QALYs as a Factor in Decision Making for Pharmaceuticals in the U.S.

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Question 1

How can we best use our resources to improve public health?

Level of Economic Analysis

- Macro level--informs policy
- Micro level-informs clinical decisions

Example Macro Problem

- Oregon - late 1980s
- Medcaid costs were increasing 25% per year
- Medicaid coped with the problem by changing eligibility threshold
- Number of people covered reduced to 200,000 among 600,000 eligible
- Proposed rationing services rather than people
- Goal was to increase number covered

Macro Level Decision

- Fixed level of resources
- Potentially infinite demand
- Need to make effective/efficient use of resources
- Set priorities-make choices

Micro Level Decision

- I am 82 years old
- I feel good and my memory is fine
- My doctor says I have >85% stenosis of my carotid arteries
- She wants to operate ASAP
- She says I may die from the surgery
- She also thinks I may die of a stroke
- What should I do?

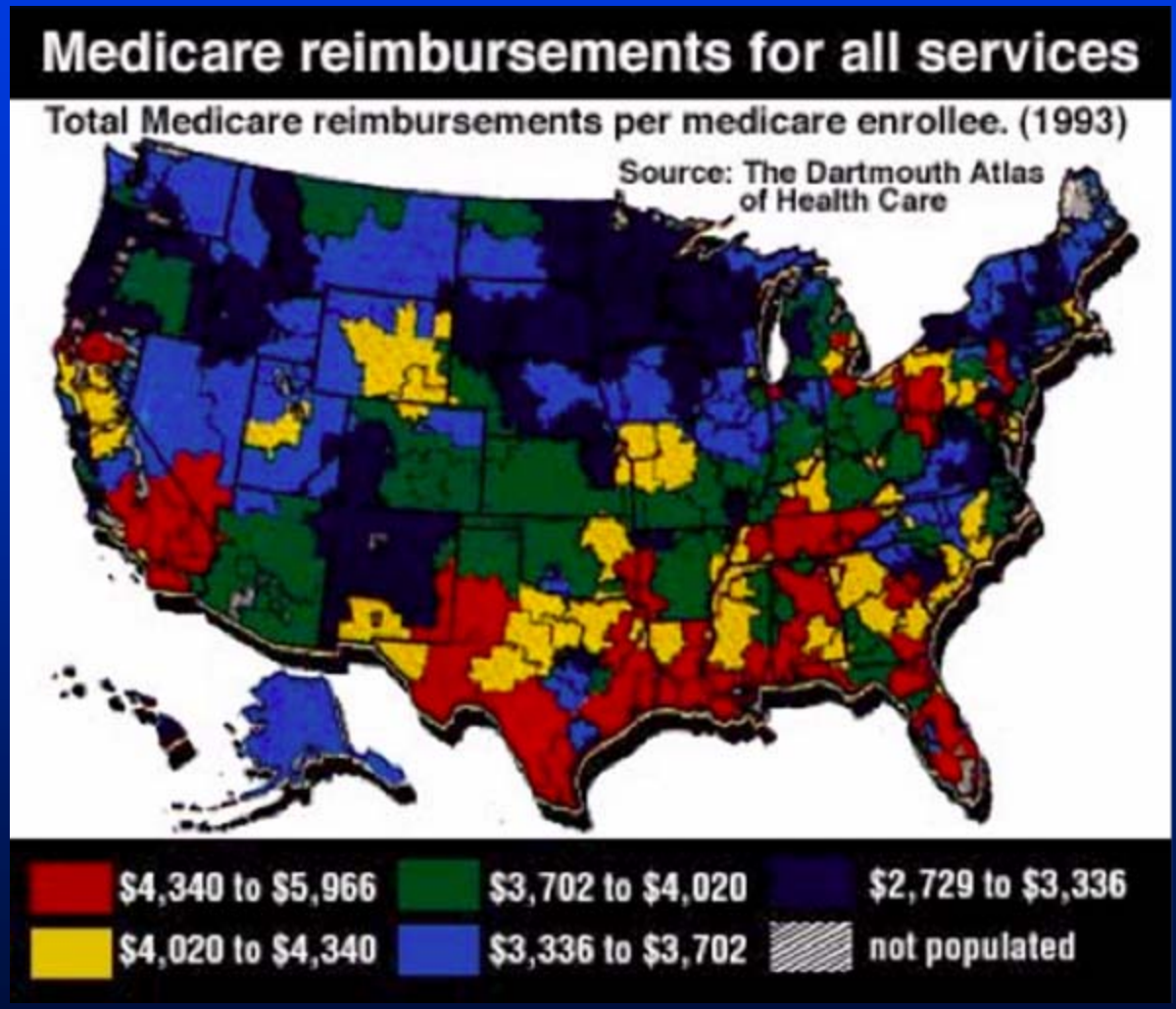
If widely different interventions are to be compared… ..

