Risk-Based Health Care of Pediatric Cancer Survivors

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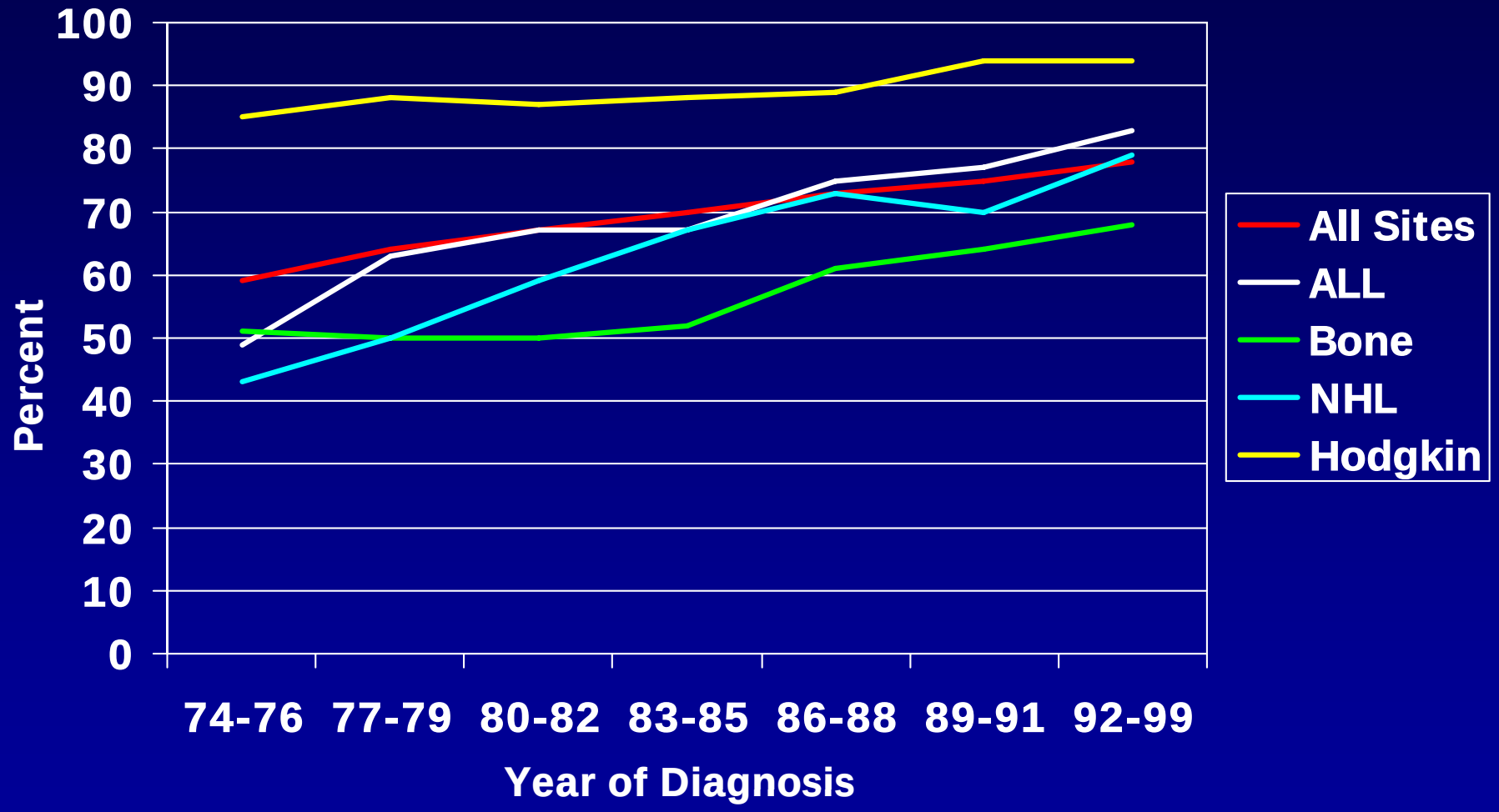
Supported by R01 CA 100474
R21 CA 106972
U24 CA 55727

Outline

- Long-term health risks
- Model for risk-based health care
- Current status of survivorship-focused health care
- Future directions

5-YR Survival Rates, Ages 0-19



Ries, et al., SEER Cancer Statistics, 1975-2000

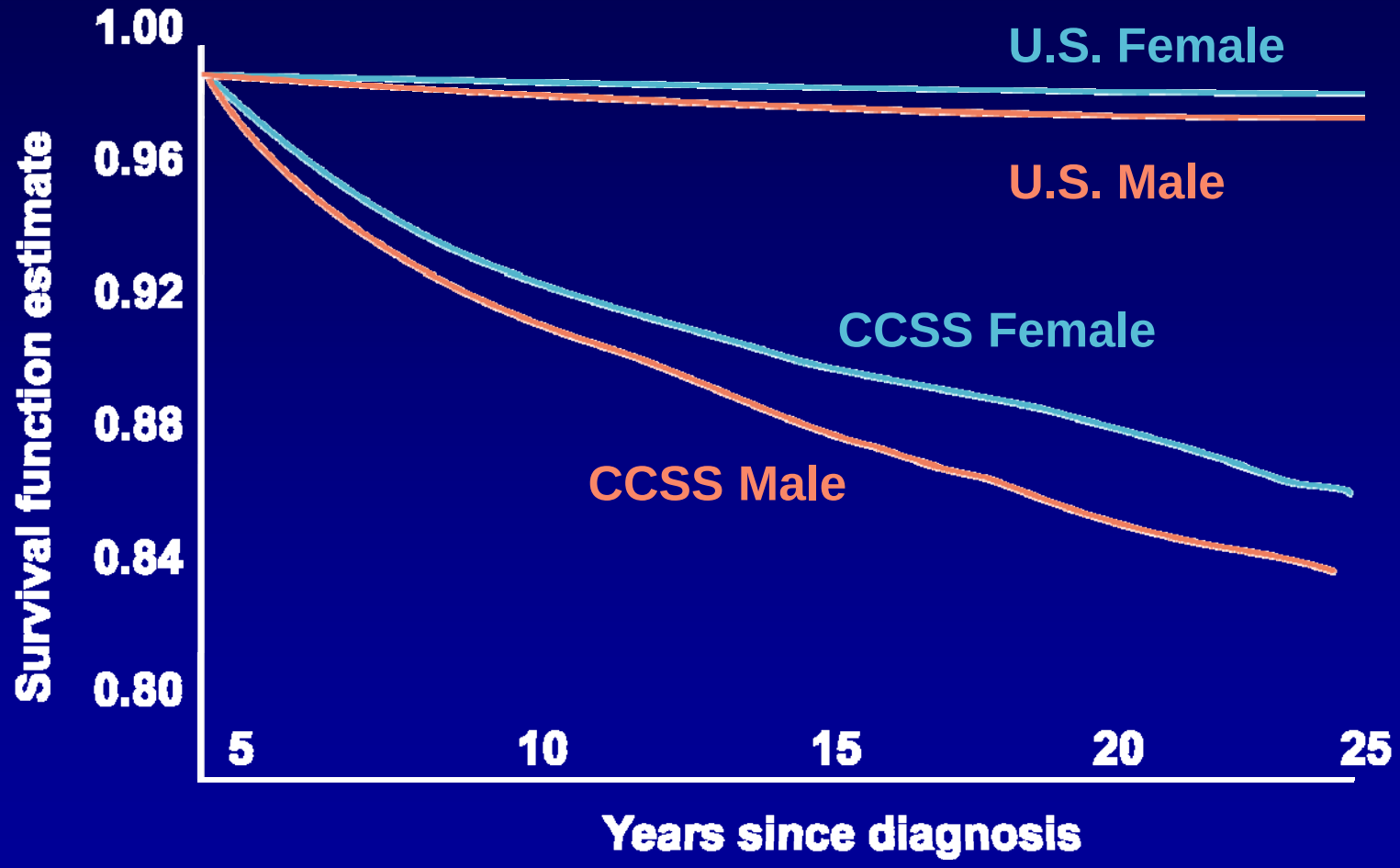
Pediatric Cancer Survivors

- All sites > 78% 5-yr survival
- 270,000 childhood cancer survivors in the United States
- 1:640 young adults in the US is a pediatric cancer survivor

Long-Term Health Risks

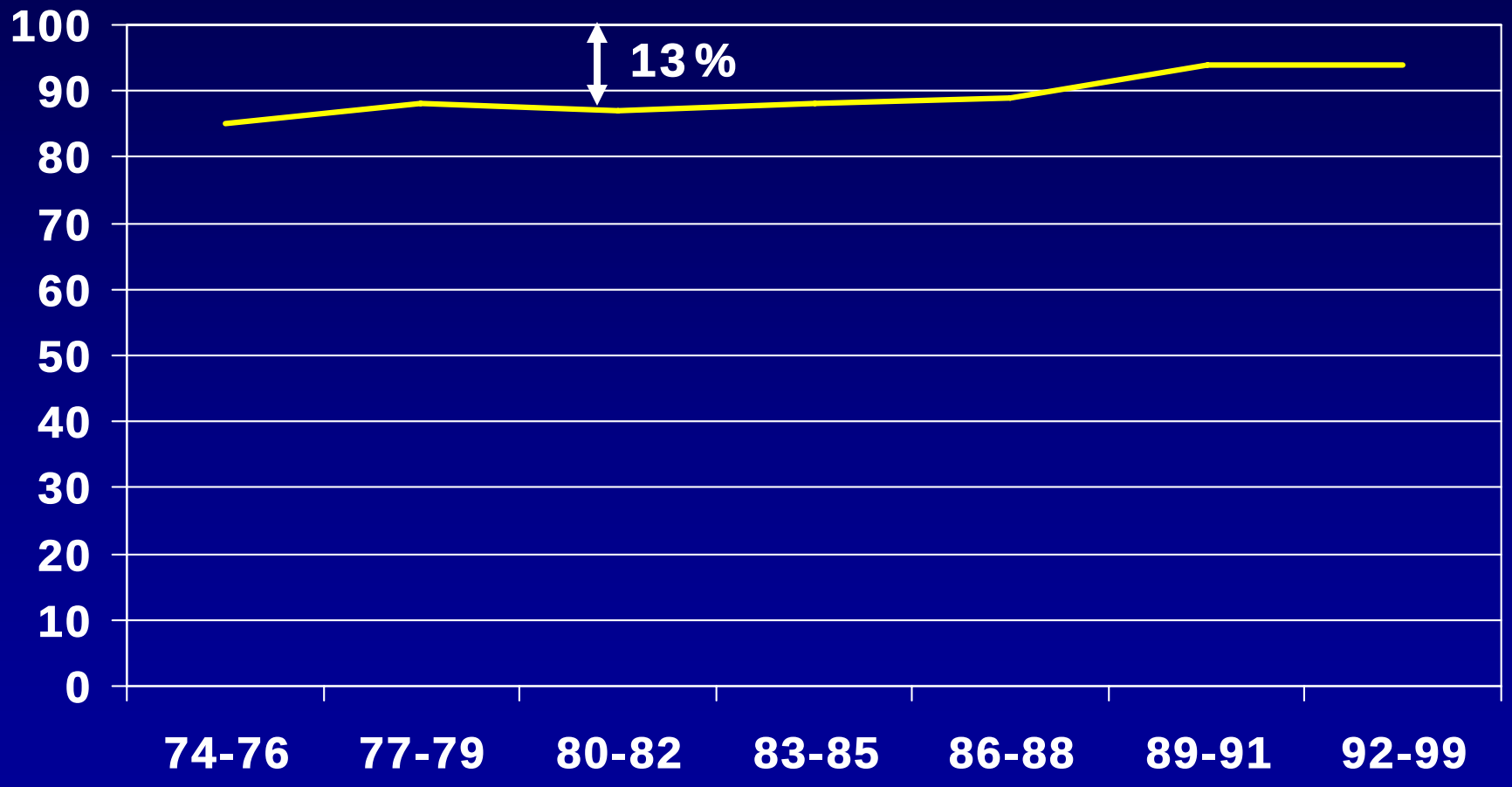
- Premature mortality
- Morbidity
- Diminished health status

Sex-Specific Mortality Rates of Childhood Cancer Survivors vs. U.S. Population



Mertens A et al, J Clin Oncol 19:3163, 2001

5-YR Survival Rates for Hodgkin Lymphoma, Ages 0-19



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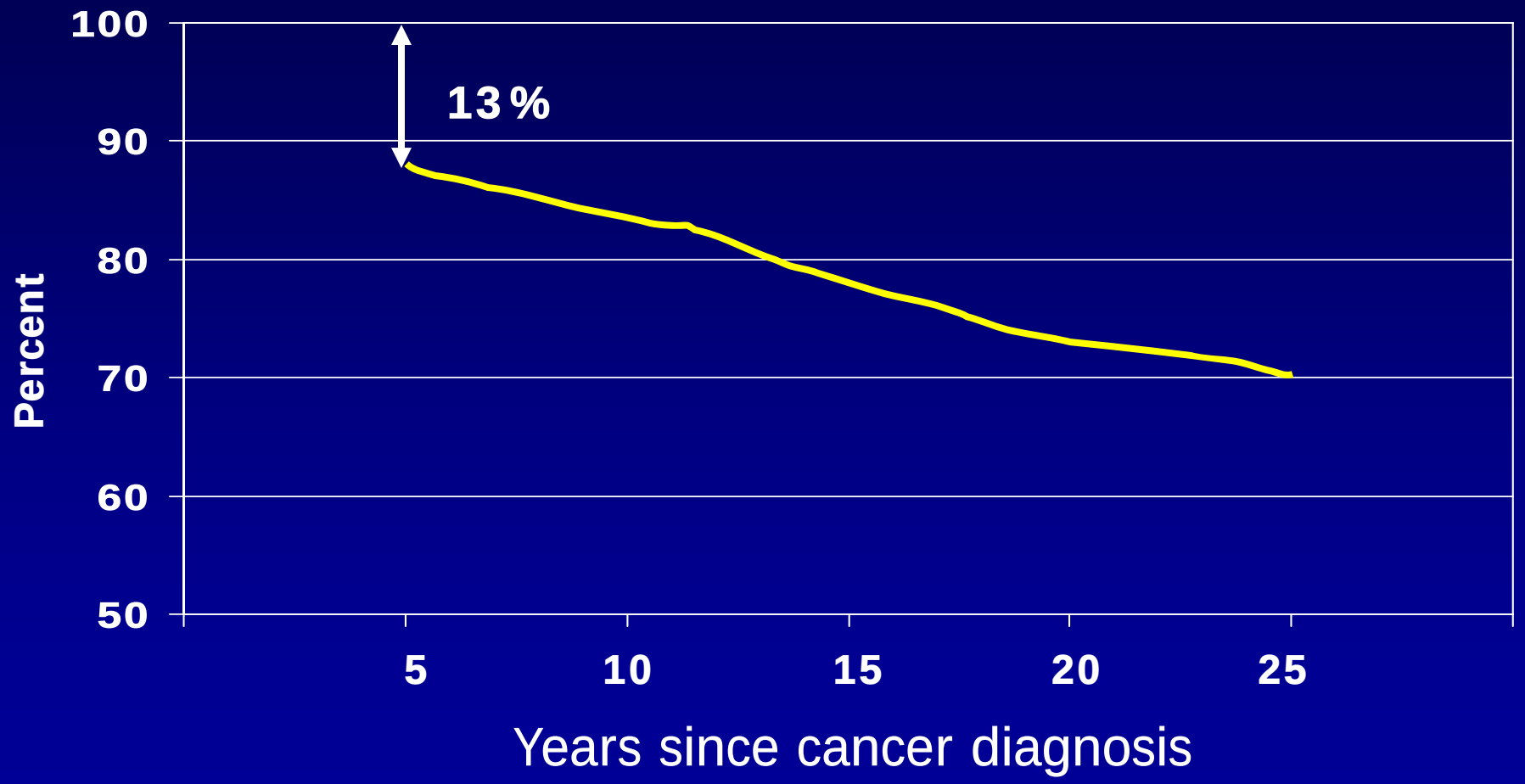
All-Cause Mortality, Hodgkin Lymphoma Diagnosis: 1970-1986



Mertens A, et al. J Clin Oncol 2001

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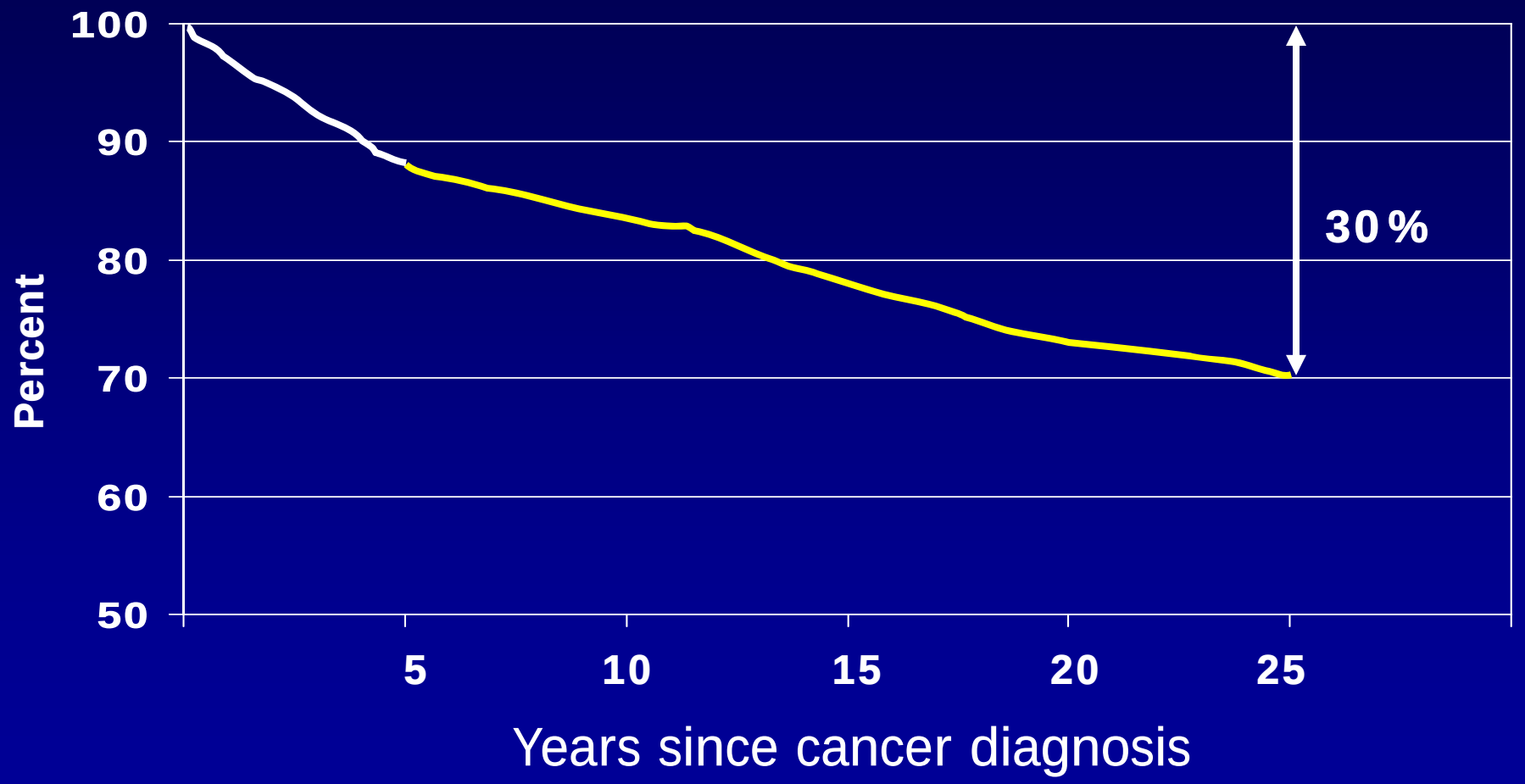

