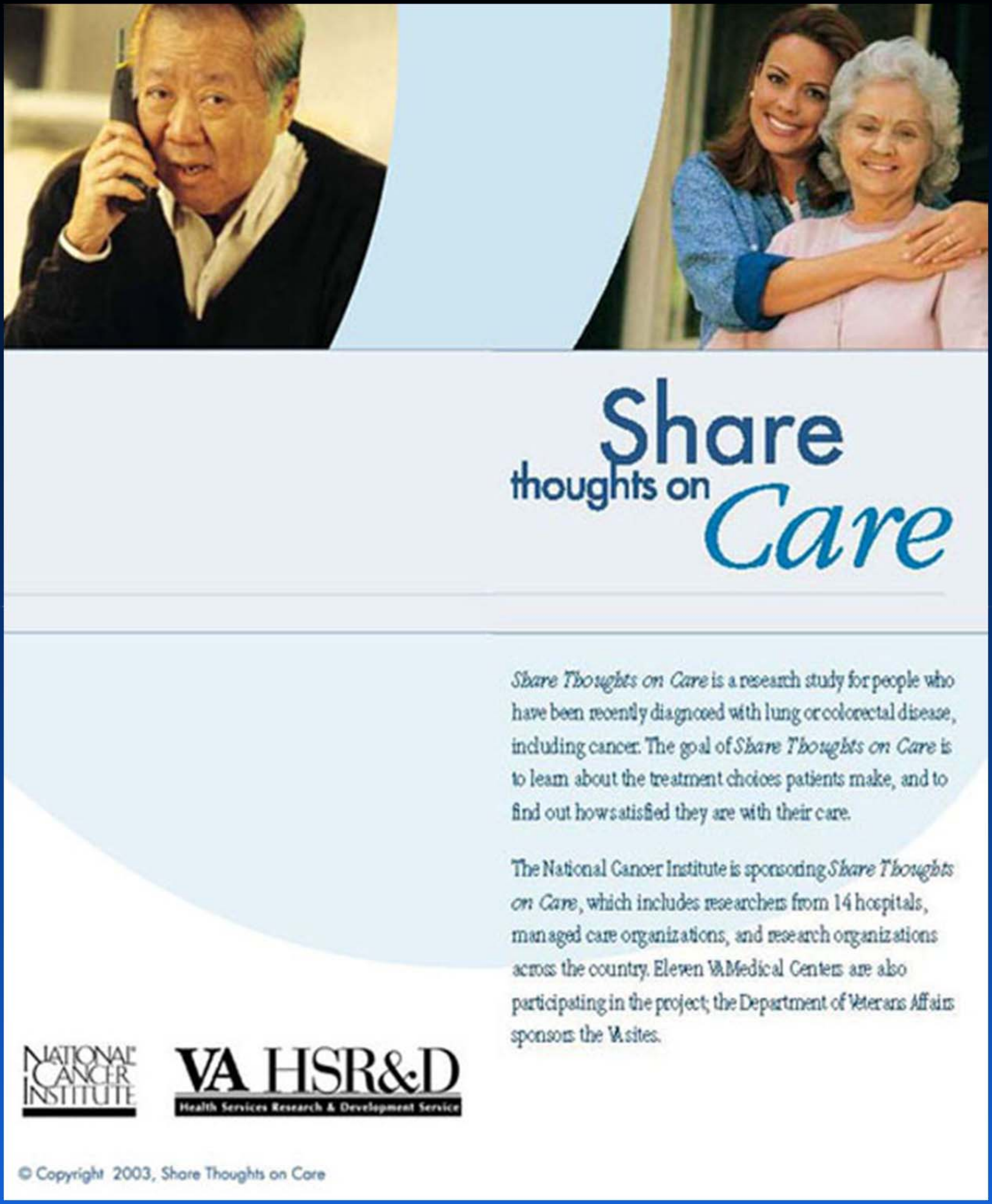
- Patient interviews
- Medical records
- Physician surveys
- Caregiver surveys

Linkage with Medicare claims

Population-based recruitment

Oversampling of minorities

10,189 subjects enrolled; data collection completed 9/07



Share thoughts on Care

Share Thoughts on Care is a research study for people who have been recently diagnosed with lung or colorectal disease, including cancer. The goal of *Share Thoughts on Care* is to learn about the treatment choices patients make, and to find out how satisfied they are with their care.

The National Cancer Institute is sponsoring *Share Thoughts on Care*, which includes researchers from 14 hospitals, managed care organizations, and research organizations across the country. Eleven VA Medical Centers are also participating in the project; the Department of Veterans Affairs sponsors the VA sites.

NATIONAL CANCER INSTITUTE

VA HSR&D
Health Services Research & Development Service

Design Goals

- Representativeness
  - Establish a cohort of newly diagnosed patients with minimal selection bias
  - Obtain sufficiently large sample to provide statistical power to compare important subgroups
- Comprehensiveness
  - Design and field data collection instruments to learn about care from patients, caregivers, physicians and clinical data from medical records

CanCORS Sites

Group Health Cooperative
(Seattle metropolitan area)

Seattle, WA

Kaiser Permanente Northwest
(Portland metropolitan area)

Portland, OR

Northern California
(8 counties in San Jose, San Francisco/Oakland, and Sacramento areas)

Los Angeles County

Kaiser Permanente Hawaii
(4 major islands)

State of Iowa

Minneapolis, MN

Chicago, IL
(Lakeside and Hines)

Henry Ford Health System
(Detroit metropolitan area)

Indianapolis, IN

Harvard Pilgrim Health Care
(Boston metropolitan area)