- The measure of health must be able to encompass not only differences in length of life but differences in the quality of that life, in symptoms and ability to function.

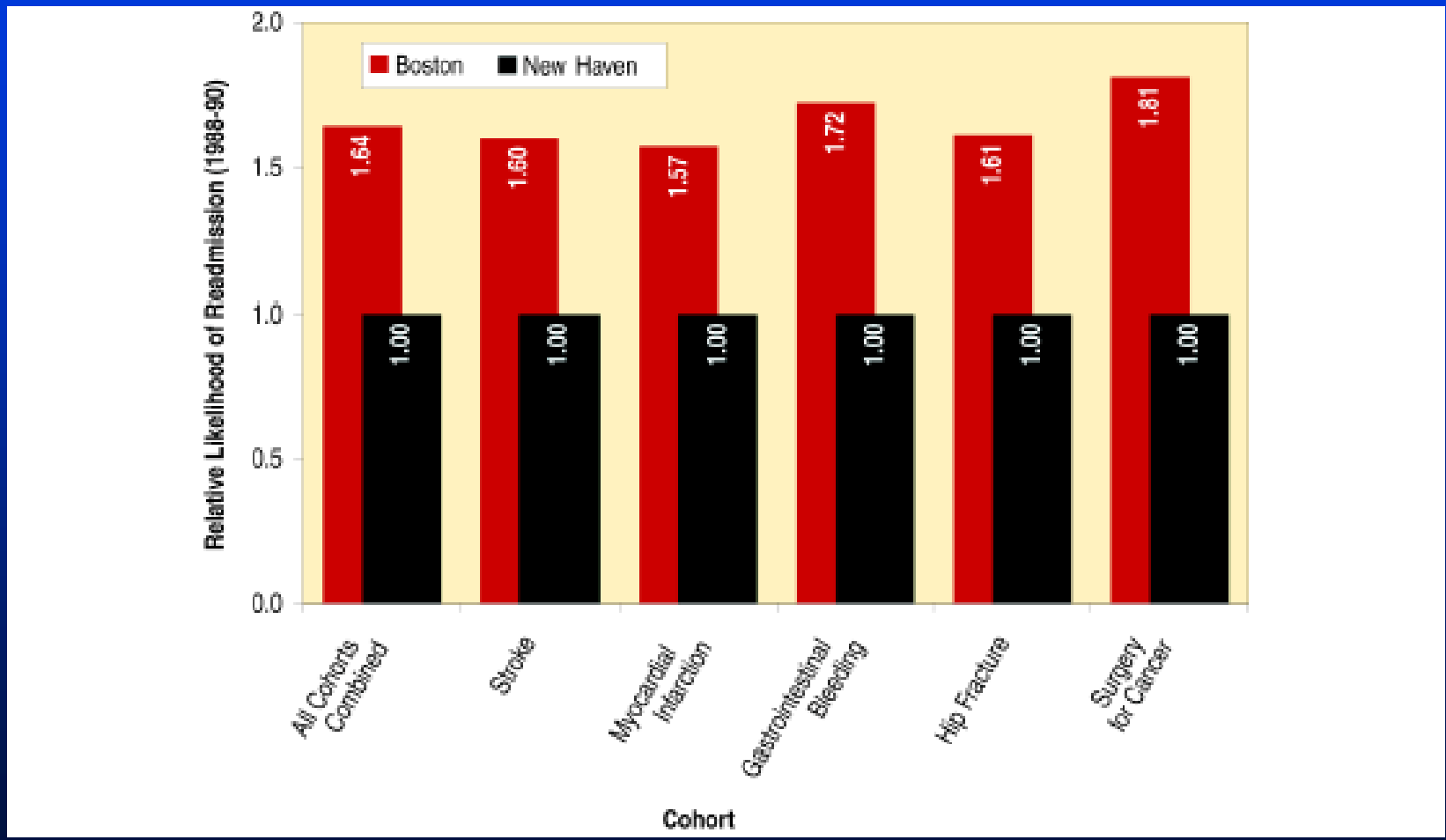
Overview

- Cost-utility analysis
  - Effectiveness measured as Quality Adjusted Life Years
- Societal Perspective
  - Related medical and nonmedical costs included
- Time Horizons
  - Primary: within trial
  - Secondary: projected 5- and 10-year outcomes