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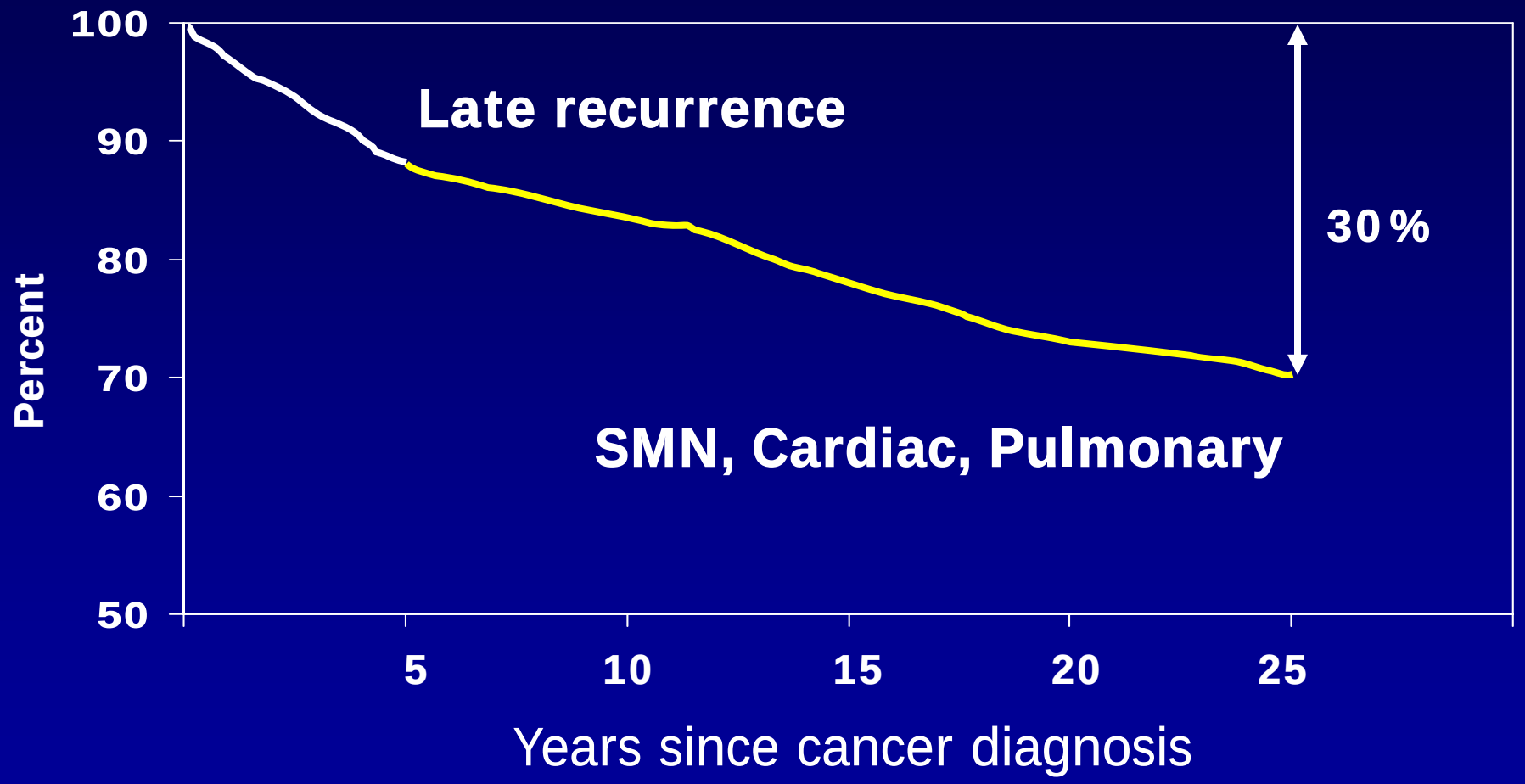


Mertens A, et al. J Clin Oncol 2001

Morbidity

- 10,397 survivors, diagnosed 1970-1986
- 3,034 siblings

Grading of conditions: CTCAE v3.0

Common Terminology Criteria for Adverse Events

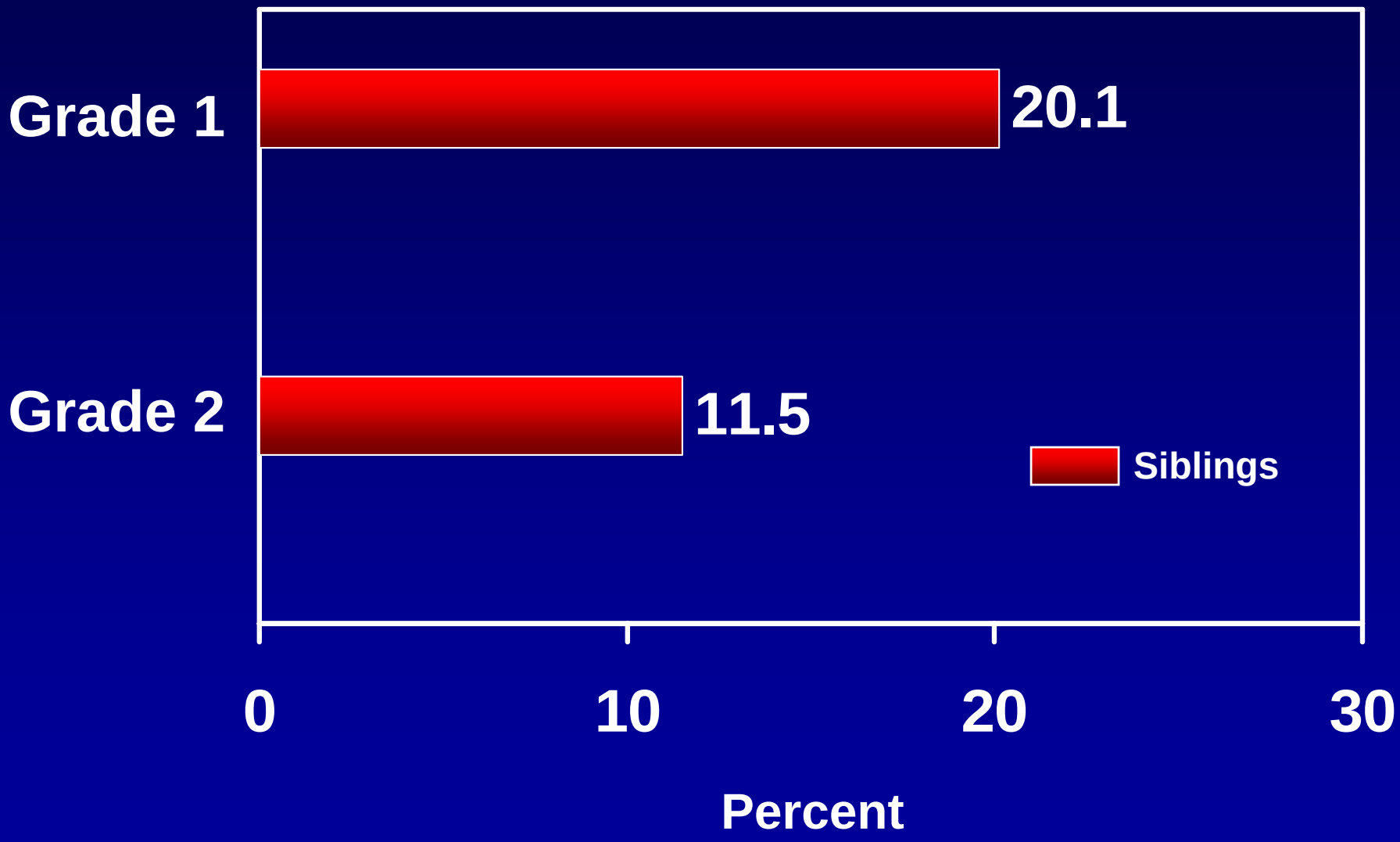
- Grade 1 Mild
- Grade 2 Moderate
- Grade 3 Severe
- Grade 4 Life-threatening or disabling
- Grade 5 Death

Oeffinger KC, et al. N Engl J Med 2006

Demographics

Characteristics	Survivors (N=10,397)	Siblings (N=3,034)
Gender: female	46%	53%
Race		
Non-Hispanic white	84%	92%
Minorities	16%	8%
Age at interview	27	29
Mean (range), years	(18 - 48)	(18 - 56)
Interval from cancer dx	18	
Mean (range), years	(6 - 31)	NA

Percent with a chronic health condition:



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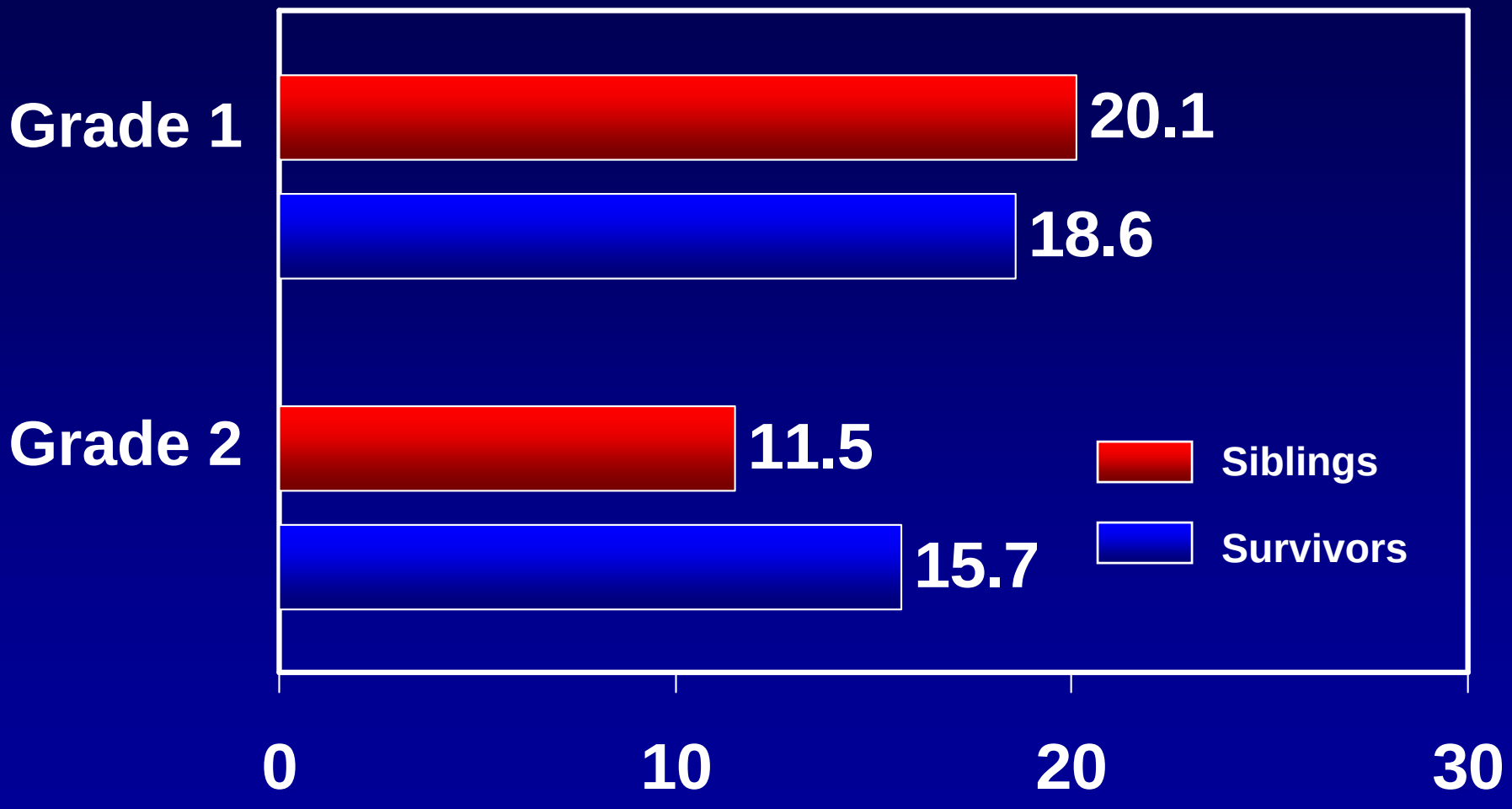
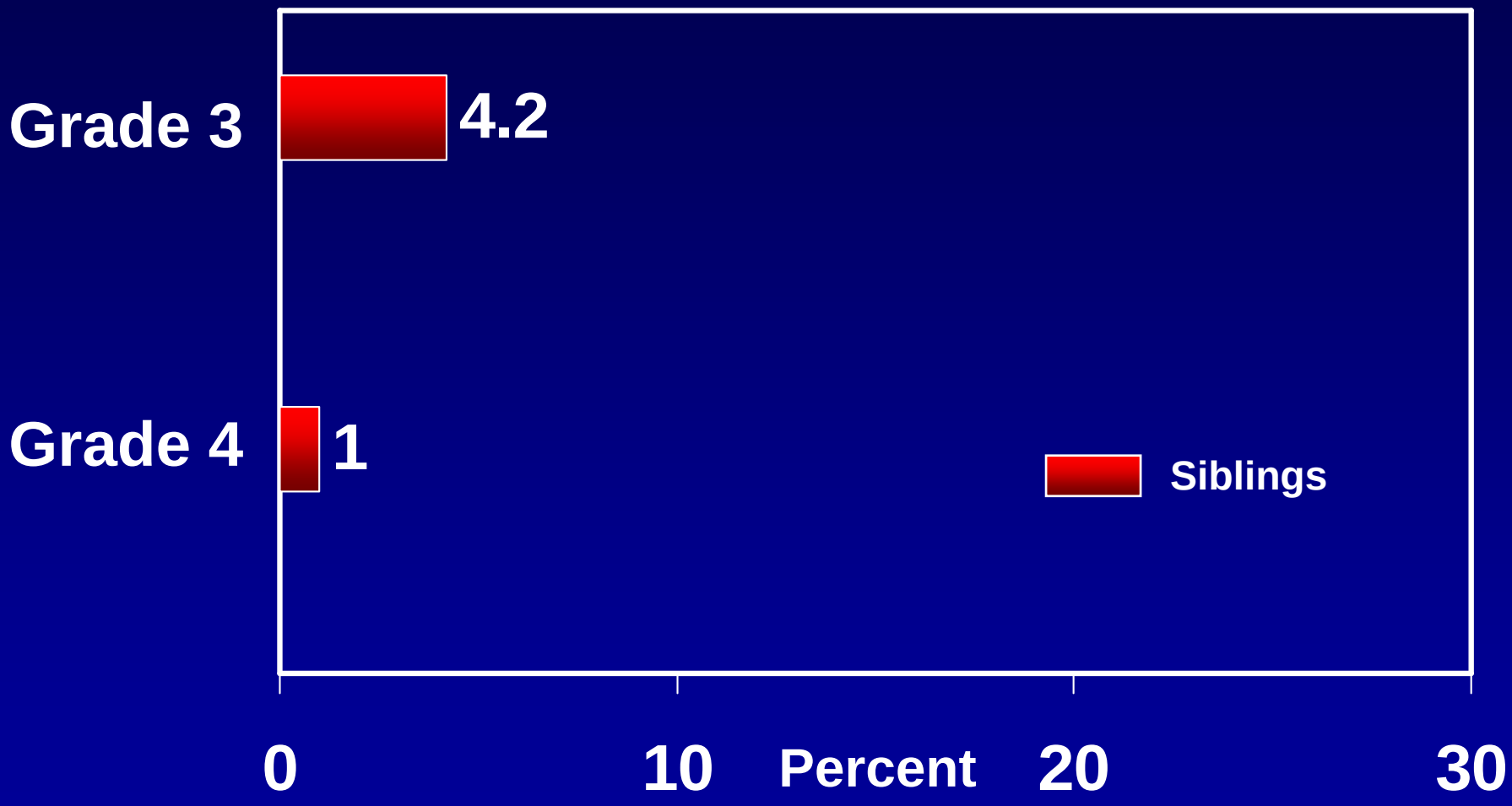


- Similar percentage with mild or moderate conditions.