New York, NY

Baltimore, MD

Durham, NC

North Carolina
22 central/eastern counties

Nashville, TN

Atlanta, GA

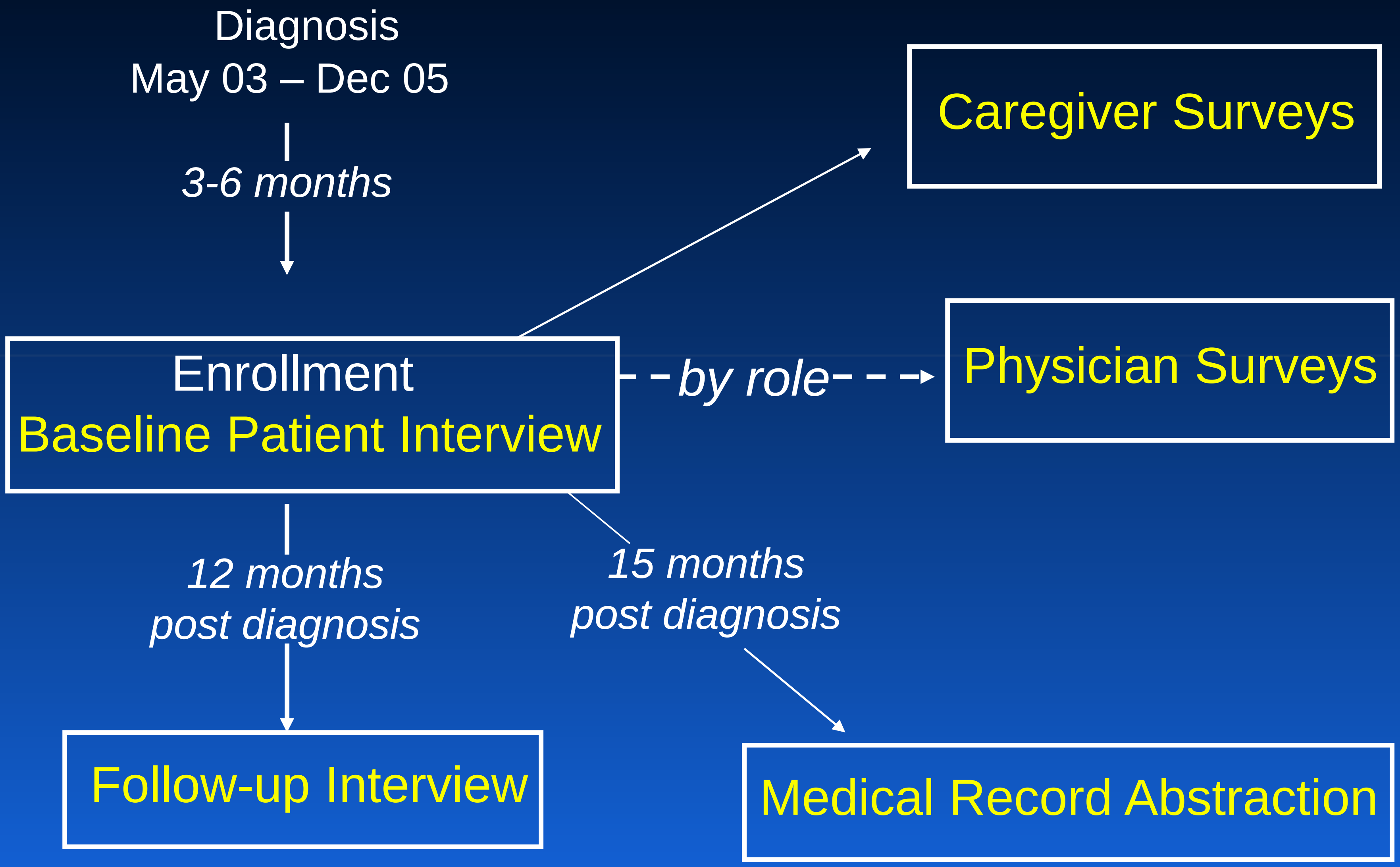
Houston, TX

Biloxi, MS

State of Alabama

- ● Patients from population-based cohorts in geographic areas
- ○ Patients from integrated health-care delivery systems
- ■ Patients at Veterans Health Administration hospitals