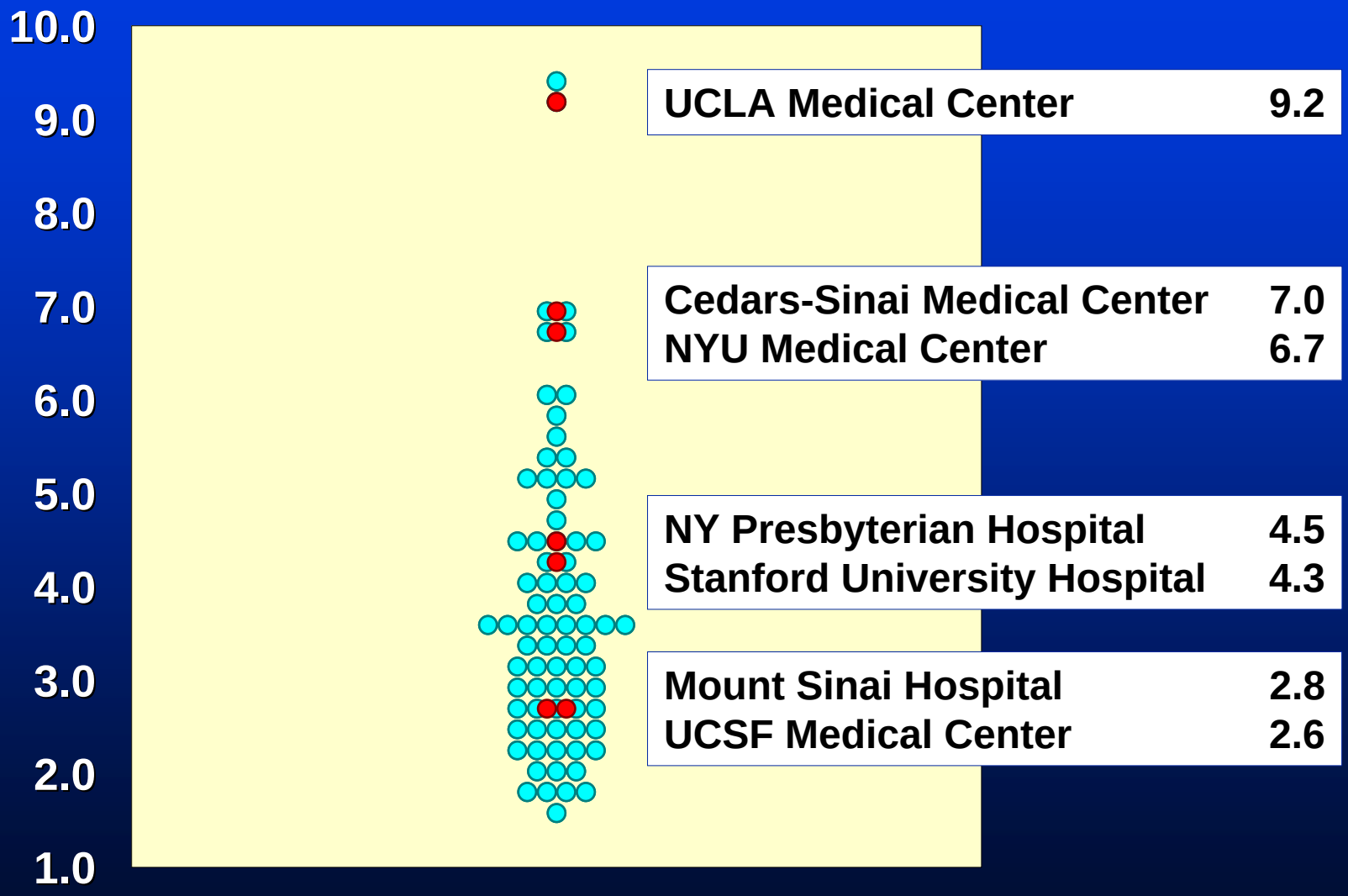
Medicare Expense Variations

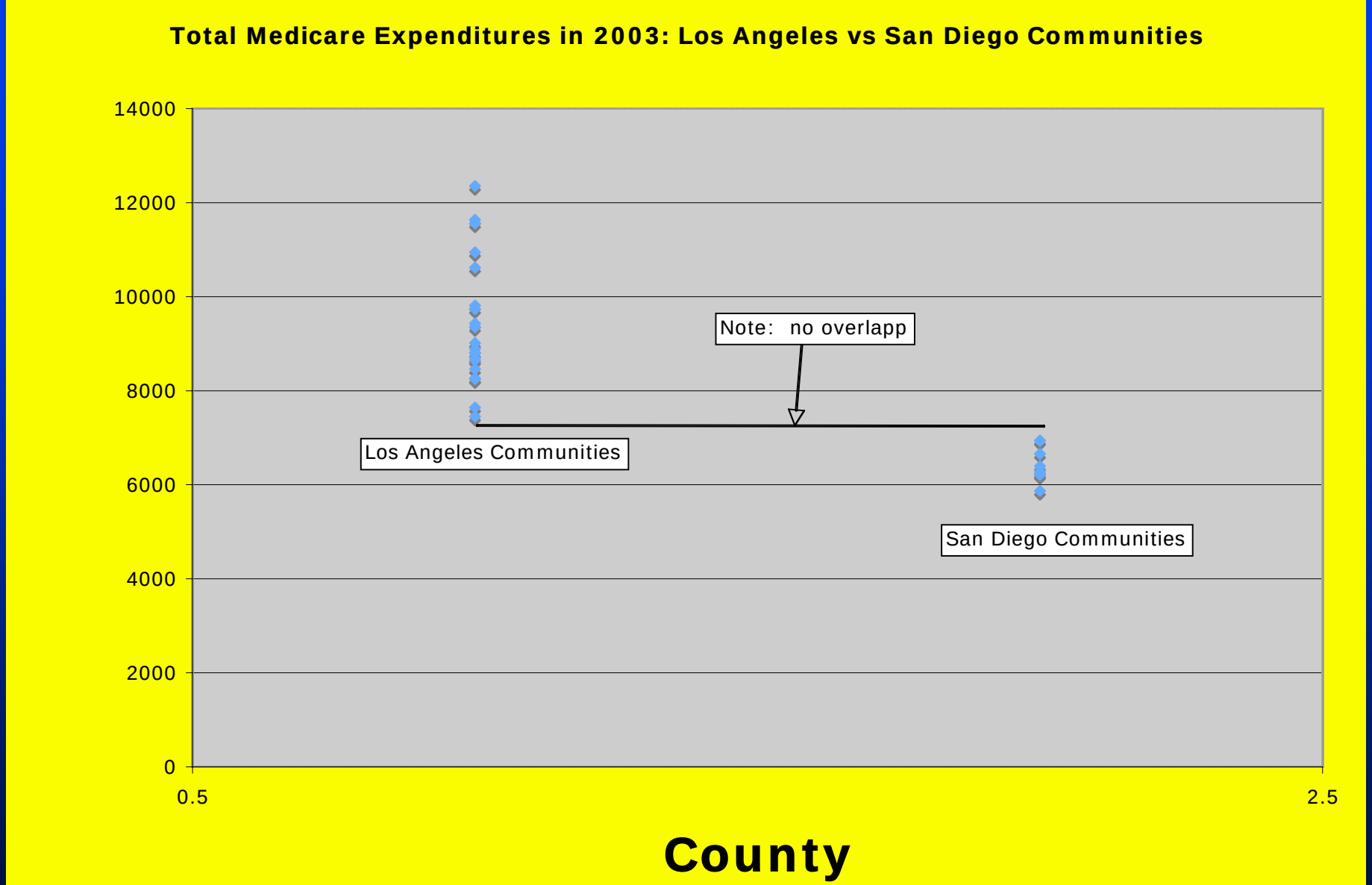


The Boston New Haven Difference Continues Through 2000