Percent with a chronic health condition:



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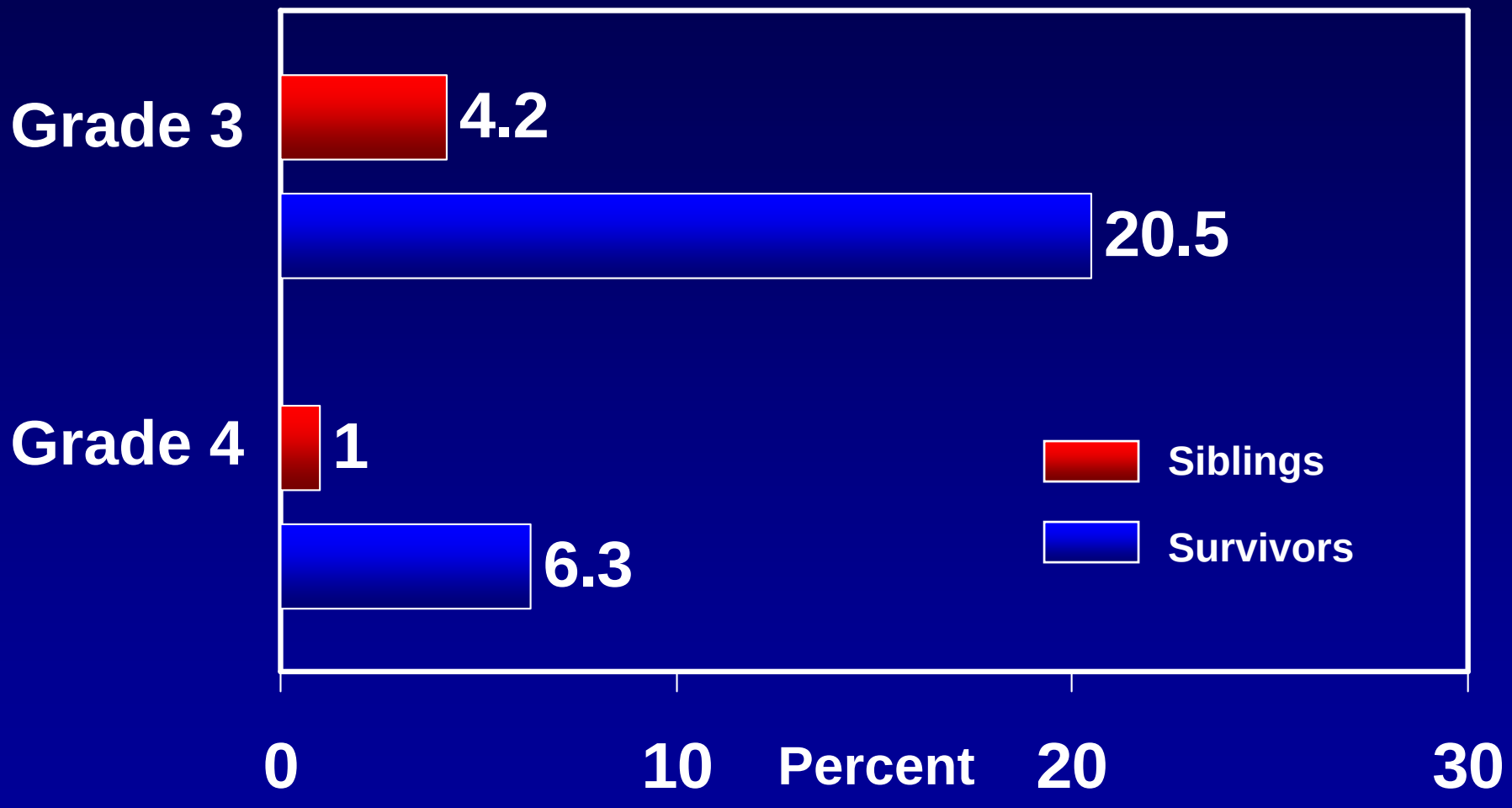
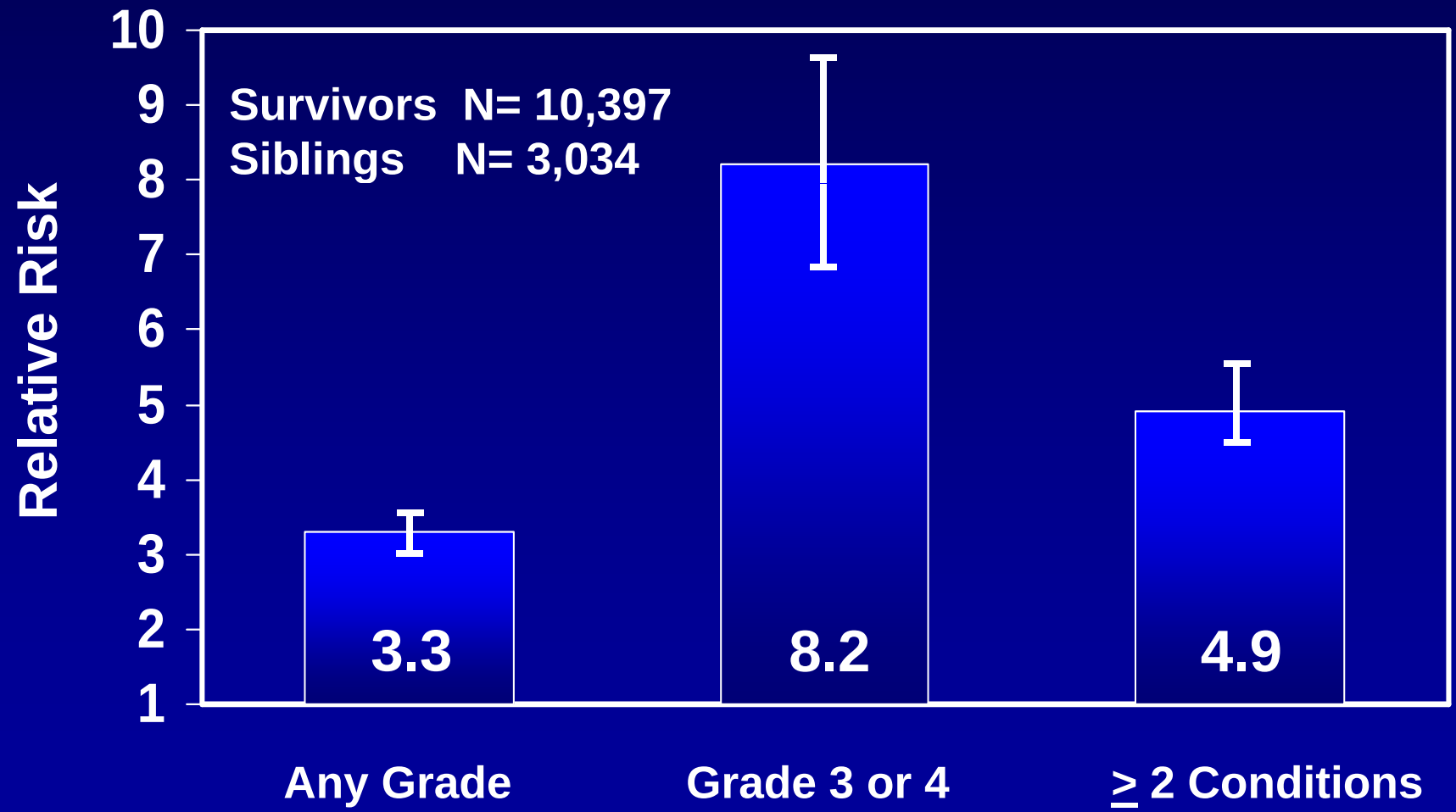


- Significant difference in severe or life-threatening conditions.

Relative risk with 95% CI of chronic health conditions in survivors compared with siblings

Adjusted for age, sex, and race



Relative risk of chronic health conditions in survivors compared with siblings

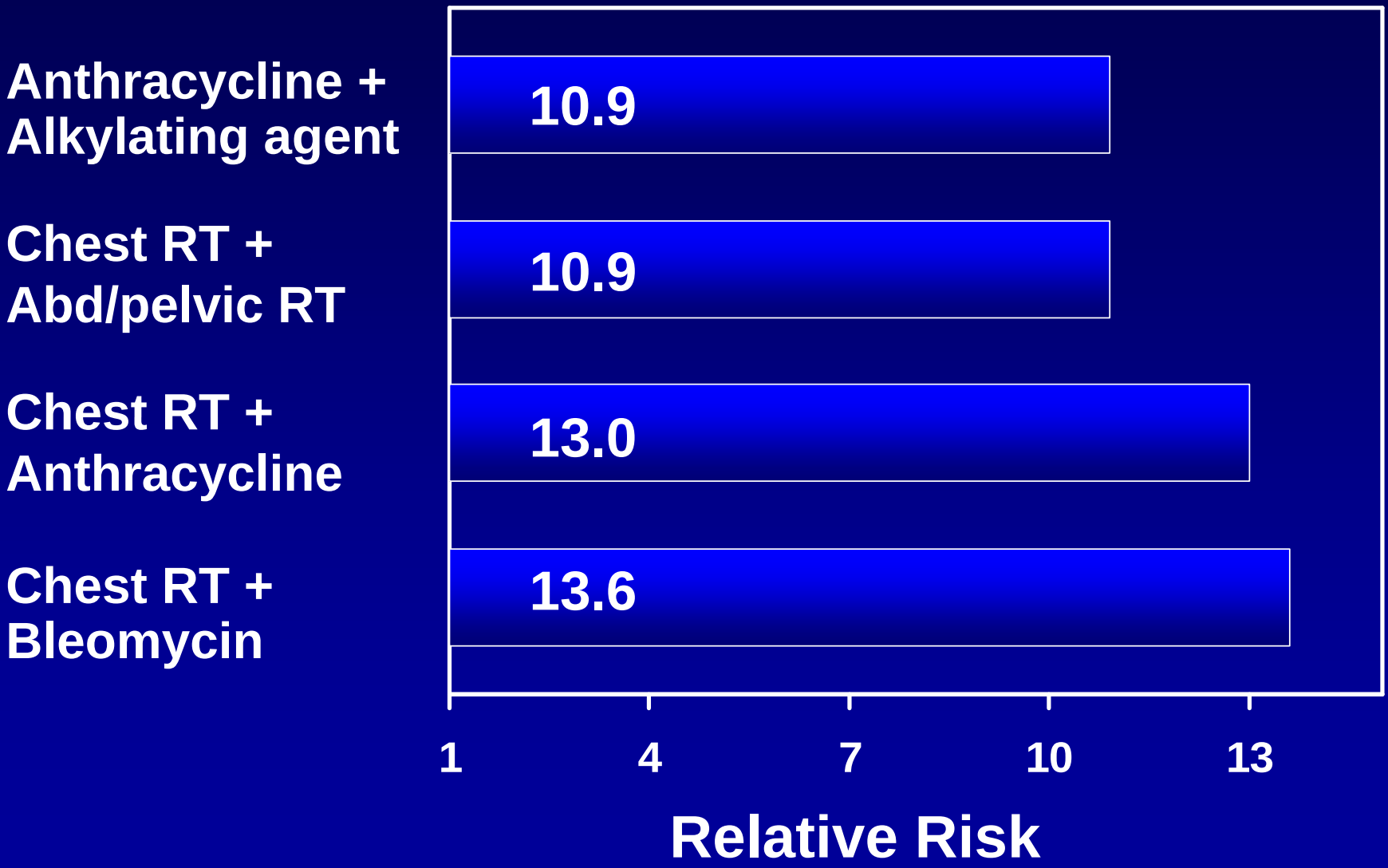
Adjusted for age, sex, and race

Primary Cancer	Any Grade	Grade 3 or 4	≥ 2 Conditions
Bone tumor	10.3	38.9	10.7
CNS tumor	7.1	12.6	12.4
Hodgkin's	4.6	10.2	8.7
Sarcoma	3.5	8.9	5.2
NHL	3.2	6.8	4.3
Neuroblastoma	2.0	4.7	2.5
Leukemia	2.2	4.1	2.8
Wilms' tumor	1.9	4.1	2.5

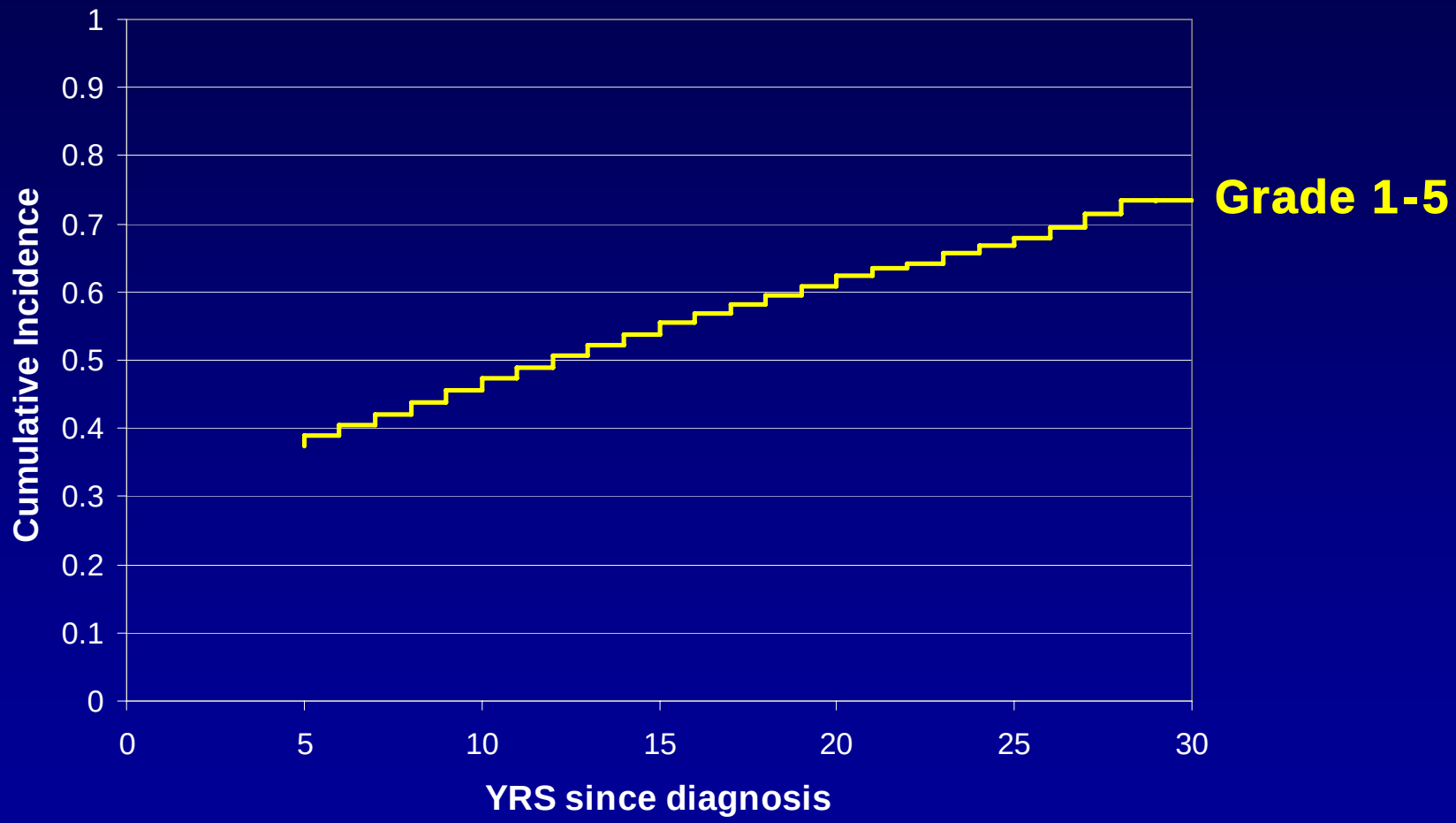
All estimates are significant at $p < 0.001$

Relative risk with 95% CI of Grade 3 or 4 conditions in survivors compared with siblings

Adjusted for age, sex, and race



Cumulative incidence curves of chronic health conditions in survivors, by GRADE 1-5 and GRADE 3-5



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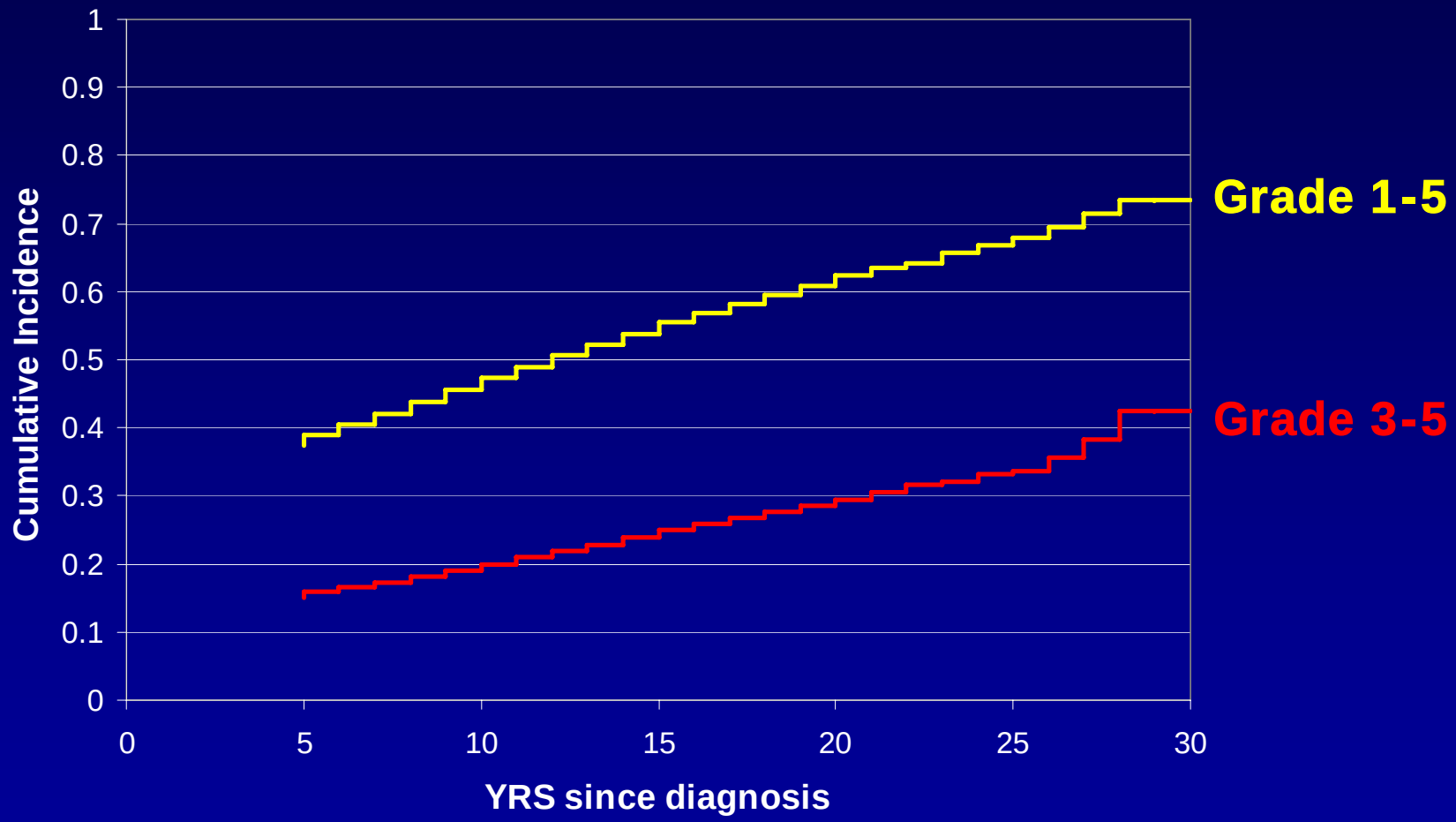