Data Collection



Diagnosis
May 03 – Dec 05

3-6 months

Enrollment
Baseline Patient Interview

by role

Caregiver Surveys

Physician Surveys

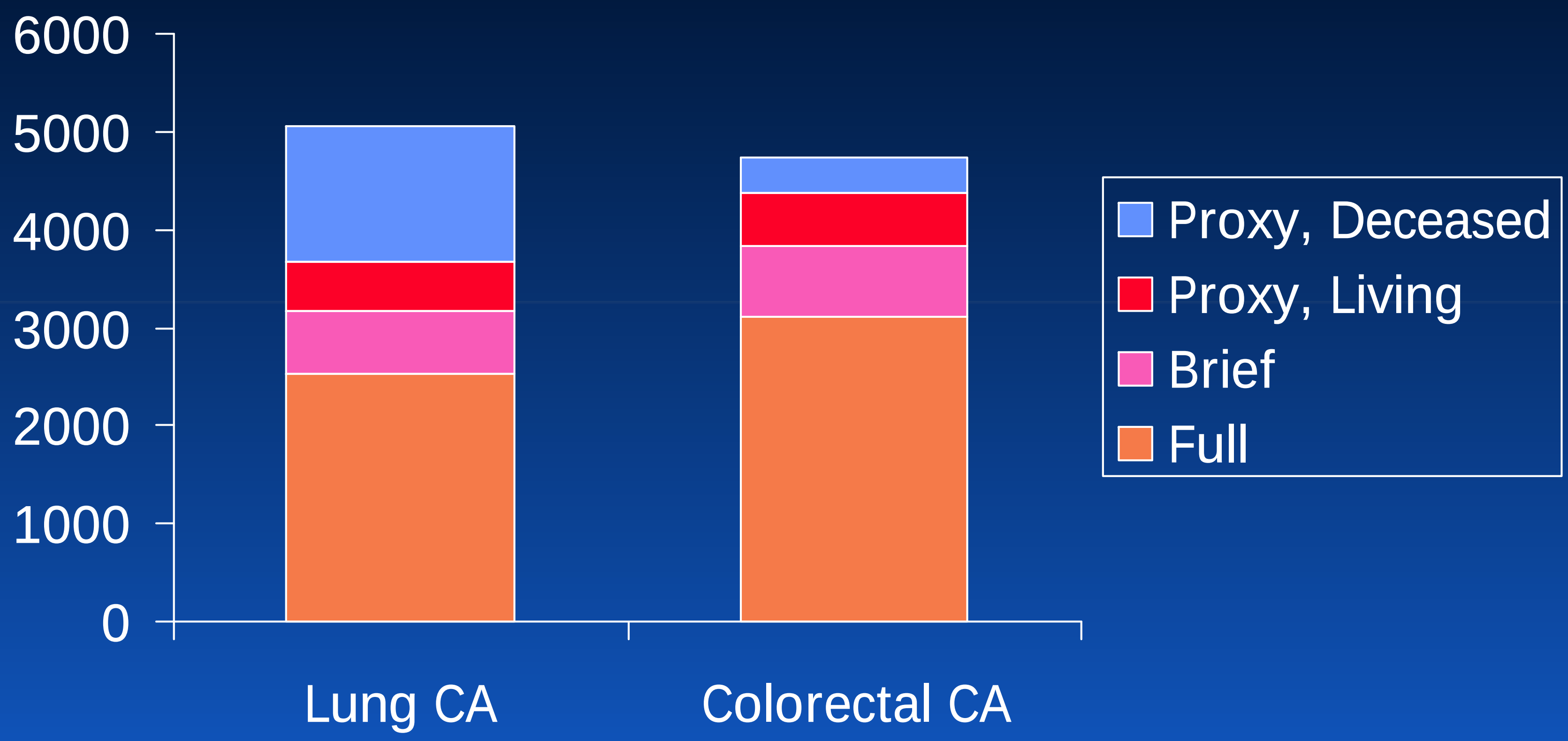
12 months
post diagnosis

Follow-up Interview

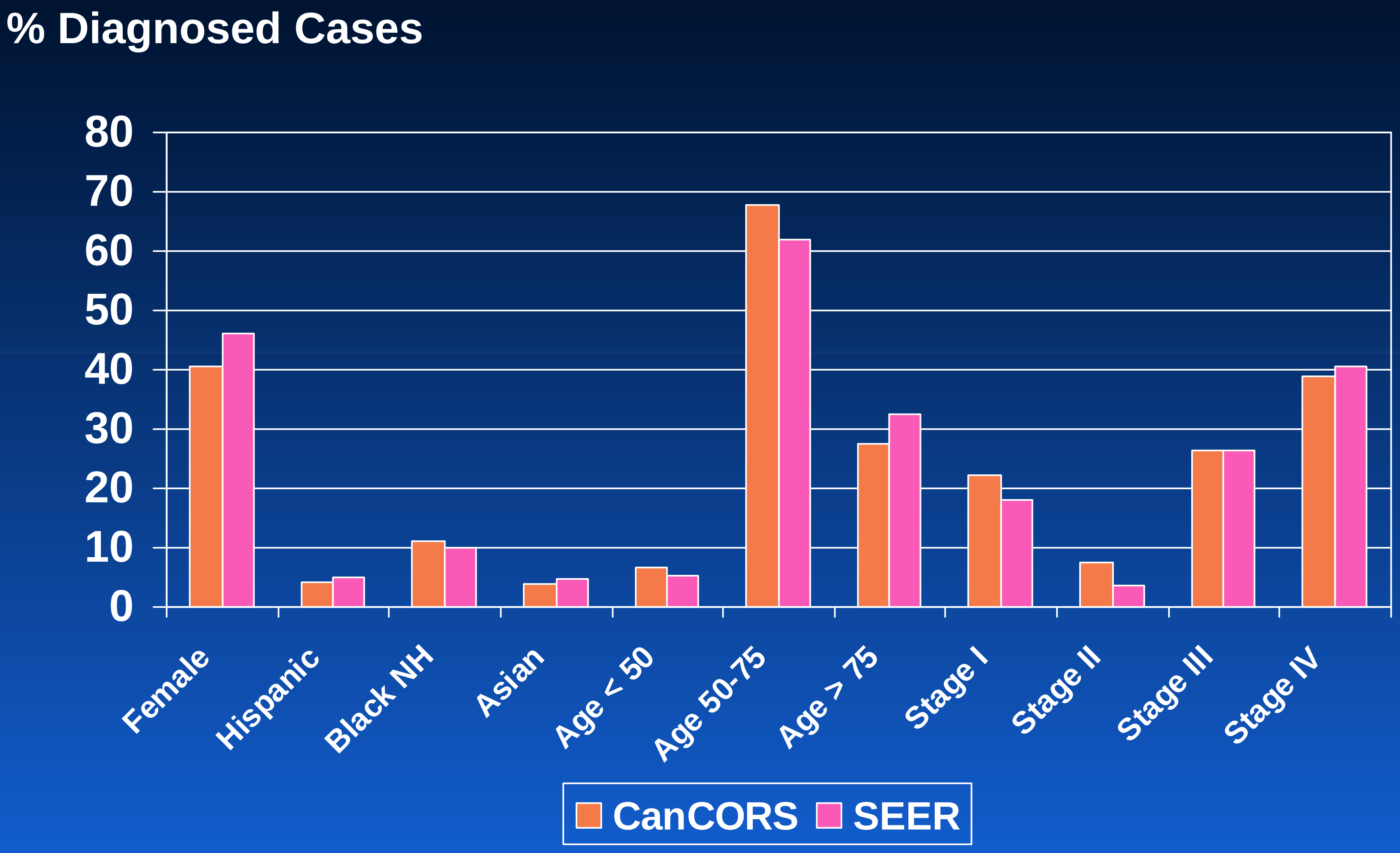
15 months
post diagnosis

Medical Record Abstraction

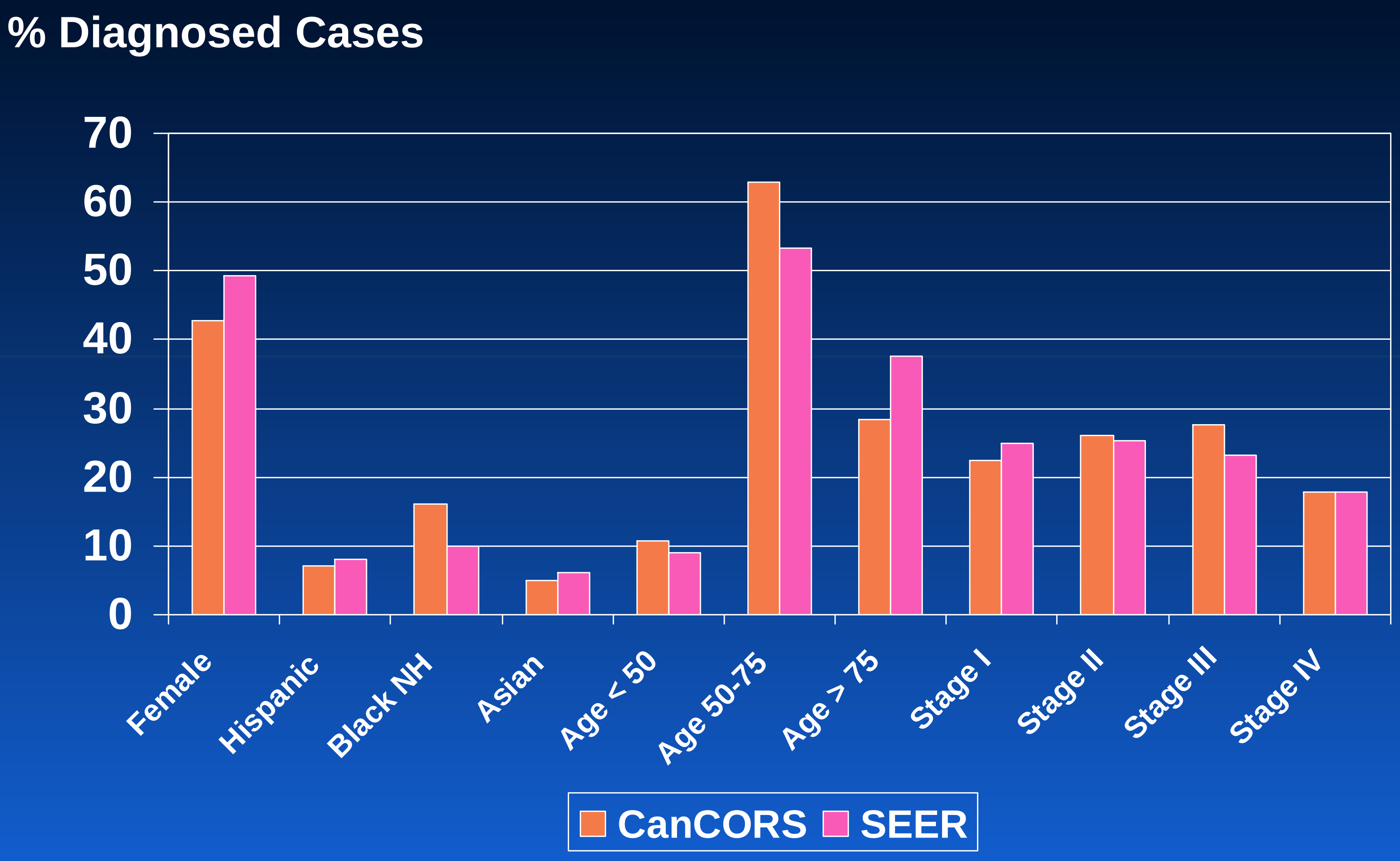
Types of Baseline Interviews



CanCORS vs SEER
Lung Cancer



CanCORS vs SEER
Colorectal Cancer

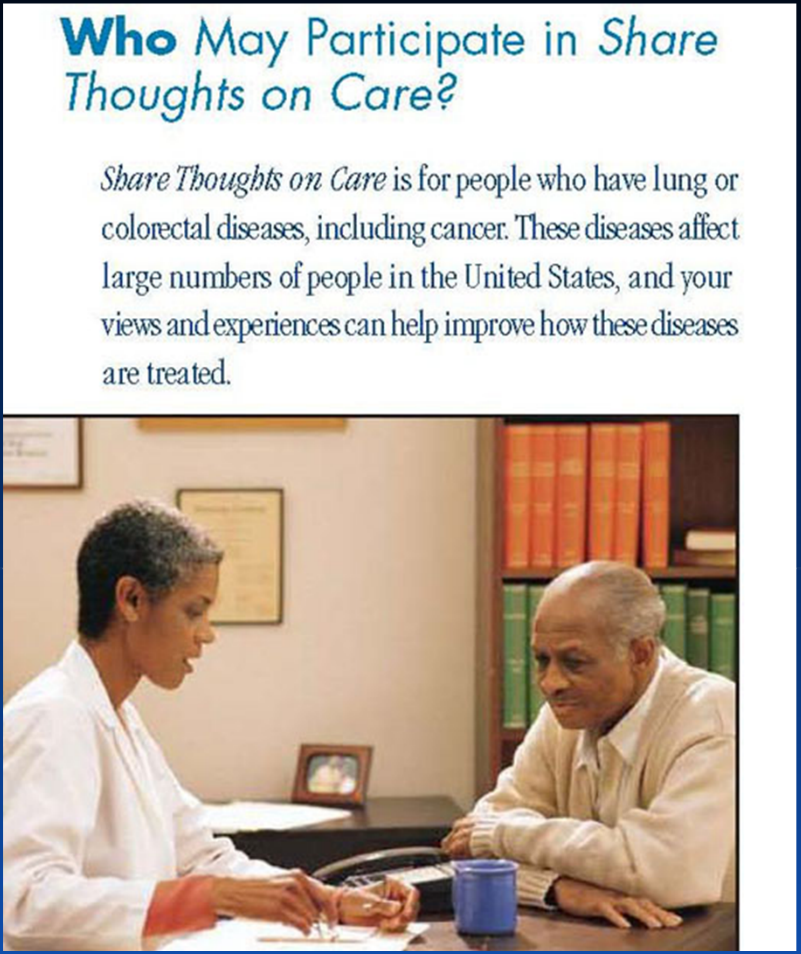


Enrolling the Elderly

CanCORS vs SEER vs Clinical Trial			
	Colorectal Cancer		
	CanCORS	SEER	ECOG
Median Age at Diagnosis	67	72	63
% Age 75-84	23.3%	29.2%	9.5%
% Age 85+	8.2%	12.6%	0.4%

Additional Data Sources

- **Pending data augmentation**
  - **Medicare claims data**
  - **Geo-coding for enrolled patients and treating institutions**
  - **Measures of hospital volume**



Who May Participate in *Share Thoughts on Care?*

Share Thoughts on Care is for people who have lung or colorectal diseases, including cancer. These diseases affect large numbers of people in the United States, and your views and experiences can help improve how these diseases are treated.