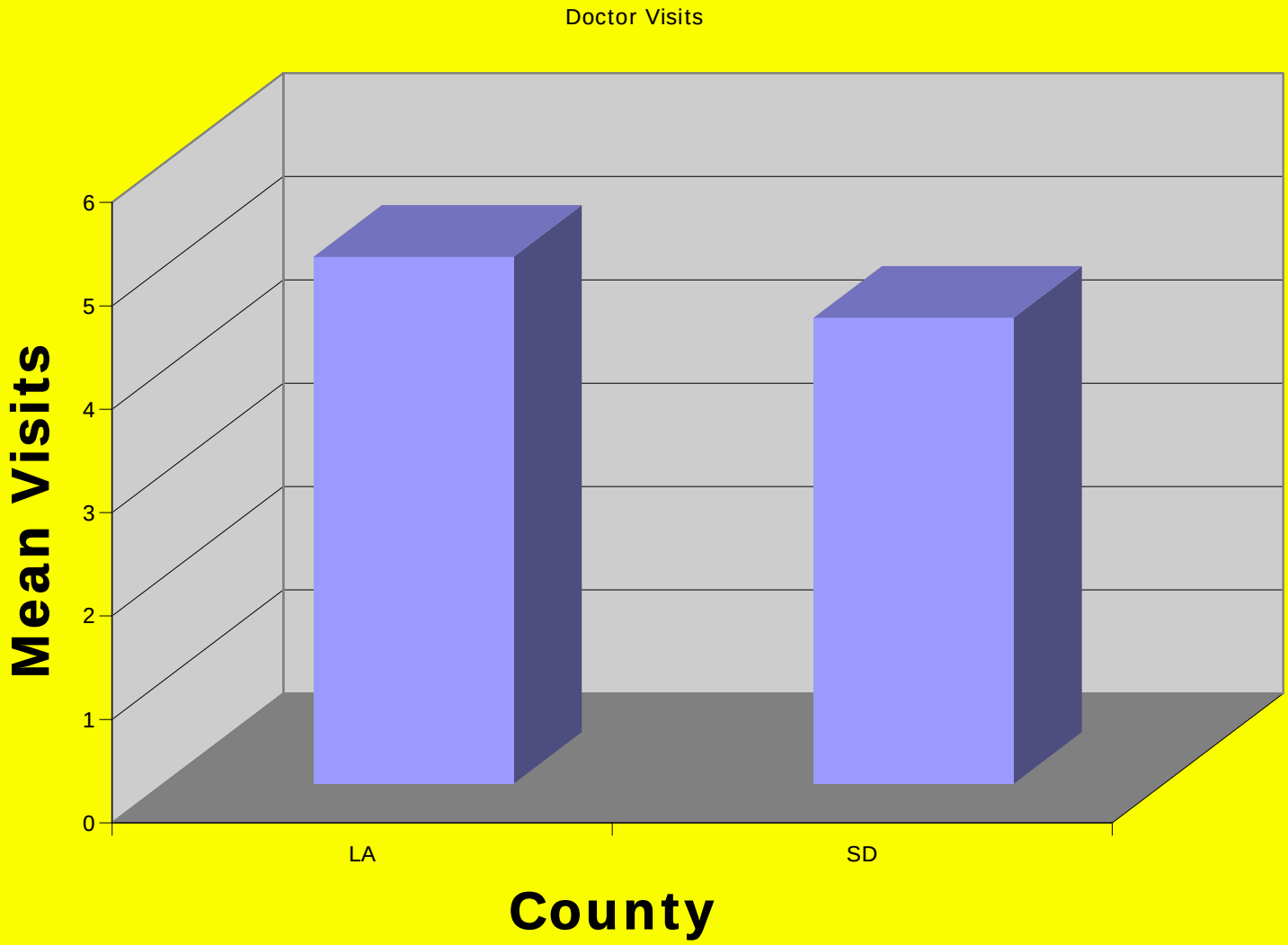


Days spent in intensive care during last six months of life among patients receiving most of their care in one of 77 “best” US hospitals (Wennberg, 2005)