Morbidity of Survivors

- By 30 years post cancer:
  - 73% survivors with at least one condition
  - 42% with a grade 3-5 condition
  - 32% with multiple conditions
- Survivors – 8.2 times more likely to have a severe or life-threatening health condition than siblings

Health Status of Survivors

- 9535 young adult survivors
- Moderate-extreme adverse outcomes
  - General health 10.6%
  - Mental health 17.2%
  - Functional impairment 11.8%
  - Limitations in activity 13.5%
  - Pain post cancer 10.2%
  - Anxiety/fears post cancer 13.2%
  - ❖ **Any adverse HS domain 43.2%**

Hudson MM et al. JAMA 290:1583, 2003

Foundations of Risk-Based Care

- High-risk population
- Wide array of potential late effects
- Risk often does not plateau with aging
- Clinically silent period for many late effects – 20-30 yrs

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- High-risk population
- Wide array of potential late effects
- Risk often does not plateau with aging
- Clinically silent period for many late effects – 20-30 yrs
- ❖ Potentially modifiable by secondary or tertiary prevention and early diagnosis/intervention

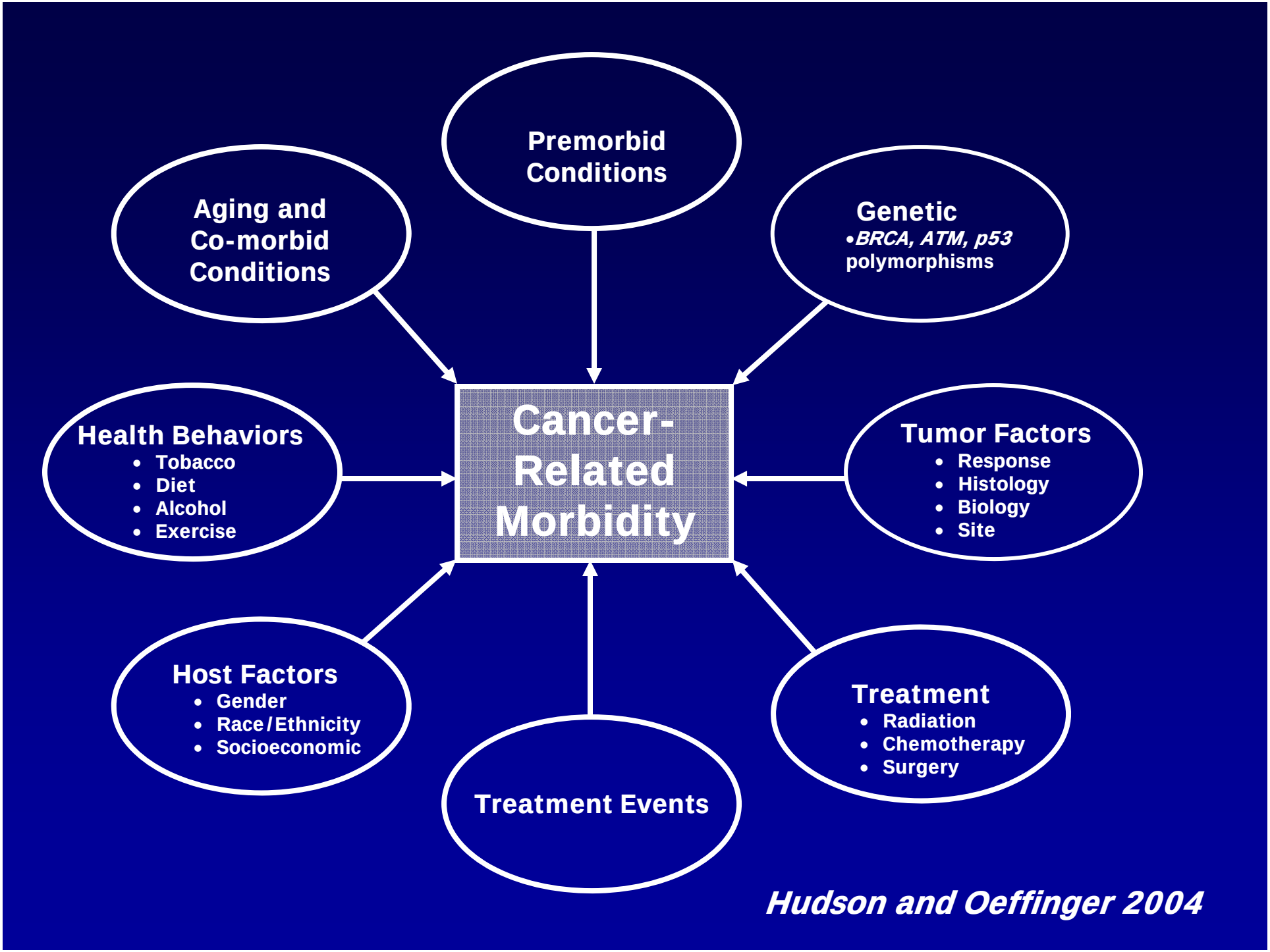
Paradigm Shift

Shift from a focus solely on cure to

maximize the cure
and
minimize the cost

(late occurring health problems associated with the cancer therapy)


UMPK IN


Premorbid Conditions
Aging and Co-morbid Conditions
Genetic
•BRCA, ATM, p53 polymorphisms
Health Behaviors
• Tobacco
• Diet
• Alcohol
• Exercise
Cancer-Related Morbidity
Tumor Factors
• Response
• Histology
• Biology
• Site
Host Factors
• Gender
• Race/Ethnicity
• Socioeconomic
Treatment Events
Treatment
• Radiation
• Chemotherapy
• Surgery
Hudson and Oeffinger 2004

Basis for Risk Estimate

Determine risk for potential late effects, based on:

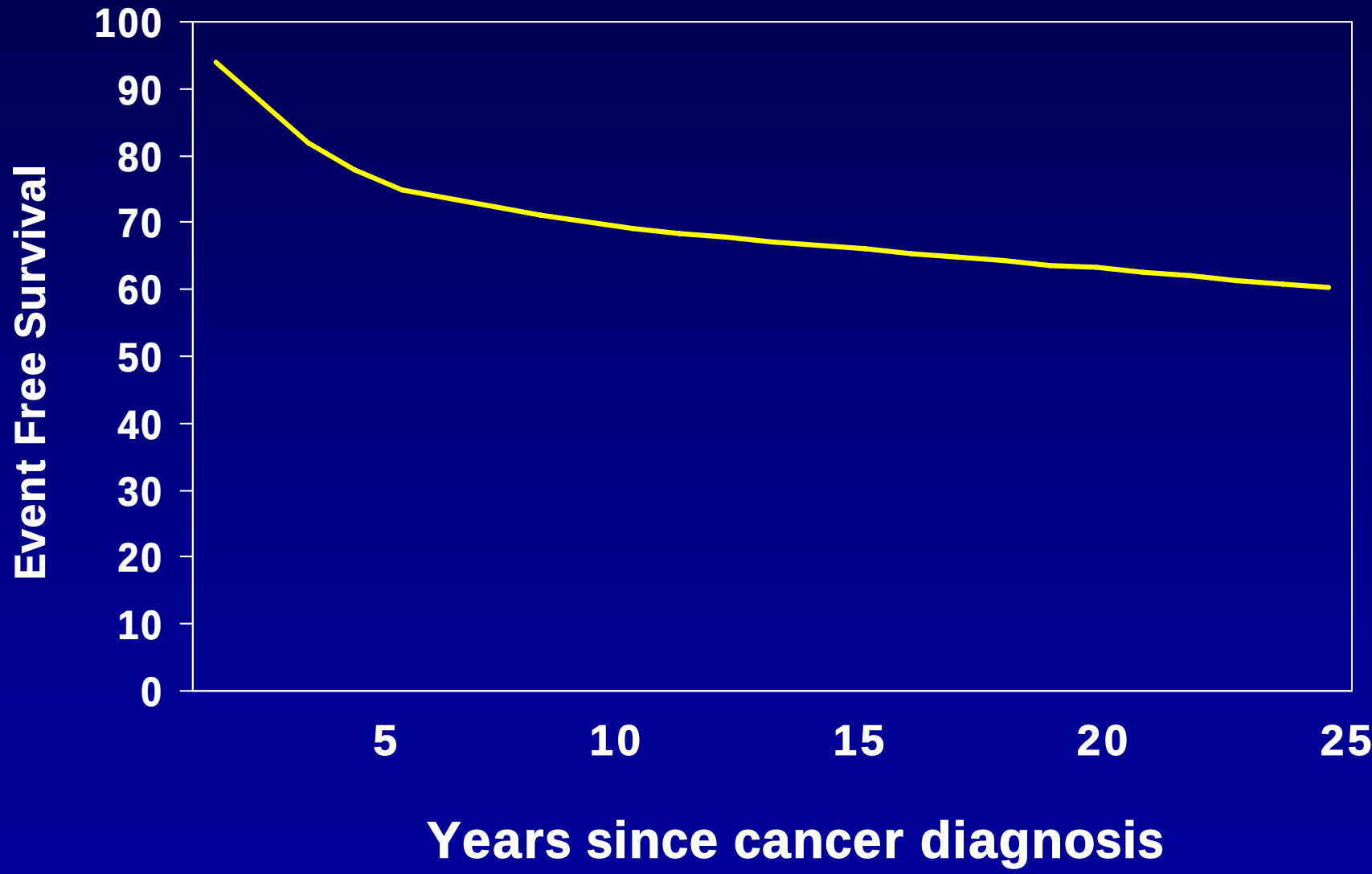
- Cancer – type, site, etc.
- Therapeutic exposures
- Treatment events
- Genetic predispositions
- Co-morbid conditions
- Lifestyle behaviors and practices

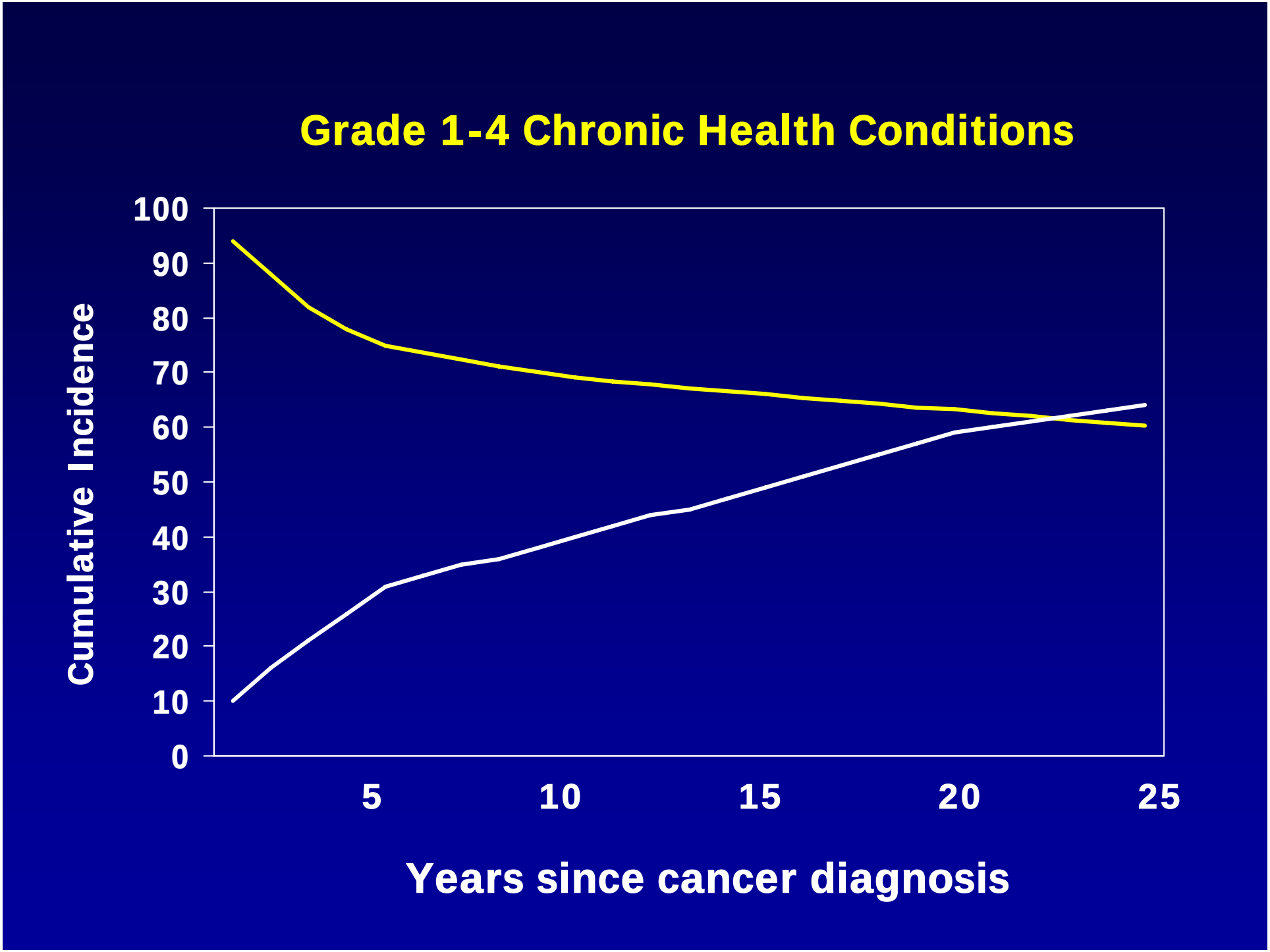
Plan for Risk-Based Care

- Monitor for recurrence of cancer
- Surveillance for second cancers and late effects
  - Early diagnosis and intervention
- Prevention
  - Tobacco use, physical activity, calcium intake
- Counseling and education

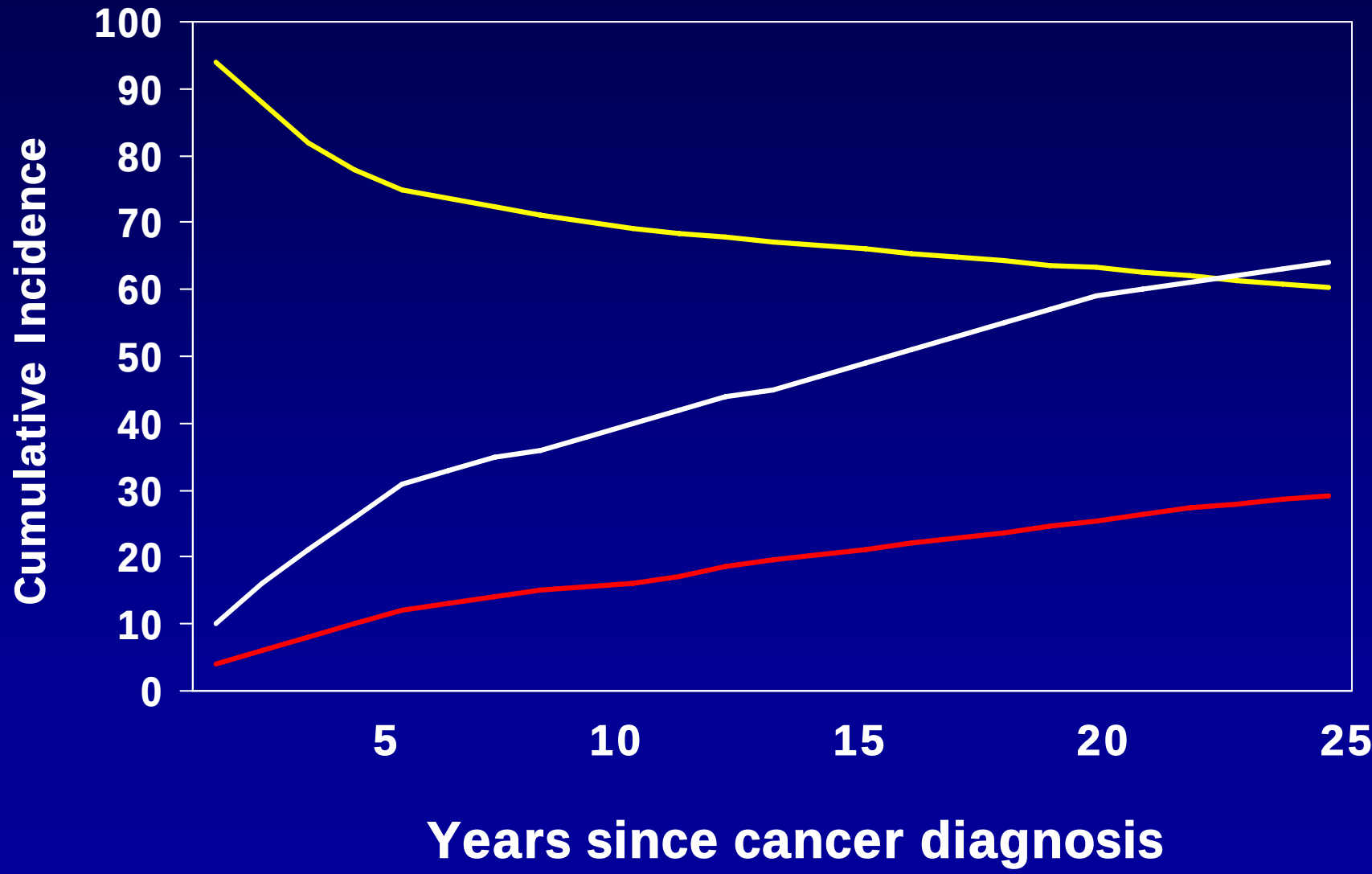
Oeffinger KC. Institute of Medicine, 2003
Oeffinger KC. Curr Probl Cancer 27:143-67, 2003
Oeffinger KC, Hudson MM. CA Cancer J Clin 54:208-236, 2004