What Does Participation Involve?

If you choose to participate in *Share Thoughts on Care*, you will take part in a personal interview about your health and treatment, and how they have affected your quality of life. This interview will take place over the phone with a specially trained *Share Thoughts on Care* research interviewer.

Quality of care by race and age — what has CanCORS revealed?

- **Some racial disparities in evidence-based cancer care no longer evident: *e.g. adjuvant chemotherapy for stage III colon cancer***

- **But other troubling racial disparities persist:**
  - ***<u>Analysis in progress</u>*: Surgery for early-stage lung cancer: *Black:White adjusted odds ratio 0.38***

- **Pervasive age-related disparities persist**
  - **Insights from CanCORS on the “why” question…**

Why are elderly patients much less likely to receive adjuvant chemotherapy?

- **37% of all patients diagnosed with colon cancer are age 75 and older**
- **Limited RCT, NCDB and SEER-Medicare data suggest elderly gain similar relative survival benefit with adjuvant chemo as younger patients**
- **Yet elderly much less likely to receive chemo**

Paid Advertisement

Why is age still a barrier to CRC treatment?

By 2030, 1 in every 5 Americans will be elderly (aged 65 or older).[1] The elderly population has a significantly greater likelihood of developing CRC than do younger individuals. In patients ages 60 to 79, CRC incidence is 50 times higher than it is for those under the age of 40.[2] Yet, the average life expectancy for these patients is 10 or more years,[3] which is often longer than their prognosis with CRC. Therefore, maximizing survival should be a primary goal when treating elderly patients with CRC.[4]

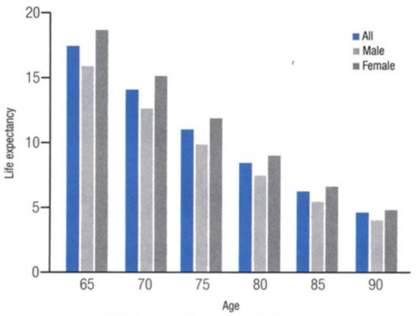
Maximizing survival should be a primary treatment goal for *all* patients with CRC

A growing body of evidence suggests that older patients with adequate performance status should receive the same therapies as younger patients. Data from clinical trials demonstrate that older patients receive similar clinical benefits from chemotherapy as younger patients.[5-8] Toxicities associated with combination chemotherapy are generally comparable between older and younger patients.[5,7] Similar findings have been demonstrated in both the adjuvant and metastatic treatment settings.[5-8]

Elderly patients experience similar clinical benefits and toxicities from chemotherapy treatment as younger patients

Elderly patients should be given the full range of treatment options as deemed appropriate based on their functional status and life expectancy.[9] Factors that are relevant when weighing treatment options include performance status, the presence of comorbid medical conditions, and social factors.[5] Elderly patients should also be offered enrollment in clinical trials whenever possible. Current evidence does not support age-based treatment disparities in CRC treatment.

The average 65-year-old has a life expectancy of >15 years



US life expectancy (years) by age, 2002

Adapted from Arias E, *National Vital Statistics Reports.* 2004;53(Nov 10):1-39.

Chronologic age alone should no longer be a factor limiting the use of aggressive treatment

References: 1. Yancik R. Cancer burden in the aged: an epidemiologic and demographic overview. *Cancer.* 1997;80:1273-1283. **2.** American Cancer Society. *Colorectal Cancer Facts and Figures Special Edition 2005.* Atlanta: American Cancer Society, 2005. **3.** Arias E. United States life tables, 2002. *Natl Vital Stat Rep.* 2004;53:1-39. **4.** Zagonel V, Fratino L, Ferrucci L. Therapeutic choice with regard to life expectancy and cost benefit analysis in cancer diagnosis and treatment. *Crit Rev Oncol Hematol.* 1998:27:121-123. **5.** Goldberg RM, Tabah-Fisch I, Bleiberg H, et al. Pooled analysis of safety and efficacy of oxaliplatin plus fluorouracil/leucovorin administered bimonthly in elderly patients with colorectal cancer. *J Clin Oncol.* 2006;24:4085-4091. **6.** Sargent DJ, Goldberg RM, Jacobson SD, et al. A pooled analysis of adjuvant chemotherapy for resected colon cancer in elderly patients. *New Engl J Med.* 2001;345:1091-1097. **7.** de Gramont A, Figer A, Seymour M, et al. Leucovorin and fluorouracil with or without oxaliplatin as first-line treatment in advanced colorectal cancer. *J Clin Oncol.* 2000;18:2938-2947. **8.** Jessup JM, Stewart A, Greene FL, Minsky BD. Adjuvant chemotherapy for stage III colon cancer: implications of race/ethnicity, age, and differentiation. *JAMA.* 2005;294:2703-2711. **9.** Lichtman SM. Management of advanced colorectal cancer in older patients. *Oncology.* 2005;19:597-602.

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Are We Undertreating Older Patients With Colorectal Cancer, and Why?

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J Clin Oncol, September 1, 2007

Adjuvant chemo for stage III colon cancer by age

Age	% Chemo	Unadjusted OR	Adjusted OR*
<55	91%	1.00	1.00
55-64	82%	0.43	0.43
65-74	82%	0.43	0.55
≥75	48%	0.09	0.11

*Adjusted for race, sex, income, education, marital status, region, and severity of comorbidity from medical records

What else could explain sharp drop in chemo by age?