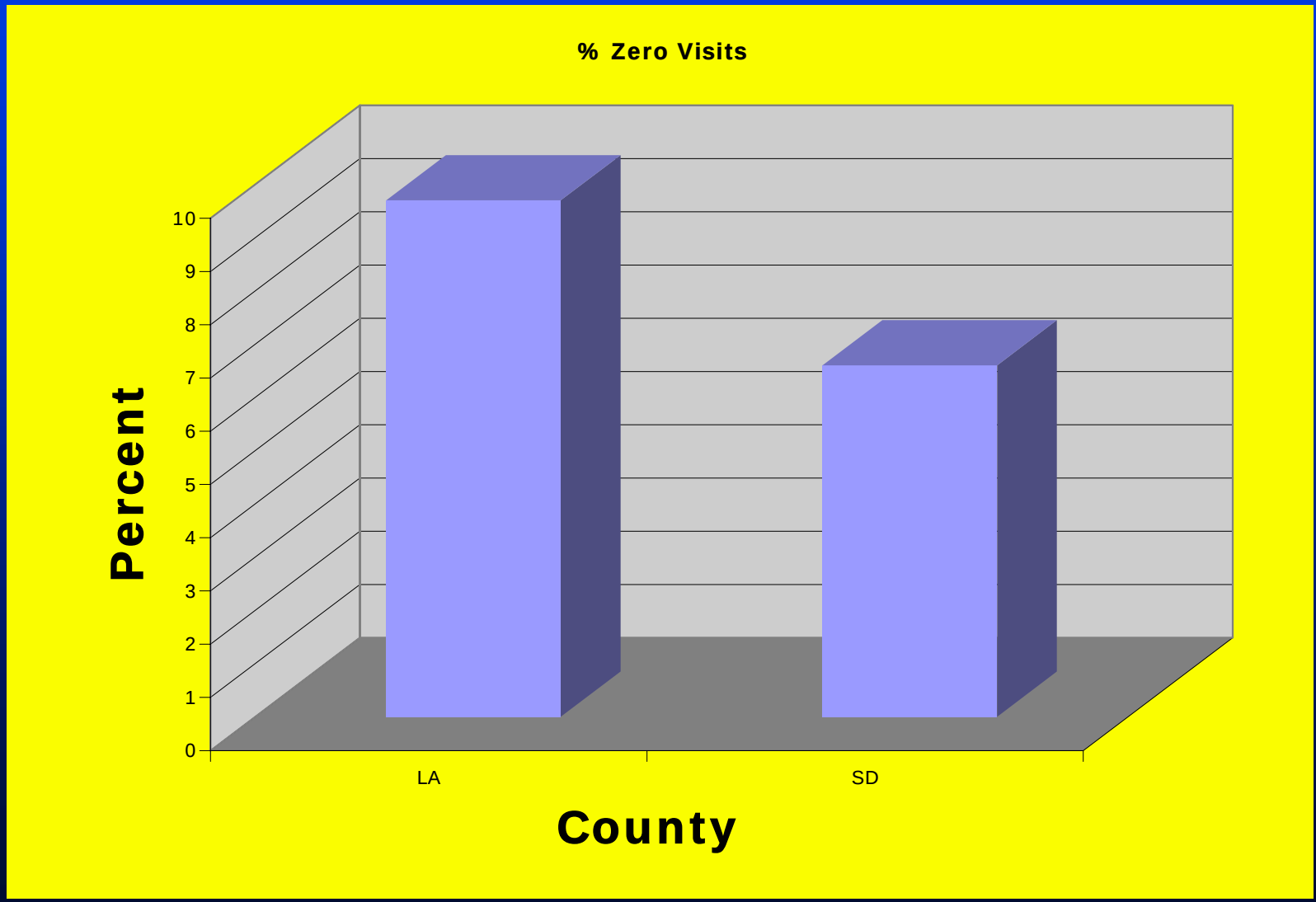



Total Medicare Expenditures in 2003: Los Angeles vs San Diego Communities
14000
12000
10000
8000
6000
4000
2000
0
0.5
2.5
Note: no overlapp
Los Angeles Communities
San Diego Communities
County