Long-Term Mortality

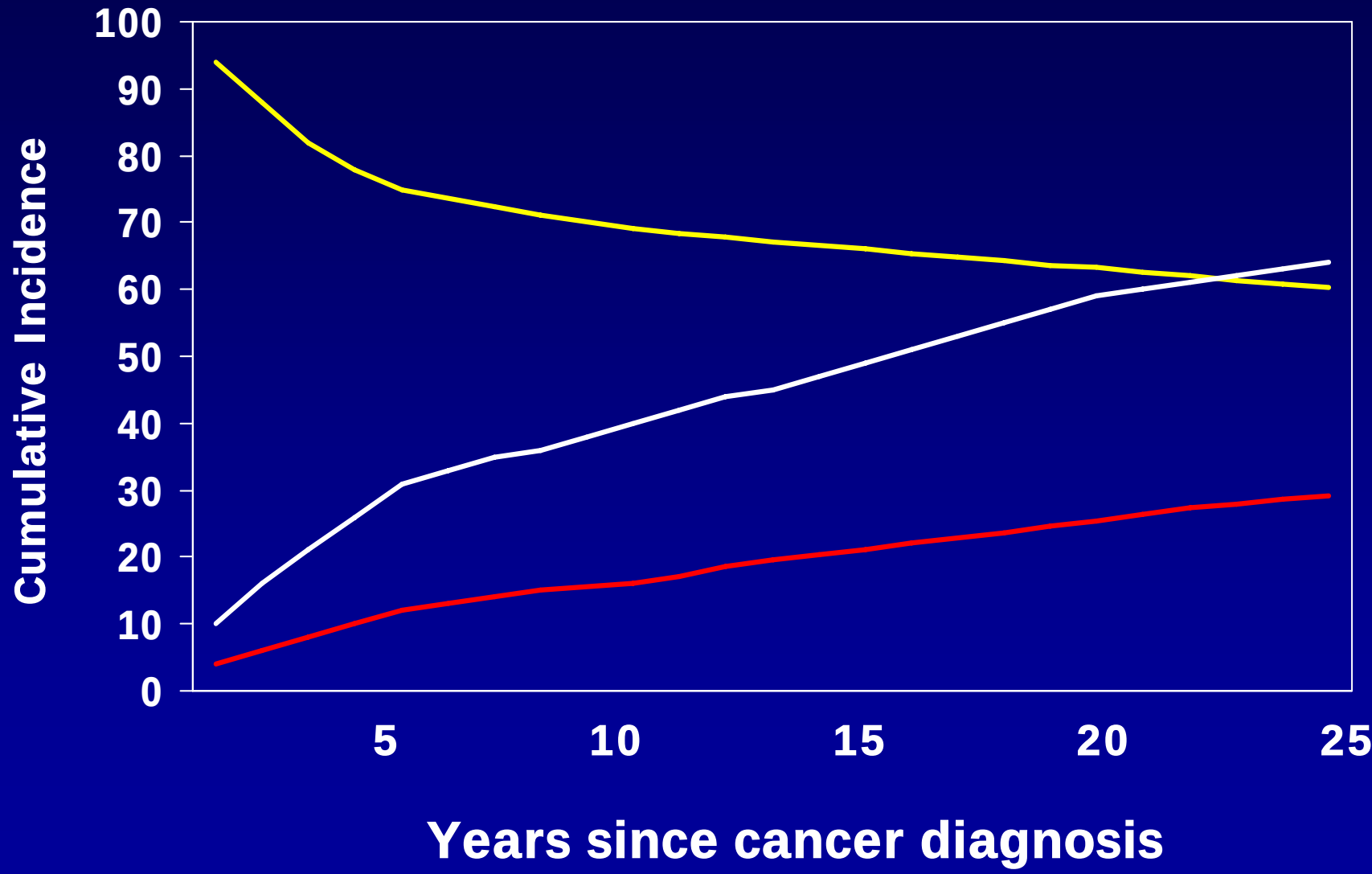


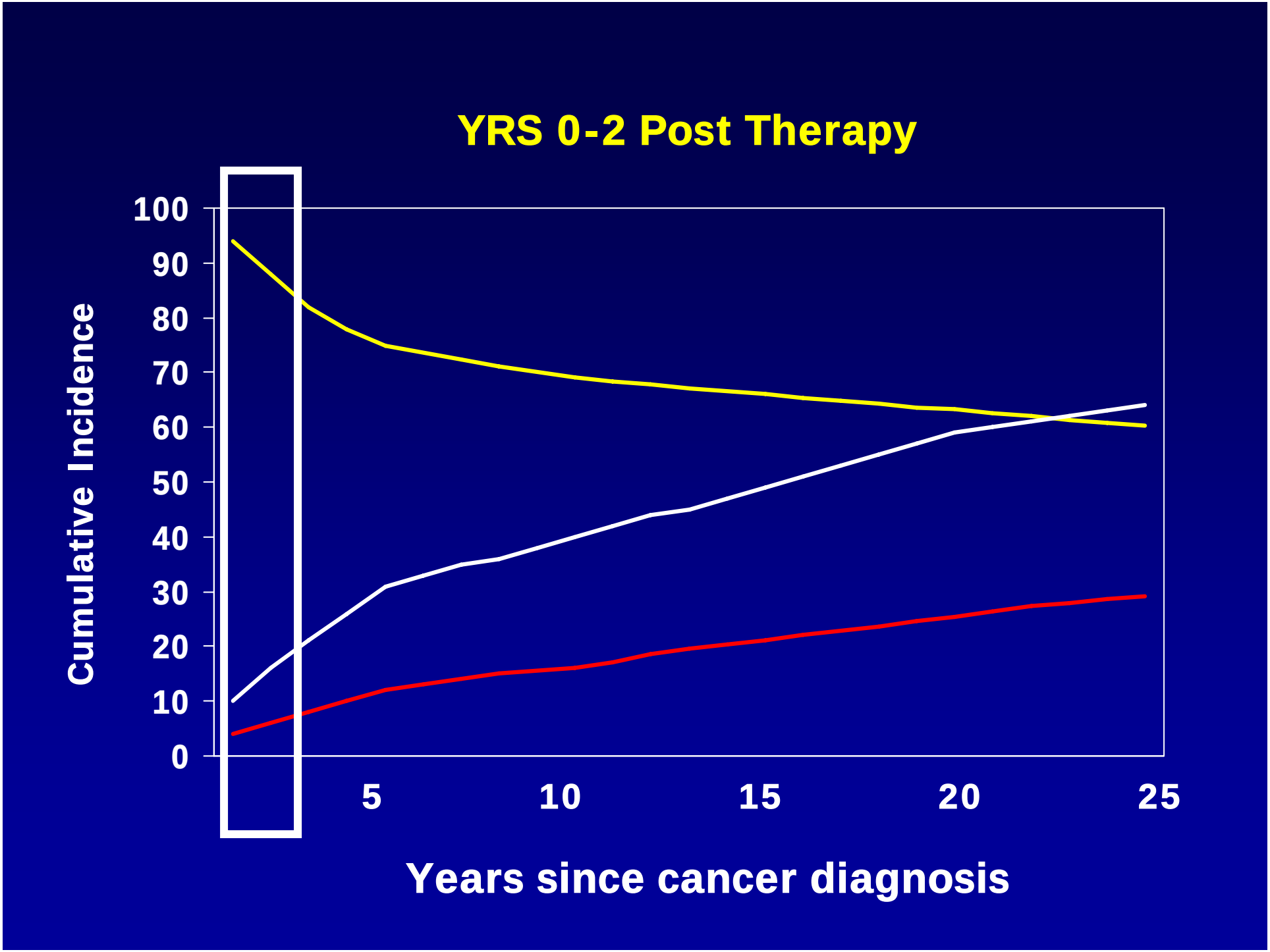

Grade 1-4 Chronic Health Conditions
Cumulative Incidence
100
90
80
70
60
50
40
30
20
10
0
5
10
15
20
25
Years since cancer diagnosis

Grade 3-4 Chronic Health Conditions

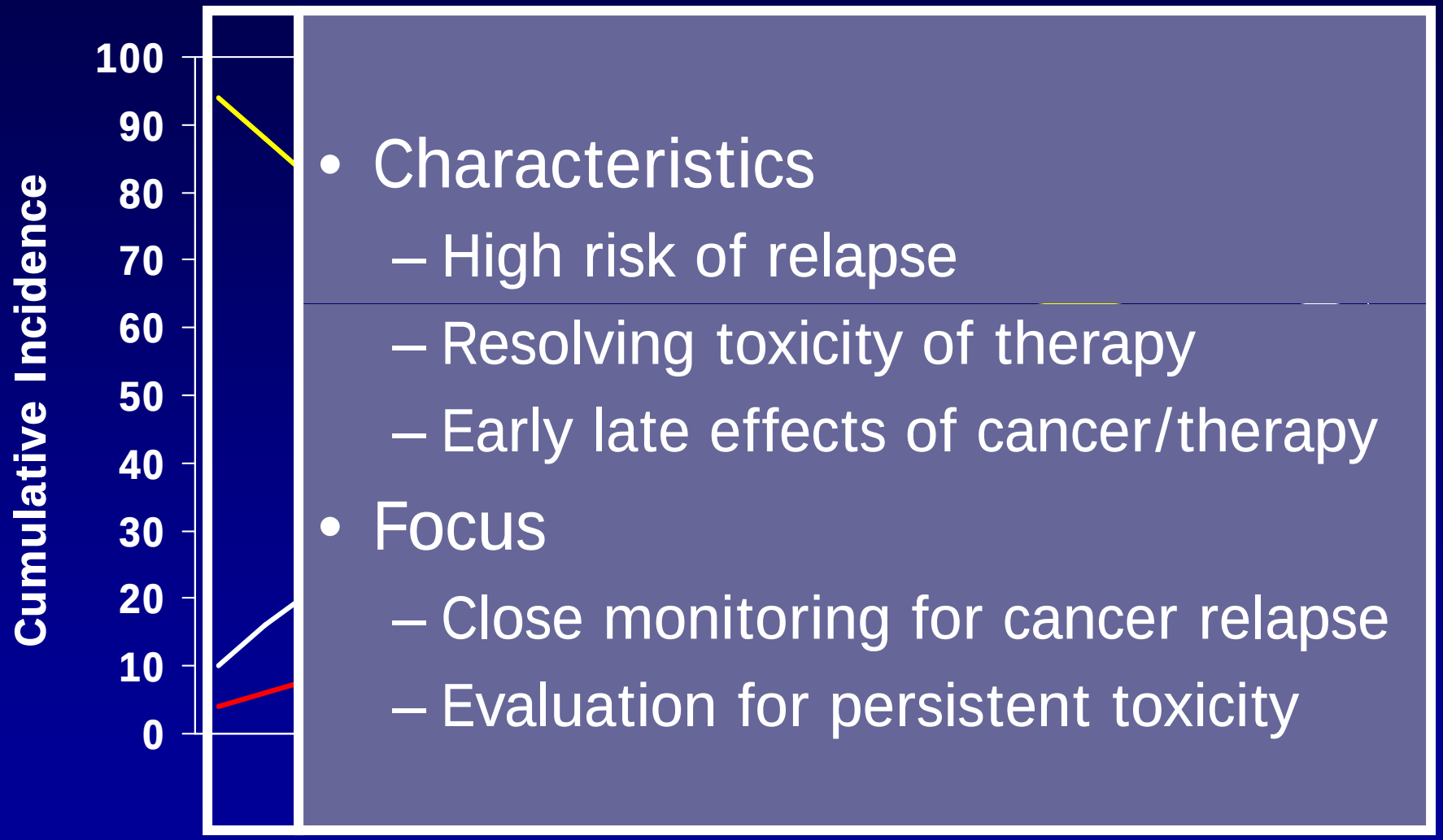


Phases of Follow Up Care

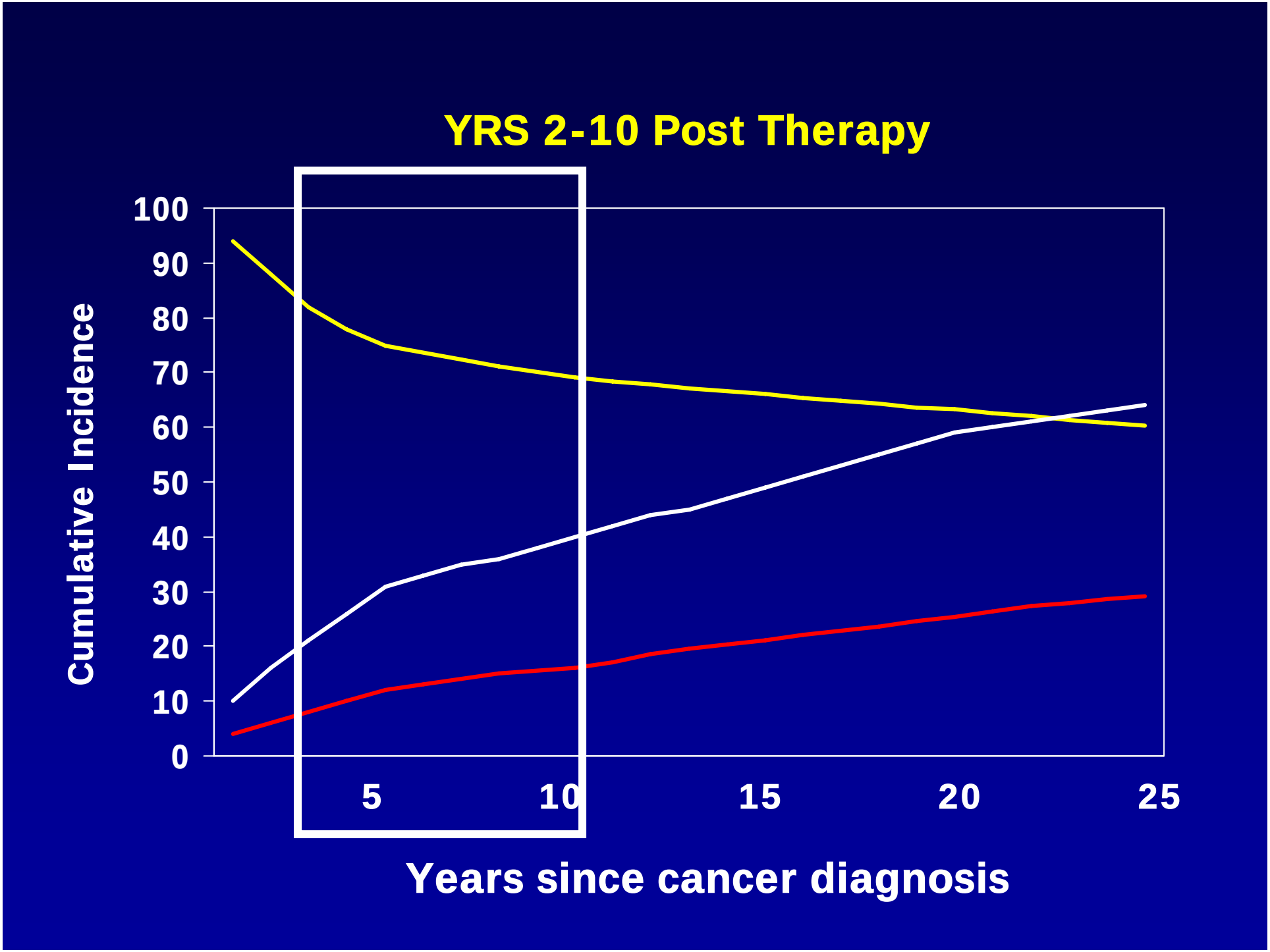



YRS 0-2 Post Therapy
Cumulative Incidence
100
90
80
70
60
50
40
30
20
10
0
5
10
15
20
25
Years since cancer diagnosis