Access to oncologists?

Among patients who did not receive chemo, most saw an oncologist in all age groups:

- 80% of age <75 vs. 84% of age ≥75

Patients' preferences or oncologists' decisions?

Among patients age ≥75 who did not receive chemo:

- 33% of patients decided against it
- 22% made joint decision with oncologist
- 45% had oncologist recommend against it

Physician recommendations for chemo

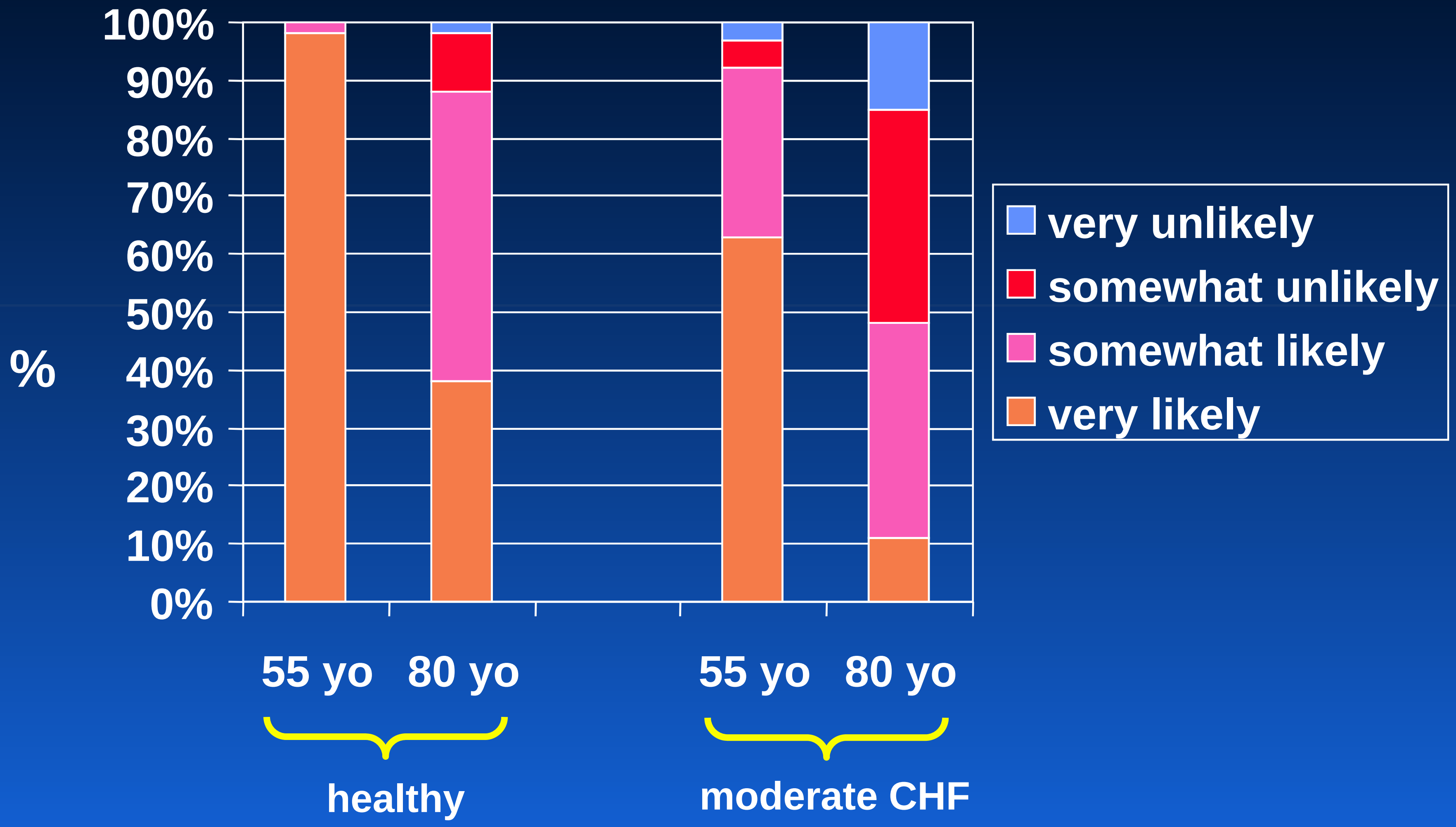
How likely are you to recommend *adjuvant chemotherapy* (i.e., chemotherapy that is provided in addition to surgery) after curative resection for stage III colon cancer?

An 80-year old man with stage III colon cancer who has…

(1) no other medical problems
(2) moderate congestive heart failure with dyspnea walking 2 blocks (EF 35-40%)
(3) severe congestive heart failure with dyspnea on dressing (EF <20%)