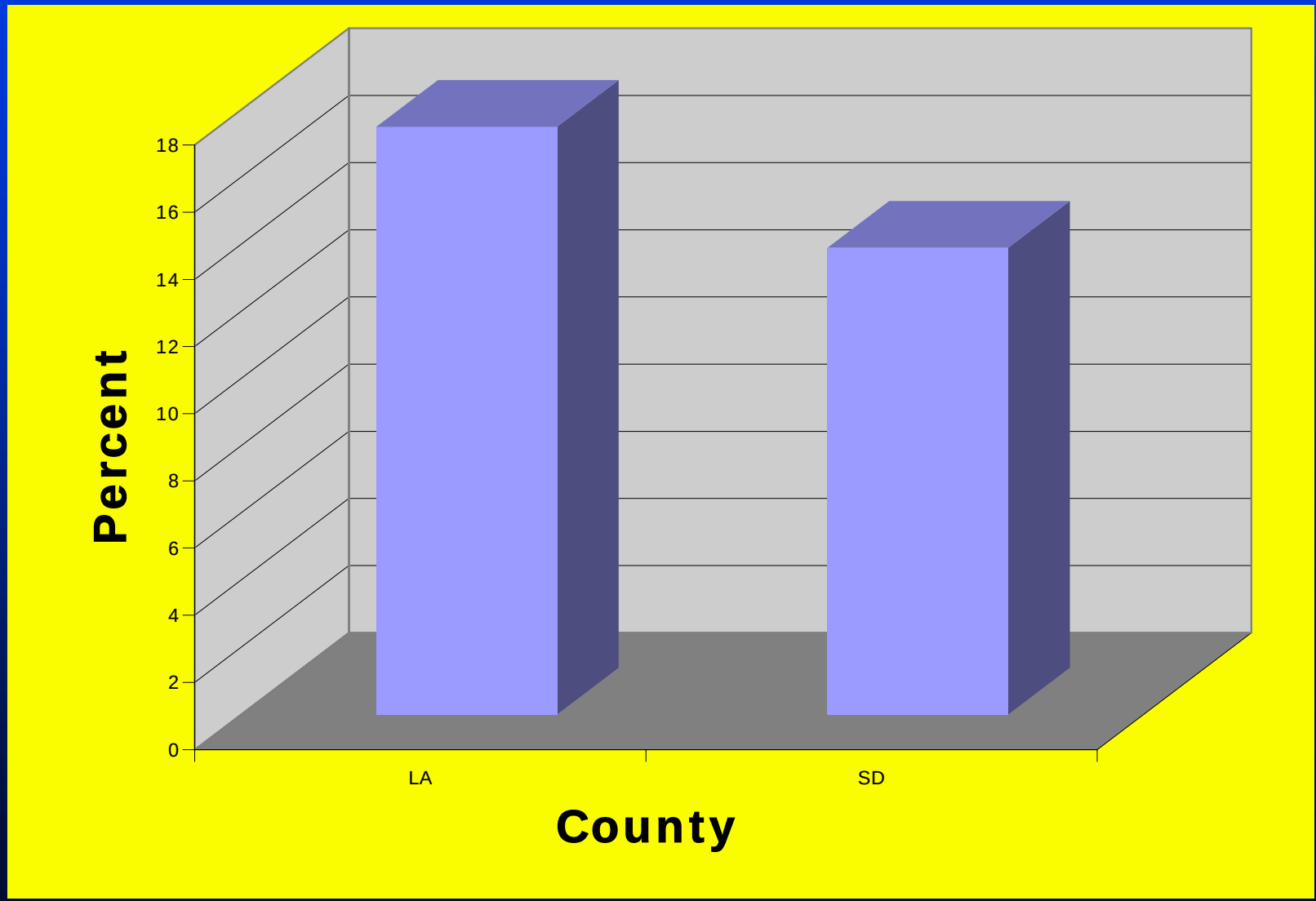
Physician Visits LA vs SD CHIS 2005