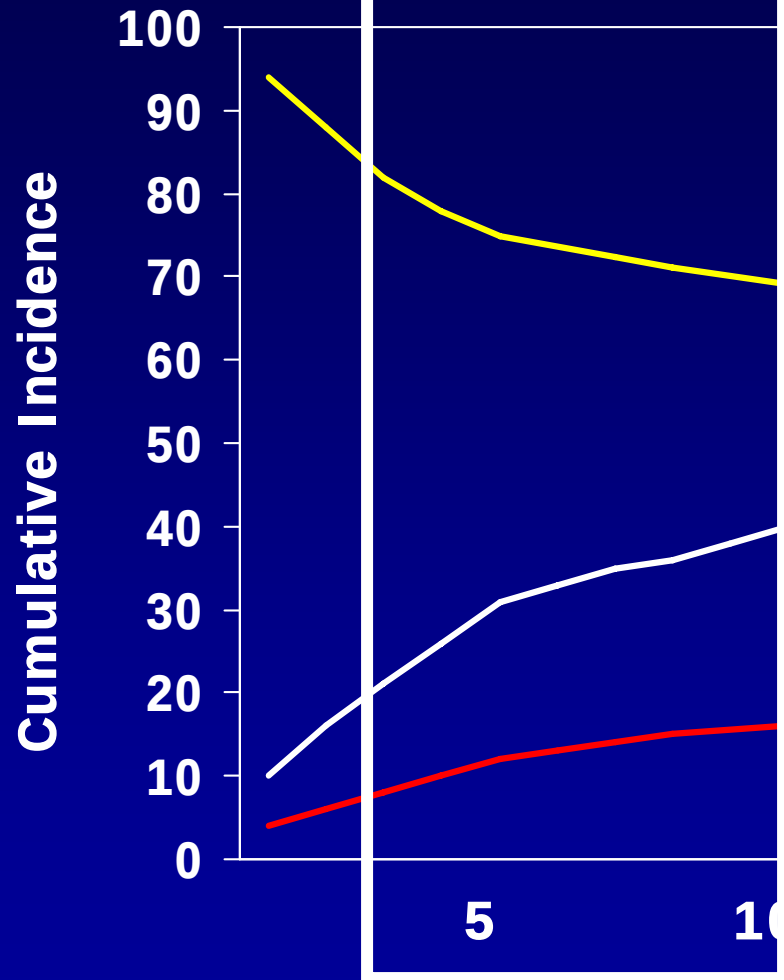
YRS 0-2 Post Therapy



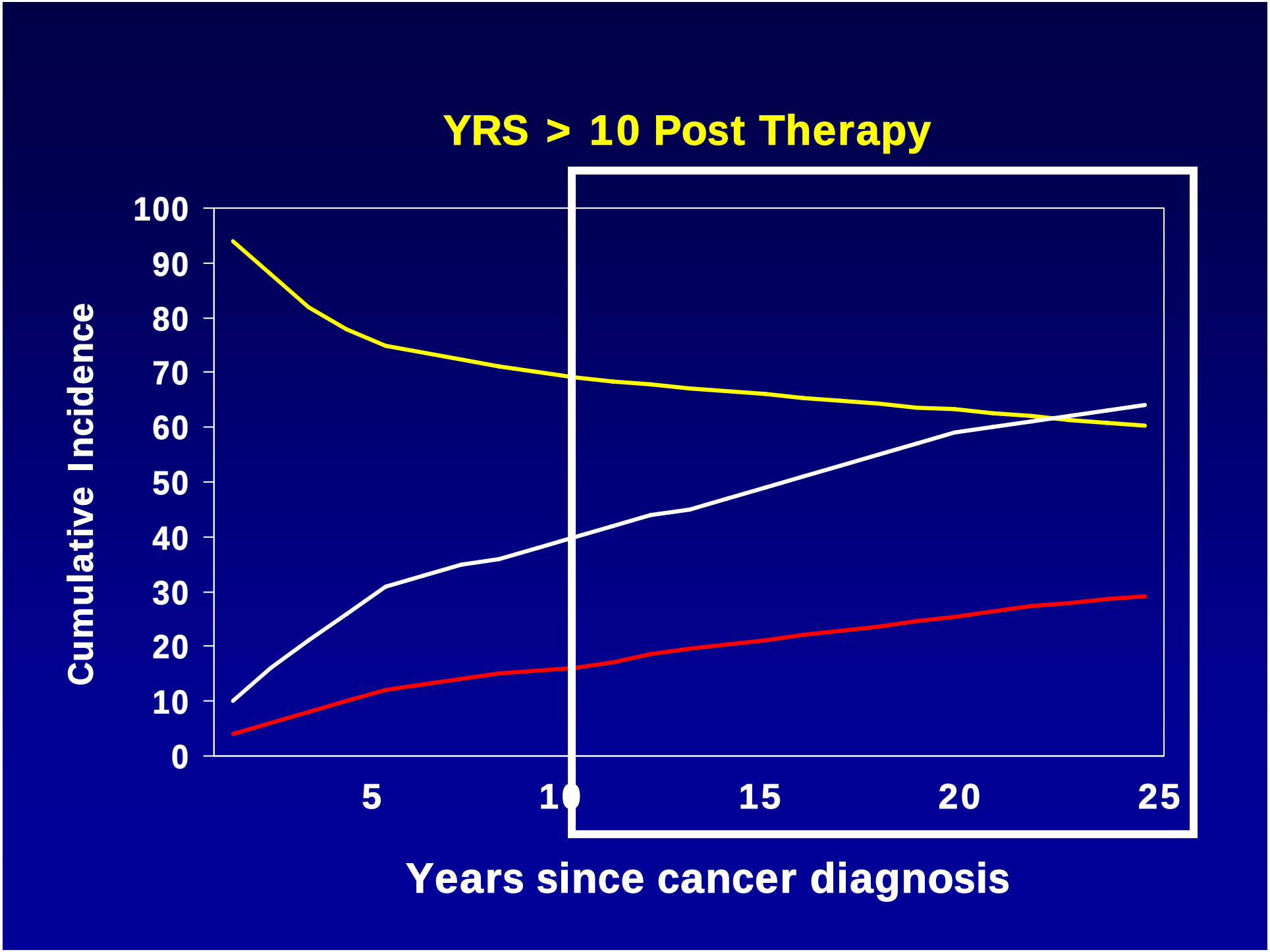
- Characteristics
  - High risk of relapse
  - Resolving toxicity of therapy
  - Early late effects of cancer/therapy
- Focus
  - Close monitoring for cancer relapse
  - Evaluation for persistent toxicity


YRS 2-10 Post Therapy
Cumulative Incidence
100
90
80
70
60
50
40
30
20
10
0
5
10
15
20
25
Years since cancer diagnosis

YRS 2-10 Post Therapy

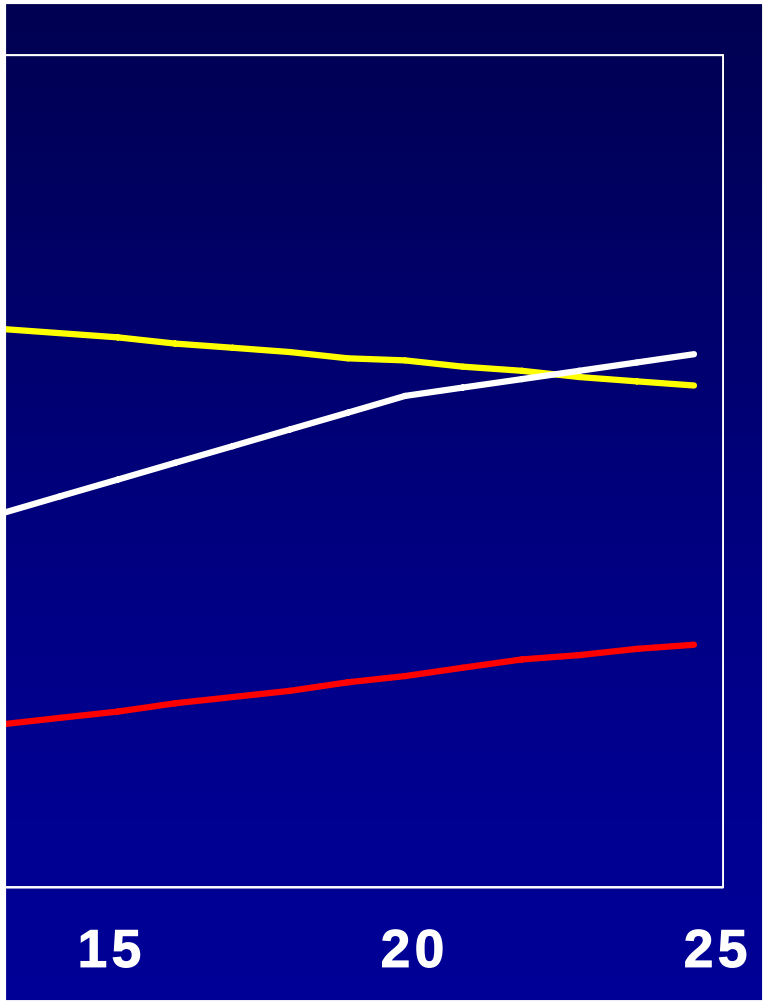


- Characteristics
  - Relapse/recurrence
  - Endocrinopathies
  - Neurocog sequelae
- Focus
  - Monitoring relapse
  - Screening
  - Counseling/school


YRS > 10 Post Therapy
Cumulative Incidence
100
90
80
70
60
50
40
30
20
10
0
5
10
15
20
25
Years since cancer diagnosis

YRS > 10 Post Therapy

- Characteristics
  - Increasing incidence of SMN and late effects
  - Fertility issues
  - Independence/work
- Focus
  - Surveillance
  - Manage late effects
  - Counseling



Years since cancer diagnosis

Long-Term Follow-up Programs

- LTFU programs created for care of cancer survivors in 1980-1990's
- Based at a children's hospital or a cancer center
- Variation between programs: resources, size, research

Long-Term Follow-up Programs

- LTFU programs created for care of cancer survivors in 1980-1990's
- Based at a children's hospital or a cancer center
- Variation between programs: resources, size, research
- 1997 - 50% centers in US and Canada with a LTFU program

Oeffinger KC, et al. J Clin Oncol 16:2864-7, 1998

LTFU Program

- Team approach (MD/NP/SW)
- Multi-disciplinary network of consultants
- Annual evaluation
  - History and physical
  - Screening based on exposures
  - Targeted education on risk and lifestyle behaviors
  - Medical summary of treatment

Aziz NM, Oeffinger KC, et al. Cancer 2006

SUMMARY OF CANCER TREATMENT
Date Prepared: 08/22/2005

Name: John Doe		**Date of Birth:**	
Treatment Center: Memorial Sloan Kettering Cancer Center			
Cancer Diagnosis: Ewing's Sarcoma			
Date of Diagnosis: 06/18/1978		**Age at Diagnosis:** 14 years	
Date of Completion of Therapy: 2/23/1981			
Cancer Treatment			
Surgery			
Date		**Procedure**	
03/20/1978		Biopsy of left thigh mass	
04/06/1978		EnBloc Resection left anterior medial thigh	
06/10/1985		Excision of left distal thigh mass	
Radiation Therapy			
Date start	**Date Stop**	**Field**	**Dose (cGy)**
None			
Chemotherapy			
Drug Name		**Dose (units or mg/m^2)**	
Actinomycin-D		Yes – 6.96 mg/m^2	
BCNU (Carmustine)		Yes – 177.78 mg/m^2	
Bleomycin		Yes – 80 mg/m^2	
Cyclophosphamide (Cytoxan)		Yes – 19644.44 mg/m^2	
Doxorubicin (Adriamycin)		Yes – 345 mg/m^2	
Methotrexate		Yes – 77.04 mg/m^2	
Vincristine		Yes	
Late Effects Risks		**Screening Recommendations****	
Cardiomyopathy		Echo every year	
Pulmonary fibrosis		PFTs with DLCO baseline	
Hypogonadism		Testosterone, FSH, LH as indicated	
Hemorrhagic cystitis		Urinalysis yearly	
Bladder cancer		Urinalysis yearly	

**Screening recommendations from the CureSearch Children's Oncology Group Long-Term Follow-Up Guidelines at http://www.survivorshipguidelines.org.

Standardized Screening

- Late Effects Screening Guidelines from the Children's Oncology Group
- www.survivorshipguidelines.org
- Melissa Hudson/Wendy Landier
- Multi-disciplinary

Standardized Screening

- Late Effects Screening Guidelines from the Children's Oncology Group
- www.survivorshipguidelines.org
- Melissa Hudson/Wendy Landier
- Multi-disciplinary
- Strength of the association of treatment exposure to late effect
- Principles of screening/surveillance in a high-risk population

Long-Term Follow-Up Guidelines

for Survivors of Childhood, Adolescent, and Young Adult Cancers

Version 2.0 – March 2006

CureSearch

Children's Oncology Group

www.survivorshipguidelines.org

CHEMOTHERAPY

ALKYLATING AGENTS

Sec #	Therapeutic Agent(s)	Potential Late Effects	Risk Factors	High Risk Factors	Periodic Evaluation	Health Counseling Further Considerations
7 (Male)	**ALKYLATING AGENTS** Busulfan Carmustine (BCNU) Chlorambucil Cyclophosphamide Ifosfamide Lomustine (CCNU) Mechlorethamine Melphalan Procarbazine Thiotepa **HEAVY METALS** Carboplatin Cisplatin **NON-CLASSICAL ALKYLATORS** Dacarbazine (DTIC) Temozolomide	**Gonadal dysfunction (testicular)** Hypogonadism Infertility	**Treatment Factors** Higher cumulative doses of alkylators or combinations of alkylators Combined with radiation to: - Abdomen/pelvis - Testes - Brain, cranium (neuroendocrine axis) **Health Behaviors** Smoking **Info Link** Doses that cause gonadal dysfunction show individual variation. Germ cell function (spermatogenesis) is impaired at lower doses compared to Leydig cell (testosterone production) function. Prepubertal status does not protect from gonadal injury in males.	**Host Factors** Male gender **Treatment Factors** MOPP > 3 cycles Busulfan > 600 mg/m² Cyclophosphamide cumulative dose > 7.5 gm/m² or as conditioning for HCT Any alkylators combined with: - Testicular radiation - Pelvic radiation - TBI	**HISTORY** **Pubertal (onset, tempo)** **Sexual function (erections, nocturnal emissions, libido)** **Medication use impacting sexual function** (Yearly) **PHYSICAL** Tanner stage Testicular volume by Prader orchiometry (Yearly) **SCREENING** **FSH** **LH** **Testosterone** (Baseline at age 14 and as clinically indicated in patients with delayed puberty and/or clinical signs and symptoms of testosterone deficiency) **Semen analysis** (As requested by patient and for evaluation of infertility. Periodic evaluation over time is recommended as resumption of spermatogenesis can occur up to 10 years post therapy)	**Health Links** Male Health Issues **Resources** Extensive information regarding infertility for patients and healthcare professionals is available on the following websites: American Society for Reproductive Medicine (www.asrm.org) Fertile Hope (www.fertilehope.org) **Counseling** Counsel regarding the need for contraception, since there is tremendous individual variability in gonadal toxicity after exposure to alkylating agents. Recovery of fertility may occur years after therapy. **Considerations for Further Testing and Intervention** Bone density evaluation for osteopenia/osteoporosis in hypogonadal patients. Refer to endocrinologist for delayed puberty or persistently abnormal hormone levels. Hormonal replacement therapy for hypogonadal patients. Reproductive endocrinology/urology referral for infertility evaluation and consultation regarding assisted reproductive technologies. **SYSTEM = Male reproductive** **SCORE =** **Alkylating Agents: 1** **Heavy Metals: 2A** **Non-Classical Alkylators: 2A**

SECTION 7 REFERENCES

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RADIATION

POTENTIAL IMPACT TO HEART

Sec #	Therapeutic Agent(s)	Potential Late Effects	Risk Factors	High Risk Factors	Periodic Evaluation	Health Counseling Further Considerations
71	**Mantle** **Mediastinal** **Chest (thorax)** **Axilla** **Spine (thoracic)** **Whole abdomen** **All upper abdominal fields**	**Cardiac toxicity** Congestive heart failure Cardiomyopathy Pericarditis Pericardial fibrosis Valvular disease Myocardial infarction Arrhythmia Atherosclerotic heart disease	**Host Factors** Younger age at irradiation Family history of dyslipidemia Coronary artery disease **Treatment Factors** Radiation dose ≥ 20 Gy to chest TBI Combined with radiomimetic chemotherapy (e.g., doxorubicin, dactinomycin) Combined with other cardiotoxic chemotherapy - Anthracyclines - Cyclophosphamide conditioning for HCT - Amsacrine **Medical Conditions** Hypertension Obesity Dyslipidemia Diabetes mellitus Congenital heart disease Febrile illness Pregnancy Premature ovarian failure (untreated) **Health Behaviors** Smoking Isometric exercise Drug use (e.g., cocaine, diet pills, ephedra)	**Host Factors** Female sex Black/ of African descent Younger than age 5 years at time of treatment **Treatment Factors** Anteriorly-weighted radiation fields Lack of subcarinal shielding Doses ≥ 30 Gy in patients who have received anthracyclines Doses ≥ 40 Gy in patients who have not received anthracyclines Longer time since treatment	**HISTORY** **SOB** **DOE** **Orthopnea** **Chest pain** **Palpitations** **If under 25 years: Abdominal symptoms (nausea, vomiting)** (Yearly) **Info Link**: Exertional intolerance is uncommon in young patients (< 25 years). Abdominal symptoms (nausea, emesis) may be observed more frequently than exertional dyspnea or chest pain. **PHYSICAL** **Cardiac murmur** **S3, S4** **Increased P2 sound** **Pericardial rub** **Rales** **Wheezes** **Jugular venous distension** **Peripheral edema** (Yearly) **SCREENING** **Fasting glucose and lipid profile** (Every 3 to 5 years. If abnormal, refer for ongoing management.) **EKG (include evaluation of QTc interval)** (Baseline at entry into long-term follow-up. Repeat as clinically indicated.) **ECHO** (Baseline at entry into long-term follow-up, then periodically based on age at treatment, radiation dose, and cumulative anthracycline dose - *see table.*)	**Health Links** Heart Health Diet and Physical Activity **Resources** A downloadable wallet card is available from the AHA website for patients requiring endocarditis prophylaxis: www.americanheart.org/downloadable/heart/1023826501754walletcard.pdf **Counseling** Counsel patients with prolonged QTc interval about use of medications that may further prolong the QTc interval (e.g., tricyclic anti-depressants, antifungals, macrolide antibiotics, metronidazole). Counsel regarding maintaining appropriate weight, blood pressure, and heart-healthy diet. Counsel regarding endocarditis prophylaxis if valvular abnormalities present. Counsel regarding appropriate exercise. Aerobic exercise is generally safe and should be encouraged for most patients. Intensive isometric activities (e.g., heavy weight lifting, wrestling) should generally be avoided. Limited high repetition weight lifting (i.e., lifting a lighter weight with ease no more than 15 to 20 times in a row) is much less stressful to the heart and is more likely to be safe. Patients who choose to engage in strenuous or varsity team sports should discuss appropriate guidelines and a plan for ongoing monitoring with a cardiologist. **Considerations for Further Testing and Intervention** Cardiology consultation for patients with subclinical abnormalities on screening evaluations or with left ventricular dysfunction, dysrhythmia or prolonged QTc interval. Additional cardiology evaluation for patients who are pregnant or planning pregnancy who: (1) received ≥ 30 Gy chest radiation, or (2) received chest radiation in combination with cardiotoxic chemotherapy (anthracyclines or high-dose cyclophosphamide). Evaluation to include echocardiogram before and periodically during pregnancy (especially during third trimester) and monitoring during labor and delivery due to risk of cardiac failure. Consider cardiology consultation (5 to 10 years after radiation) to evaluate risk for coronary artery disease in patients who received ≥ 40 Gy chest radiation alone or ≥ 30 Gy chest radiation plus anthracycline. Consider excess risk of isometric exercise program in any high-risk patient defined as needing screening every 1 or 2 years. **SYSTEM = Cardiovascular** **SCORE = 1**

RECOMMENDED FREQUENCY OF ECHOCARDIOGRAM

Age at Treatment*	Radiation Dose	Anthracycline Dose†	Recommended Frequency
<5 years old	Any	None	Every 2 years
		Any	Every year
≥5 years old	<30 Gy	None	Every 5 years
	≥30 Gy	None	Every 2 years
	Any	<300 mg/m2	Every 2 years
		≥300 mg/m2	Every year
Any age with serial decrease in function			Every year

*Age at time of first cardiotoxic therapy (anthracycline or chest irradiation, whichever was given first)
†Based on equivalent mg of doxorubicin/daunorubicin

HEMATOPOIETIC CELL TRANSPLANT (continued)

Sec #	Therapeutic Agent(s)	Potential Late Effects	Risk Factors	High Risk Factors	Periodic Evaluation	Health Counseling Further Considerations
95	**Hematopoietic Cell Transplant (HCT)**	**Hepatic toxicity** Chronic hepatitis Cirrhosis Iron overload	**Treatment Factors** History of multiple transfusions Radiation to the liver Antimetabolite therapy **Medical Conditions** Chronic GVHD Viral hepatitis History of VOD **Health Behaviors** Alcohol use	**Medical Conditions** Chronic hepatitis C with siderosis and steatosis	**SCREENING** **ALT** **AST** **Bilirubin** **Ferritin** (Baseline at entry into long-term follow-up. Repeat as clinically indicated.)	**Health Links** Liver Health Gastrointestinal Health **Considerations for Further Testing and Intervention** Prothrombin time for evaluation of hepatic synthetic function in patients with abnormal liver screening tests. Screen for viral hepatitis in patients with persistently abnormal liver function or any patient transfused prior to 1993. *Note: PCR testing for HCV may be required in immunosuppressed patients who are negative for antibody*. Gastroenterology/hepatology consultation in patients with persistent liver dysfunction or known hepatitis. Hepatitis A and B immunizations in patients lacking immunity. Consider liver biopsy in patients with persistent elevation of ferritin (based on clinical context and magnitude of elevation). Consider phlebotomy or chelation therapy for treatment of iron overload. Consider erythropoietin in patients with iron overload and low hemoglobin. **SYSTEM = GI/Hepatic** **SCORE = 1**

SECTION 95 REFERENCES

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Strasser SI, Myerson D, Spurgeon CL, et al. Hepatitis C virus infection and bone marrow transplantation: a cohort study with 10-year follow-up. *Hepatology*. Jun 1999;29(6):1893-1899.