1=very unlikely	**3=somewhat likely**
2=somewhat unlikely	**4=very likely**

Physicians' likelihood of recommending adjuvant chemo



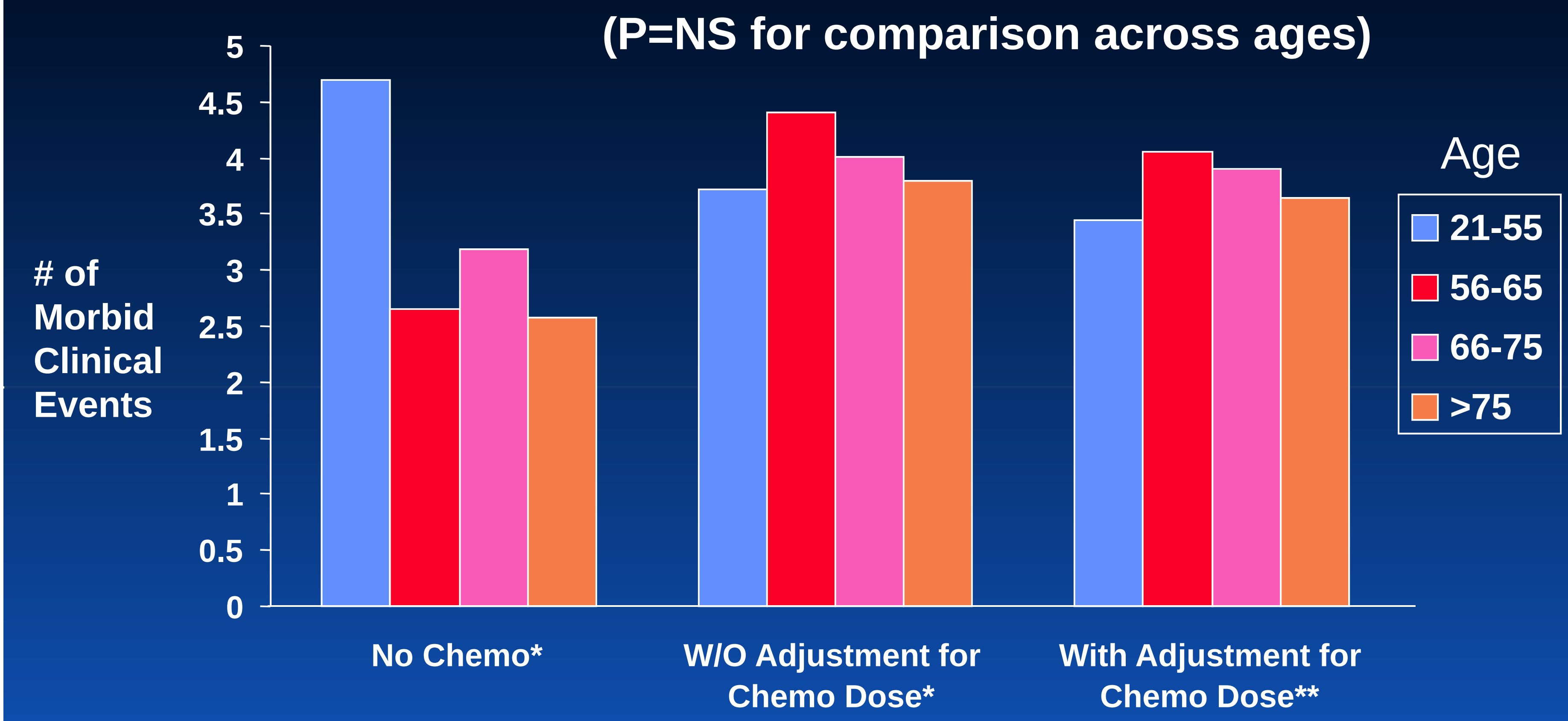
Key provider survey findings

Among surgeons and medical oncologists:

- **Younger doctors, those involved in teaching, and working at a cancer center more likely to recommend chemo…** ***but 38% would not recommend chemo to an 80 year old patient with moderate CHF***

- **Substantial variation in treatment decisions, especially for older and sicker patients**
  - **Physician factors explain little of this variation**

Clinical outcomes of stage 3 colon cancer over 15 months post surgery



*Adjusted for age, sex, marital status, race/ethnicity, income, comorbidity, health status, perioperative complications, and chemo use

**Also adjusted for 1st 5FU dose, chemo dose reduction, and chemo duration

Clinical & policy implications

Physicians follow guidelines to treat patients age <75, but differ widely about treating older patients:

- **<u>Too conservative treatment</u> OR <u>appropriate selection</u>?**

<u>Enhanced information and decision support regarding benefits & risks</u> of adjuvant chemotherapy may help older patients and their doctors make better clinical decisions

<u>Simple RCTs with inclusive eligibility criteria in older patients needed</u> to tailor adjuvant treatment for key group: *~40% of all colon cancer patients*

Dissemination of bevacizumab into routine practice

Background

- Bevacizumab (Avastin) is an anti-VEGF monoclonal antibody initially approved for first-line use in metastatic colorectal cancer (2/2004)
- The addition of bevacizumab to 5-FU/ leucovorin/irinotecan prolongs median survival in met CRC by 5 months
- Drug cost is approx $5,000 per month
- Registry data cannot be used to track dissemination
  - Cannot identify patients with metastatic recurrence

Study design

- Population
  - Patients initiating 1st line therapy for metastatic colorectal cancer
- Analysis
  - Estimate the proportion of treated patients receiving bevacizumab
  - Assess the association of sociodemographic, clinical, and health system factors with receipt of bevacizumab

Results

- Overall, 22% of patients received first-line bevacizumab in the year following drug approval
- Significant Effects

Site of care	
Geographic sites	28%
CRN	13%
Gender	
Men	17%
Women	35%
Age	
<55	33%
55-64	20%
64-75	18%
75+	14%

No effect of race, education, or comorbidity

Conclusions

- The proportion of patients in the community receiving this effective new agent in the first year after approval was surprisingly low
- It’s unclear why women were substantially more likely to receive bevacizumab
- Whether the lower rate of use in the CRN represents a long-term barrier to care (i.e., economic considerations) or just slower uptake can only be determined by ongoing follow up

Consequences of a cancer diagnosis – 2 examples of what we're learning from CanCORS:

1) Employment outcomes

2) Caregiver burden

Employment

Employment

- Cancer disrupts patients’ lives in many ways
- One sphere is employment:
  - Some have to quit or curtail work in order to undergo cancer treatment
  - Others involuntarily lose their employment
- Employment change may also lead to change in insurance status
- Limited literature largely focused on breast cancer

Study design

- Population
  - stage I-III lung and CRC
  - employed at diagnosis
  - no recurrence
- Analysis
  - estimation of rates of cancer-attributable departure from the labor force
  - logistic regression to identify sociodemographic and disease factors associated with labor force departure

Results

- **Long-term cancer attributable labor force departures occur in ~16%**

- **Factors significantly associated with *higher* rates of labor force departure:**
  - **Lung cancer (vs. CRC), stage III disease (vs. stage I-II)**
  - **Increased age**
  - **African-American/Hispanic race (vs. White/Asian)**
  - **Lower educational level, lower income**

Results

- **Statistically significant interactions also found:**
  - **Rate of departure much more sensitive to income level among African-Americans/Hispanics than among Whites/Asians**
  - **Married men *less* likely than unmarried to stop working; married women *more* likely than unmarried to stop working**

45 year old white man with Stage I CRC.