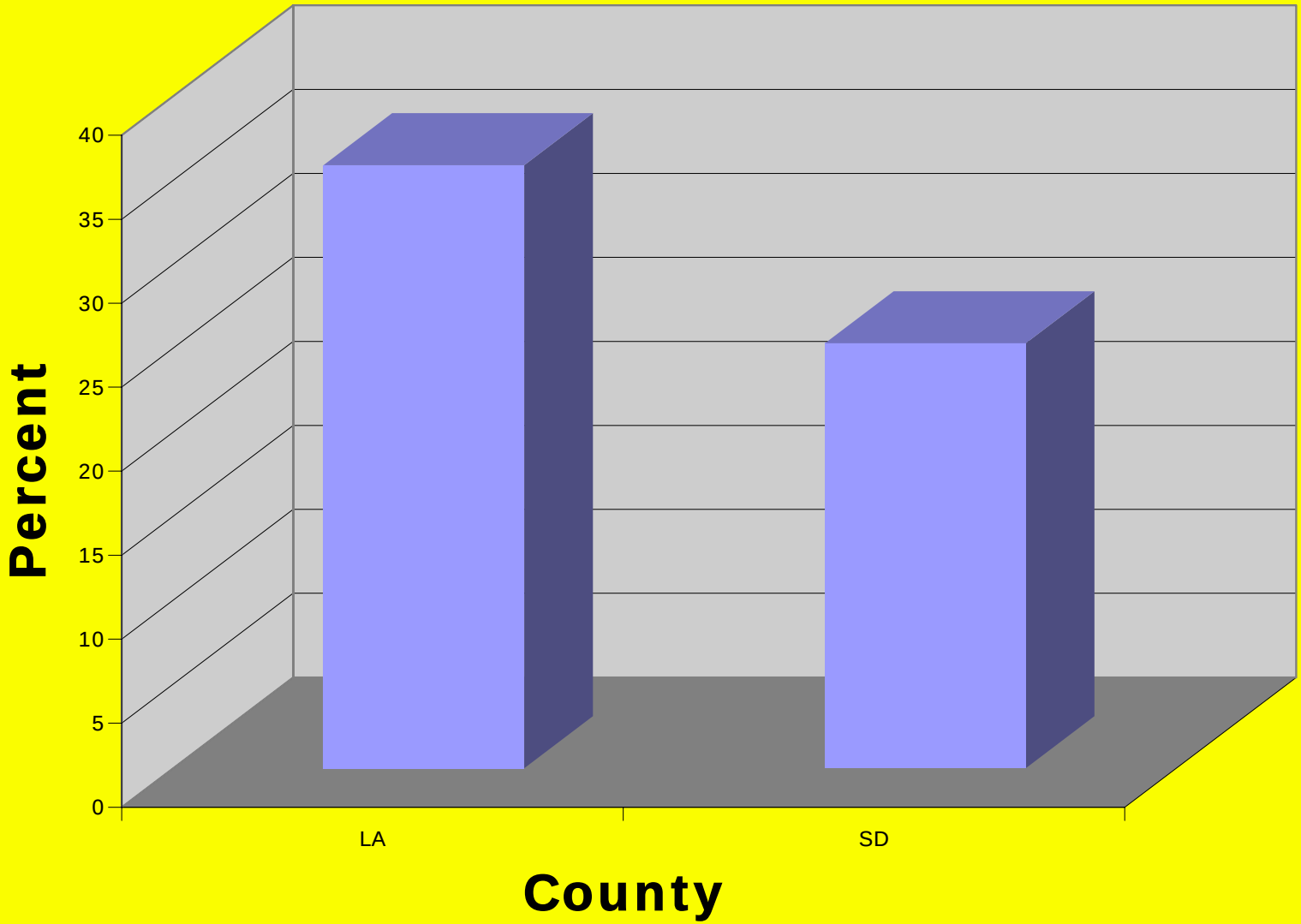
Percent Medicare Recipients With No Physician Visits: CHIS 2005