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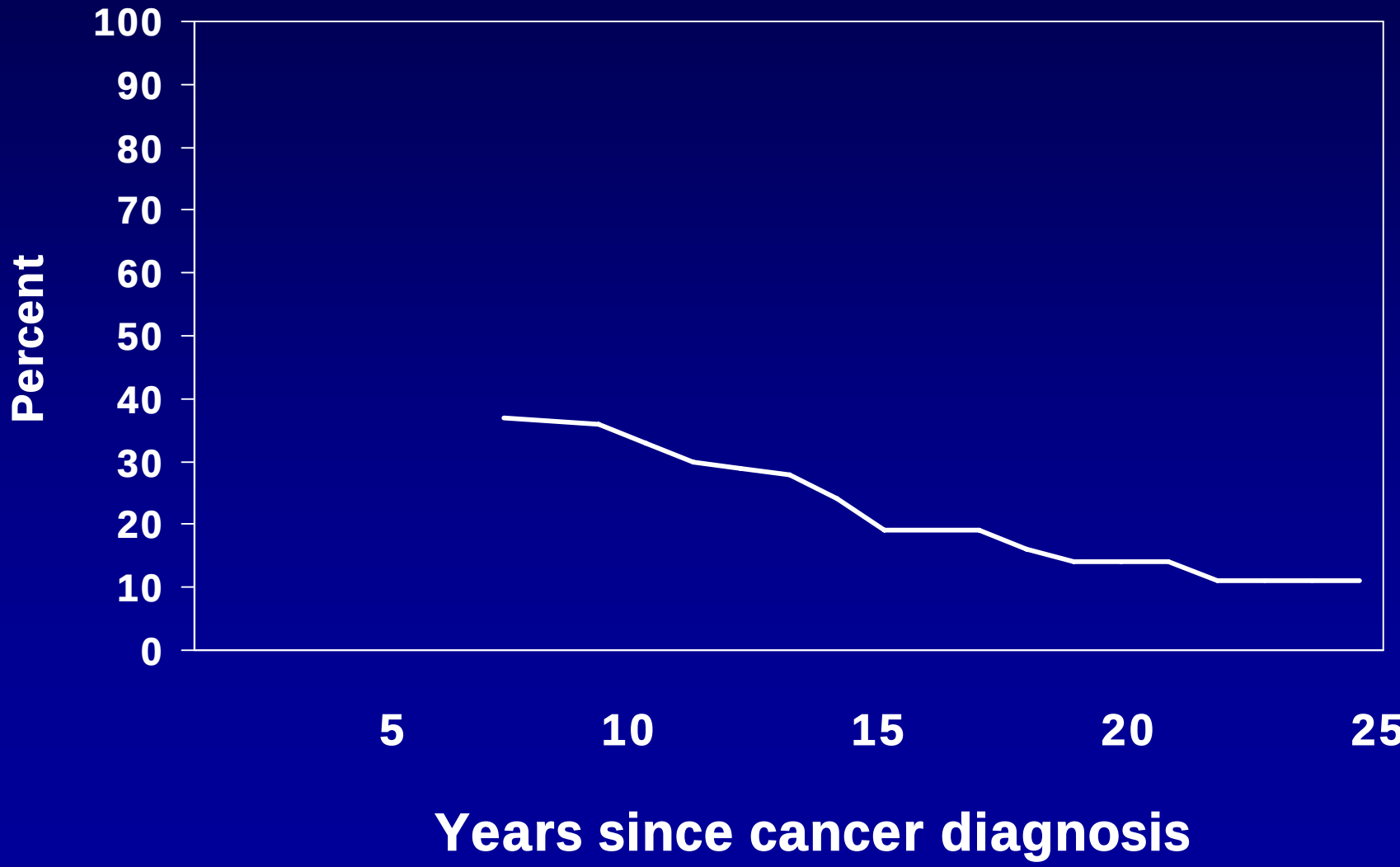
What is unique about LTFU-type care?

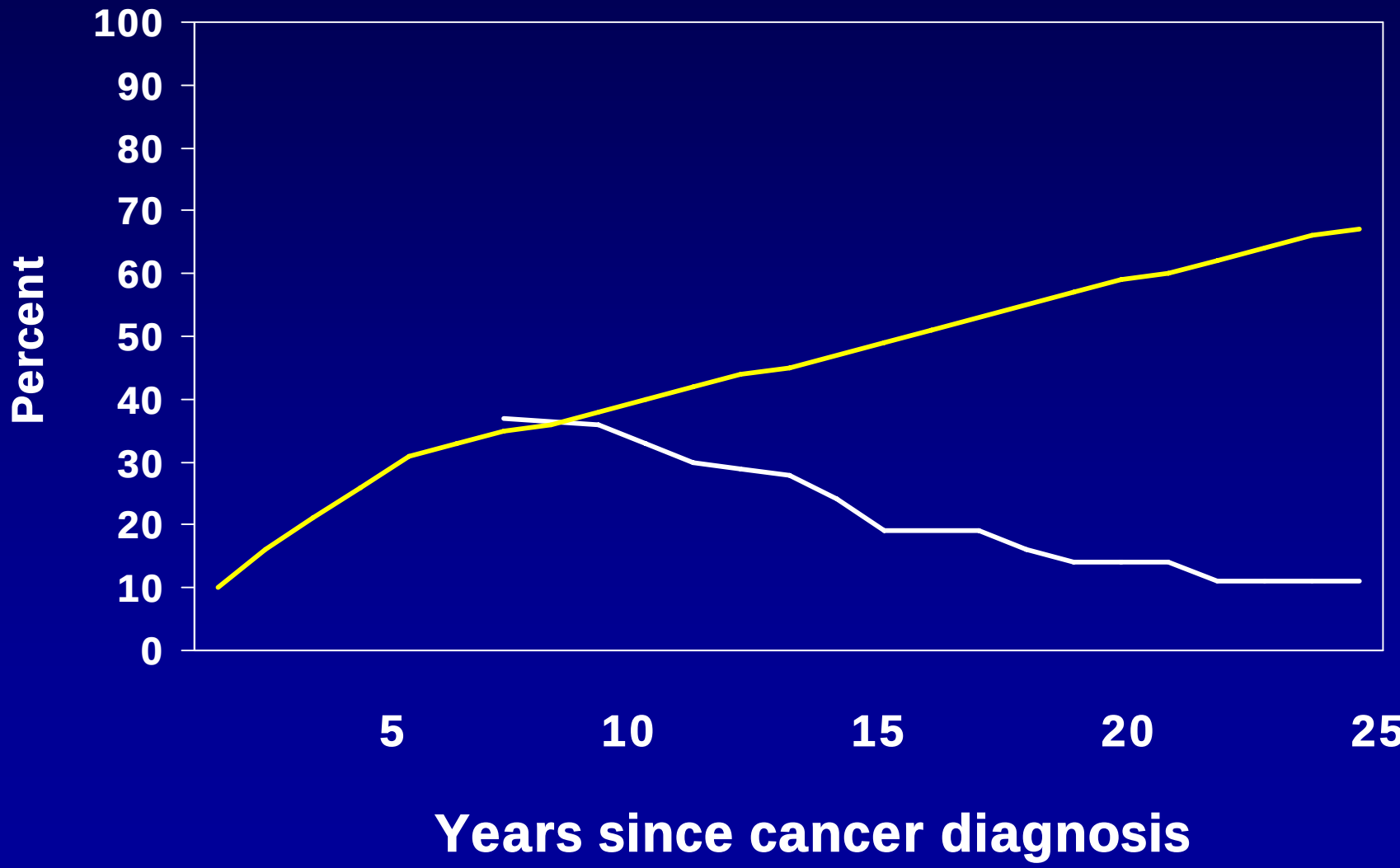
Clinicians' (MD, NP, SW, Psych) primary focus is on cancer survivors:

- Clinical care
- Research
- Critical review of the survivor literature
- National networking with other survivor clinicians