Married, college degree, income = $70,000/yr, private insurance, no chemotherapy.

Predicted probability of workforce departure = 6%

Stage I lung cancer

Predicted probability of workforce departure = 17%

Stage IIIa lung cancer

Predicted probability of workforce departure = 42%

Income = $30,000/yr, high school ed

Predicted probability of workforce departure = 61%

African-American

Predicted probability of workforce departure = 73%

The job of caring for ailing loved ones
is often daunting.
Now, many are asking...

How Can We Help Our Nation's Caregivers?

By Gail Sheehy

"IT'S CANCER."

Those words from my husband's oncologist plunged us into the whirlpool of fear, denial and confusion that suddenly drafts many in middle life into the wars against aging and physical decline. Within the first few days of sharing the news with stunned family members, Googling disease sites, tracking down doctors, comparing hospitals and growing dizzy from conflicting opinions, it began to dawn on me that my life had changed radically. I had a new role: "family caregiver." It's a job nobody applies for. You don't expect it. You won't be prepared.

When I assumed that role, I became part of an unpaid army of 44.5 million Americans who take care of adults. (An additional 6 million provide care

MY TRANSITION TO CAREGIVER began, as it does for many, when it came time for my husband to leave the hospital. A discharge planner may hand you a list of facilities that you have only a day or two to investigate. You learn that Medicare will decree whether or not a patient qualifies for "acute rehab," the type necessary to restore functionality.

A doctor tipped me off that the patient's fate often is determined by the number of steps he or she can take. Less than 12 steps, and the patient is consigned to "long-term care" in a nursing home, where little attention is paid to the possibility of ever be-

to build strength. We had gotten as far as six steps.

"Morning, sweetheart. It's showtime!"

He smiled.

"What do I have to do?"

"Twenty steps. Practice."

Later, the physical therapists were left open-mouthed as my husband pushed the walker out the door. Thirty steps! It was the difference between being warehoused in a nursing home and hope.

LIKE MOST NEW CAREGIVERS, I THOUGHT THE CRISIS WOULD RESOLVE ITSELF in six months or a year, and then we would

An unpaid army of 44.5 million is caring for our ailing adults.

Parade Magazine, September 9, 2007

Cancer caregiving: A new and growing challenge

- **Cancer care has shifted from the hospital to the outpatient and home setting**
- **This shift has translated into increased family involvement in day-to-day care**
- **We have limited information about cancer caregivers and the care they provide**
- **Most existing studies are limited to small, non-representative samples**

Objective caregiver burden at ~ 6 months post dx

	High Need Patient* (N=475) Mean (sd)	Other (N=272) Mean (sd)
Caregiving hrs/week	26 (29.4)	15 (23.22)
Care tasks/week	8.75 (5.36)	6.32 (5.35)
Clinical tasks/week	3.41 (2.13)	2.40 (2.17)

*Metastatic disease OR severe comorbidity OR cancer treatment within 2 weeks prior to survey

Specific clinical care tasks

In past two weeks, have you …	High Need Pt	Not High Need Pt
…administered medicine?	38%	22%
…made a decision about whether your Care Recipient needed medication?	36%	18%
…kept track of or watched for side effects from treatment?	73%	56%
…assisted your Care Recipient manage symptoms such as nausea/vomiting, fatigue or pain?	52%	35%
...change your Care Recipient’s bandages?	21%	13%
…give nebulizer treatment or perform chest percussions?	10%	5%
…decided whether to call a doctor?	36%	23%

Caregiver training

Did any provider give you training in…	Not needed	Yes	No
…changing bandages?	44%	18%	36%
…administering meds?	32%	22%	46%
…managing nausea?	36%	21%	43%
…managing pain?	29%	28%	42%
…managing fatigue?	24%	29%	47%
…managing other side effects or symptoms?	24%	27%	49%
…any other treatments?	29%	9%	62%

Caregiver Burden

- **Over half of cancer caregivers surveyed must balance work and caregiving tasks; and 1 in 6…**
  - **care for the cancer patient <u>and</u>**
  - **work for pay <u>and</u>**
  - **care for one or more children or other family members**
- **25% report medium to high levels of role conflict and strain**
- **Many caregivers perform "clinical" tasks but at least 25% of these did not receive training**
- **Thus, many cancer patients are receiving clinical care from unpaid, untrained caregivers**

Next steps

Ongoing analyses

Analyses for >50 manuscripts ongoing, including:

- **Prevalence of under-treated pain and depression**
- **Barriers to clinical trial participation**
- **Access to hospice services**
- **Impact of patient and health system factors on patient ratings of care**
- **Assessment of registry data accuracy**

Overarching conclusions

While these analyses are still being completed, early results suggest:

- **Physician recommendations drive patterns of care**
- **Disparities in care therefore largely attributable to**
    - **MD uncertainty and/or biases**
- **Cancer treatment in the community is surprisingly well tolerated medically**
- **But non-medical effects of cancer & treatment on patients and families have been underestimated**

Implications for research & care

Optimizing treatment of older patients:

- **Assess effectiveness of alternative strategies by following this cohort for survival**
- **Conduct large simple RCTs to define optimal care**
- **Develop decision support tools for patients & MDs**

Implications for research & care

Ensuring access to new therapeutics:

- **Fully characterize the dissemination curve**
- **Identify patient, physician, and system barriers**

Improving outcomes:

- **Examine long-term employment effects**
- **Increase support for caregivers**

CanCORS Primary Data Collection and Research Sites

- University of Alabama, Birmingham
  - Mona Fouad, Catarina Kiefe
- Dana-Farber, Cancer Research Network
  - Jane Weeks
- RAND/UCLA
  - Katherine Kahn, Patricia Ganz
- Harvard Medical School, N. Cal. Cancer Center
  - John Ayanian, Dee West
- University of Iowa
  - Robert Wallace, Elizabeth Chrischilles
- UNC, Chapel Hill
  - Robert Sandler
- Duke University VA
  - Dawn Provenzale, Michelle Van Ryn