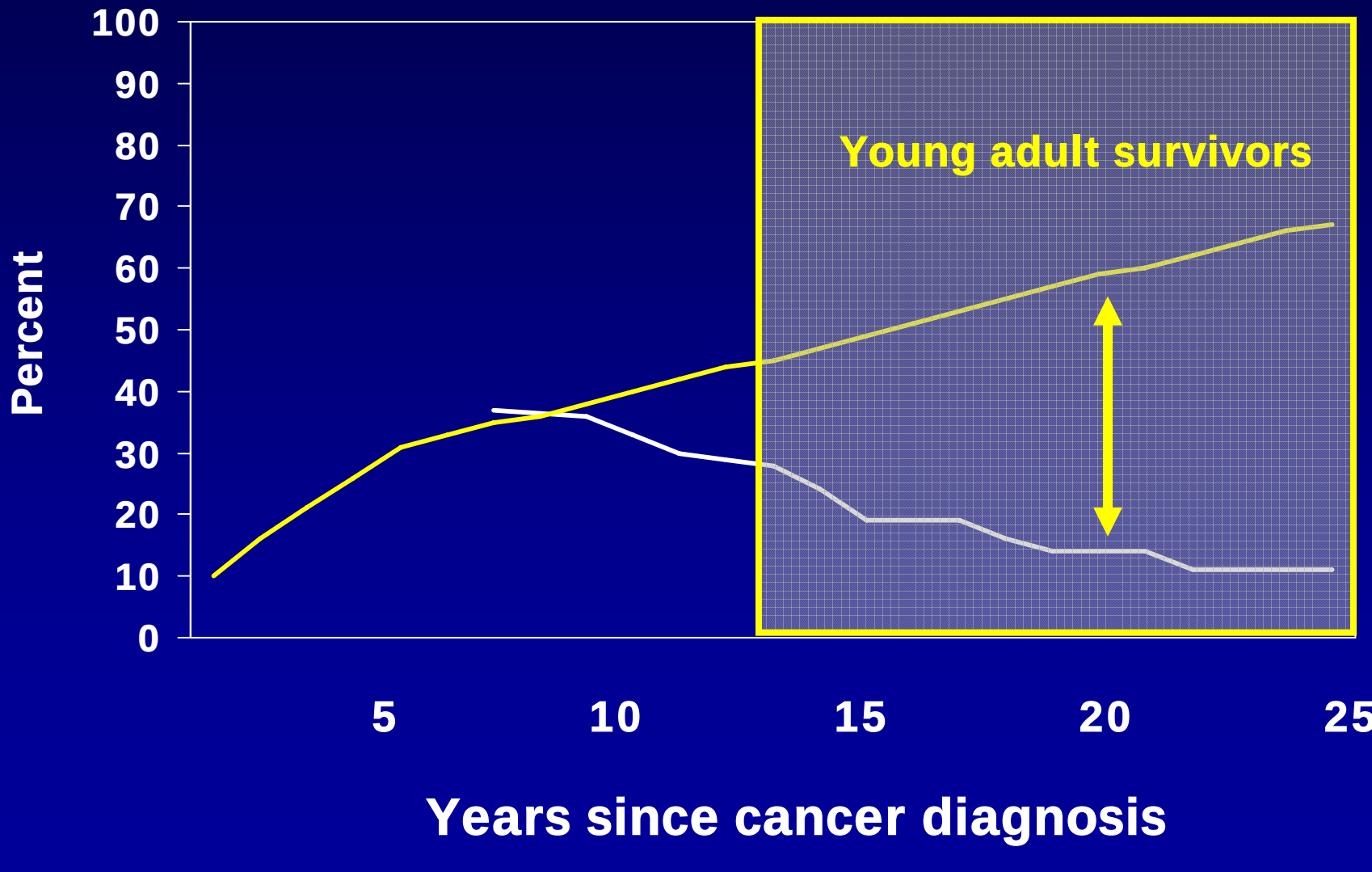
Cancer Center Visit in Last 2 YRS



Cancer Center Visits and Late Effects



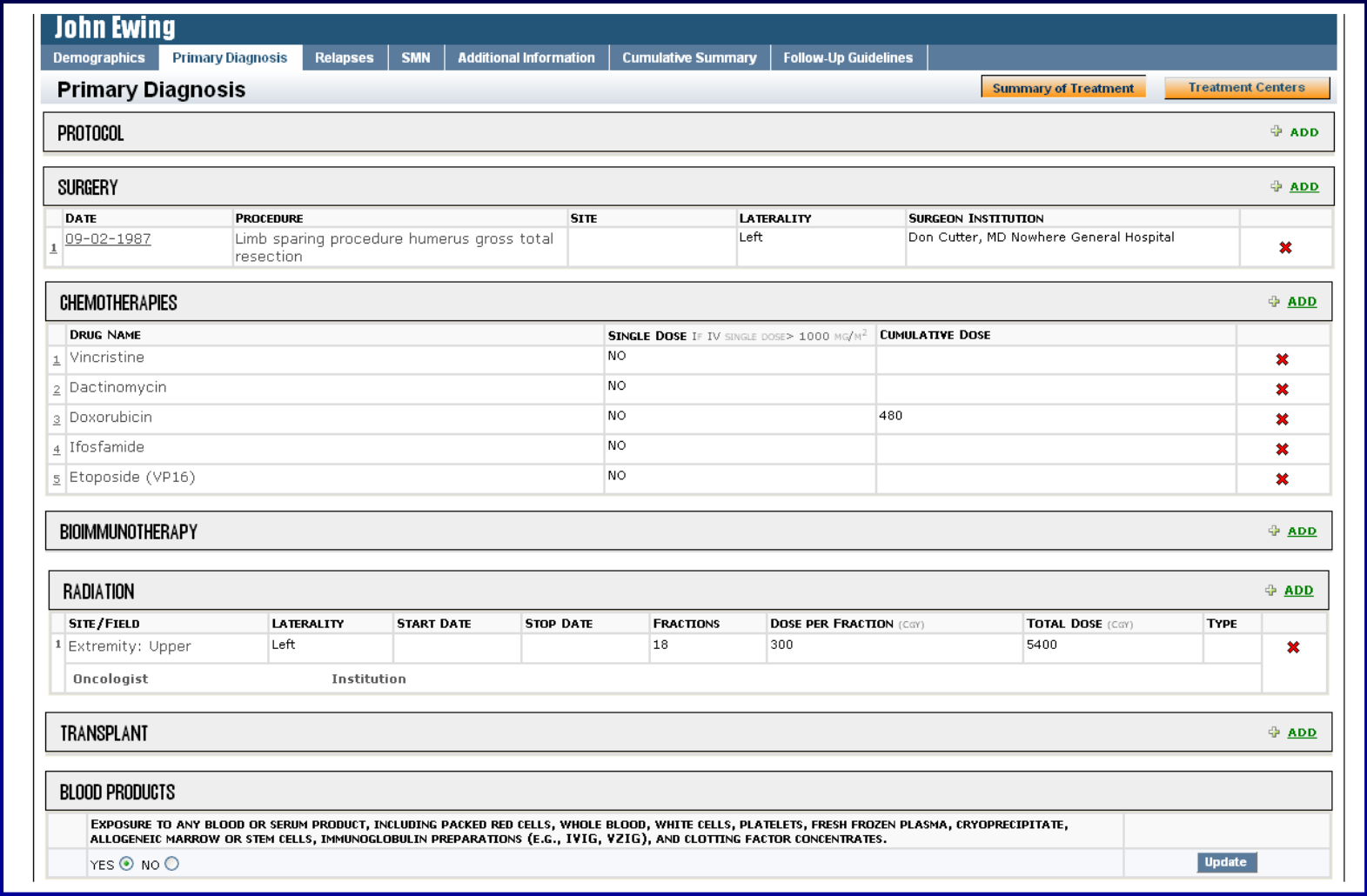
Cancer Center Visits and Late Effects



Future Directions of Care

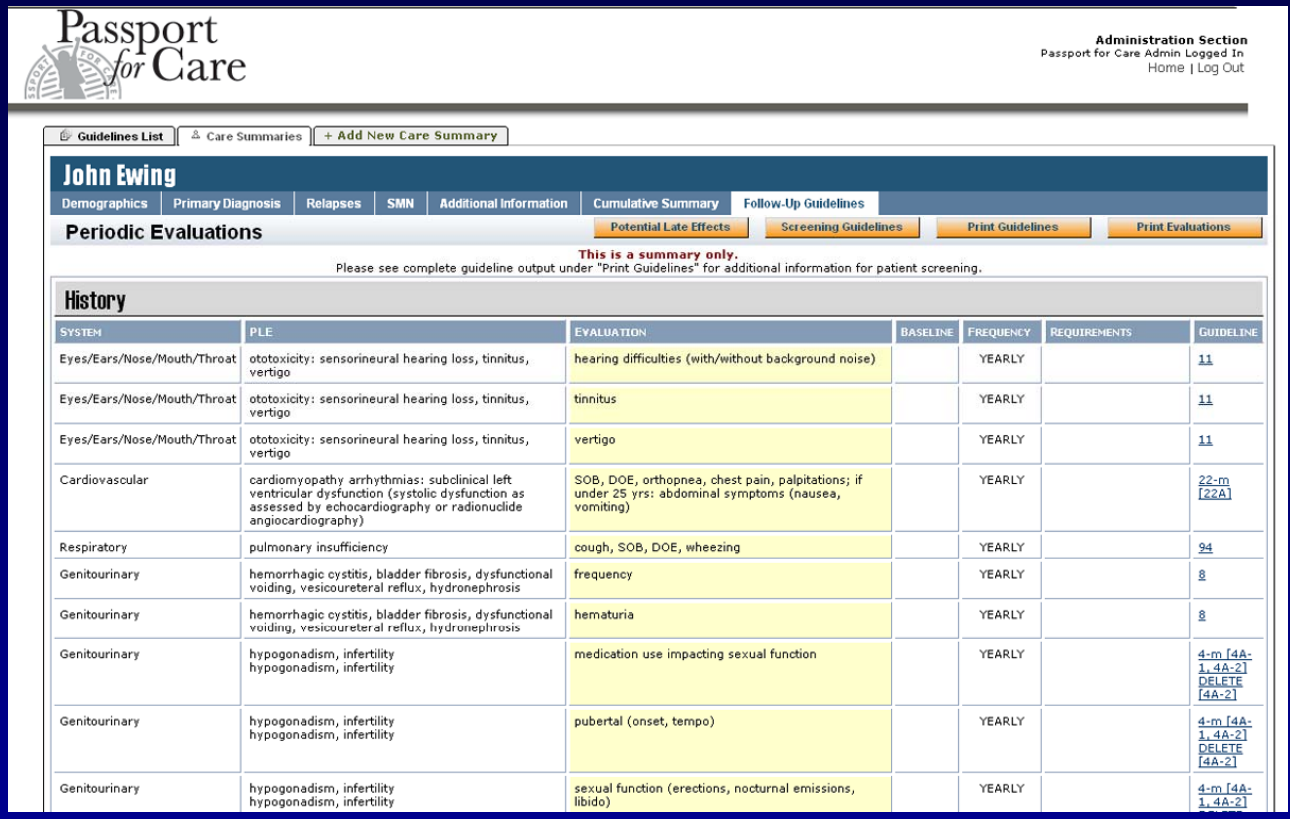
- There is not adequate capacity to care for pediatric cancer survivors in the US.
- Increasing numbers and capacity of LTFU programs
- Partnerships with the community
- Hybrid programs
  - Stratified by risk of survivor – low, med, high
  - Frequency and location based on risk

Passport for Care



Summary of treatment for the primary diagnosis

Passport for Care



SYSTEM	PLE	EVALUATION	BASELINE	FREQUENCY	REQUIREMENTS	GUIDELINE
Eyes/Ears/Nose/Mouth/Throat	ototoxicity: sensorineural hearing loss, tinnitus, vertigo	hearing difficulties (with/without background noise)		YEARLY		11
Eyes/Ears/Nose/Mouth/Throat	ototoxicity: sensorineural hearing loss, tinnitus, vertigo	tinnitus		YEARLY		11
Eyes/Ears/Nose/Mouth/Throat	ototoxicity: sensorineural hearing loss, tinnitus, vertigo	vertigo		YEARLY		11
Cardiovascular	cardiomyopathy arrhythmias: subclinical left ventricular dysfunction (systolic dysfunction as assessed by echocardiography or radionuclide angiocardiography)	SOB, DOE, orthopnea, chest pain, palpitations; if under 25 yrs: abdominal symptoms (nausea, vomiting)		YEARLY		22-m [22A]
Respiratory	pulmonary insufficiency	cough, SOB, DOE, wheezing		YEARLY		94
Genitourinary	hemorrhagic cystitis, bladder fibrosis, dysfunctional voiding, vesicoureteral reflux, hydronephrosis	frequency		YEARLY		8
Genitourinary	hemorrhagic cystitis, bladder fibrosis, dysfunctional voiding, vesicoureteral reflux, hydronephrosis	hematuria		YEARLY		8
Genitourinary	hypogonadism, infertility hypogonadism, infertility	medication use impacting sexual function		YEARLY		4-m [4A-1, 4A-2] DELETE [4A-2]
Genitourinary	hypogonadism, infertility hypogonadism, infertility	pubertal (onset, tempo)		YEARLY		4-m [4A-1, 4A-2] DELETE [4A-2]
Genitourinary	hypogonadism, infertility hypogonadism, infertility	sexual function (erections, nocturnal emissions, libido)		YEARLY		4-m [4A-1, 4A-2]

- **Follow-up guidelines are based on the cumulative summary and drawn from the guidelines database**
- **The display of periodic evaluations is organized by system and includes the PLE and frequency requirements.**

Patient Portals

e Health Record

- Medical Summary
- Progress notes
- Medications
- Labs/Tests
- Problem lists

Patient Portals

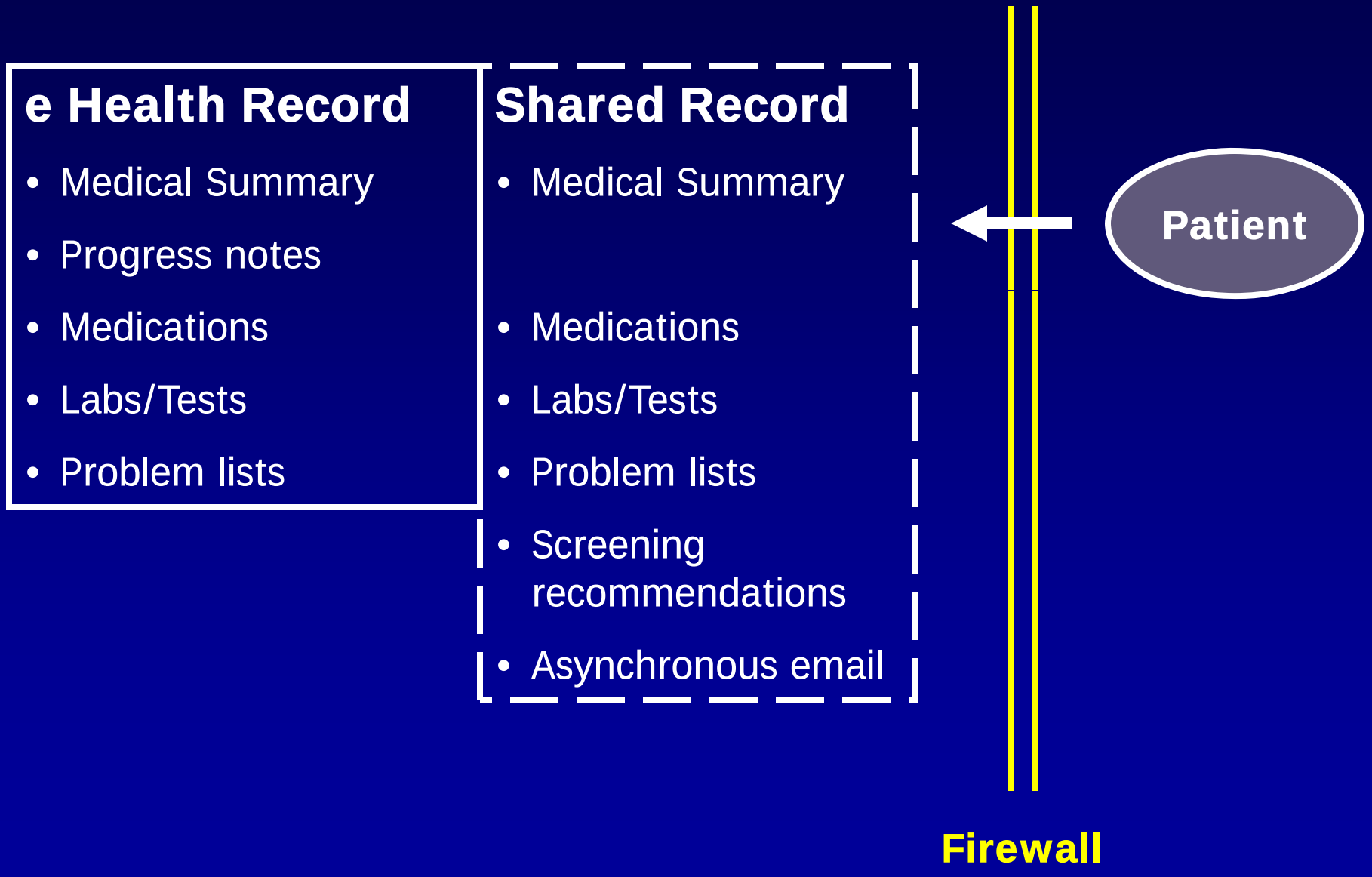
e Health Record

- Medical Summary
- Progress notes
- Medications
- Labs/Tests
- Problem lists

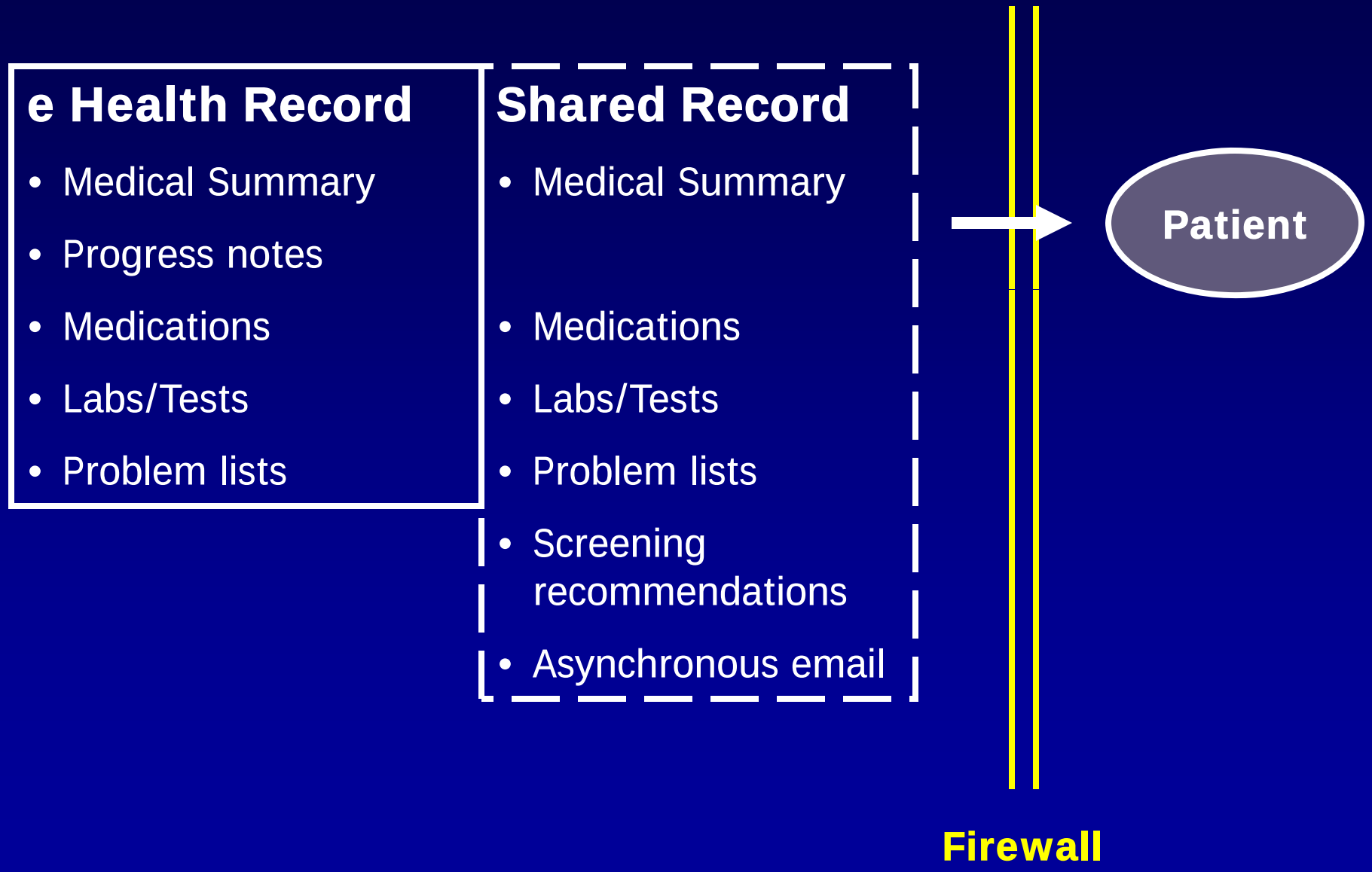
Shared Record

- Medical Summary
- Medications
- Labs/Tests
- Problem lists
- Screening recommendations
- Asynchronous email

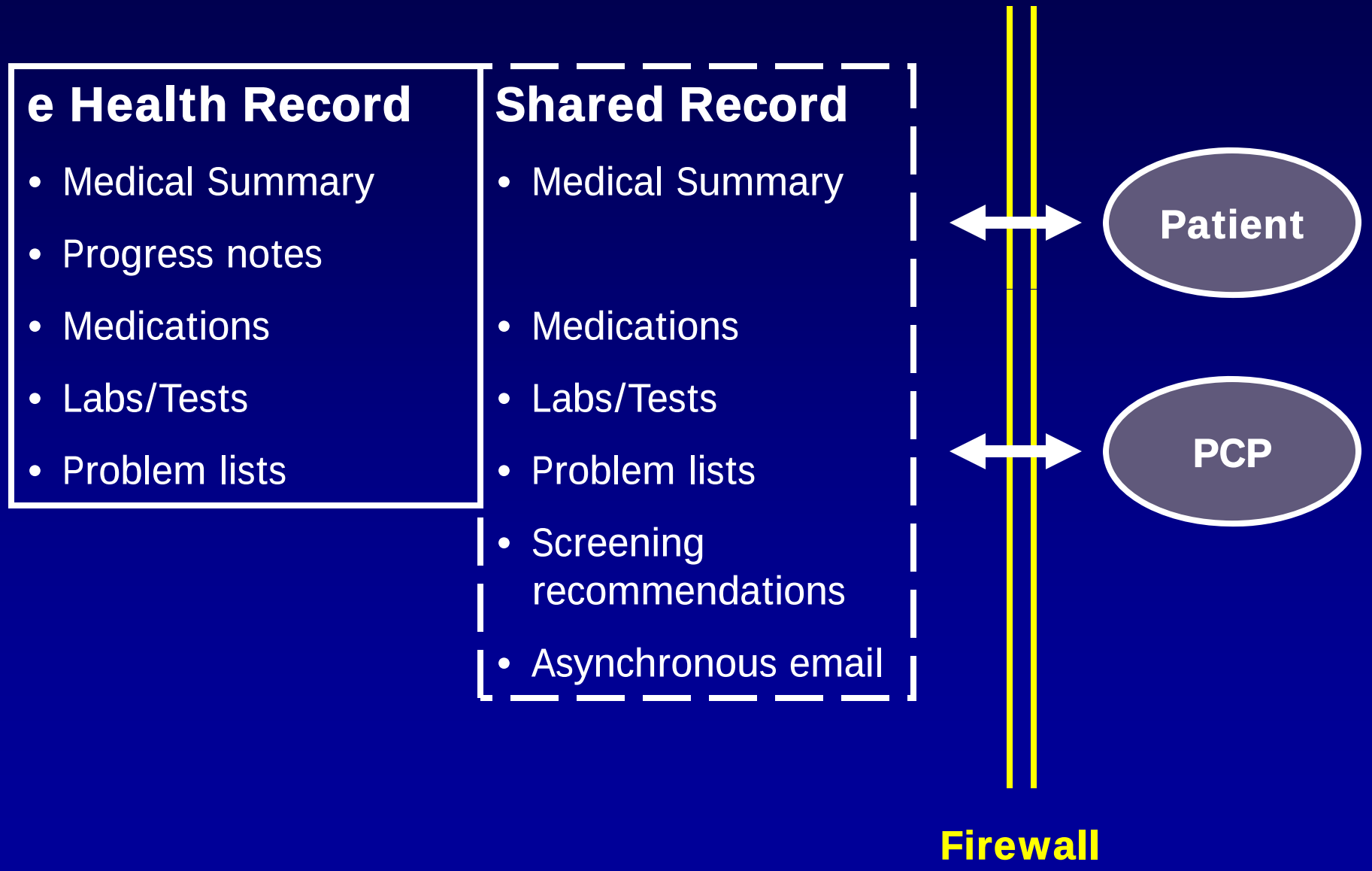
Patient Portals



Patient Portals



Patient Portals



Summary

- Cancer survivors face long-term risks
- Many late effects are modifiable
- Goal of risk-based survivor care:
  - Reduce morbidity and mortality
  - Enhance quality of life

Acknowledgments

- Leslie Robison, PhD
- Noreen Aziz, MD, PhD
- Melissa Hudson, MD
- Ann Mertens, PhD
- Charles Sklar, MD
- ❖ Our patients