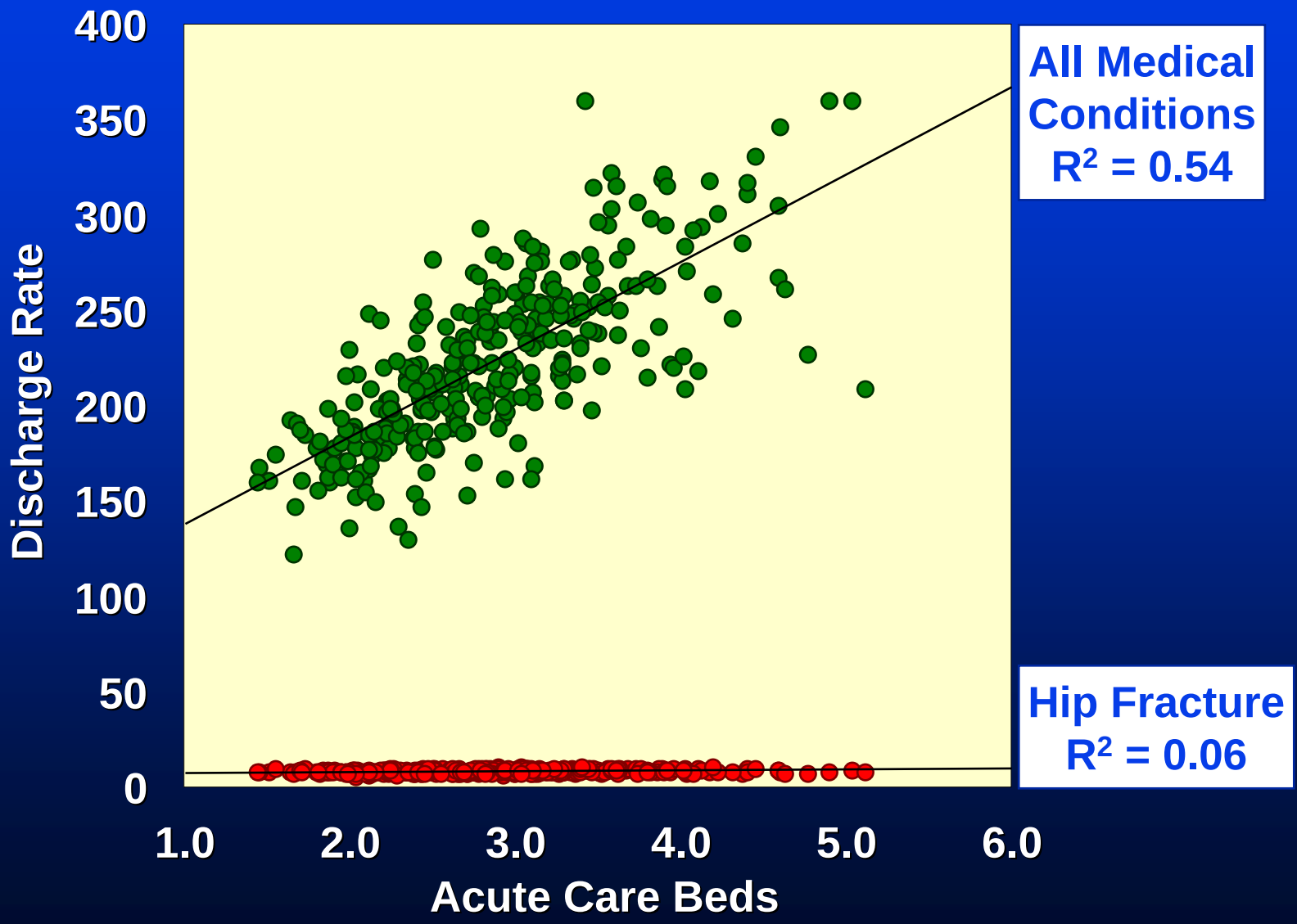
Percent Medicare Recipients In Hospital Last 12 Months: CHIS 2005



Percent Medicare Recipients In Fair or Poor Health (by self report): CHIS 2005



Association between hospital beds per 1,000 (1996) and discharges per 1,000 (1995-96) among Medicare enrollees in 306 HRRs (Wennberg, 2005)



Per capita resource inputs and health outcomes: Ratio high/low quintiles of spending among 306 HRRs

Resource Inputs	
Medicare Spending	1.61
Hospital Beds (1000)	1.32
Physician Supply*	
All Physicians	1.31
Medical Specialists	1.65
General Internists	1.75
Family Practice	0.74
Surgeons	1.37

*per 10,000

Cohort Health Outcomes

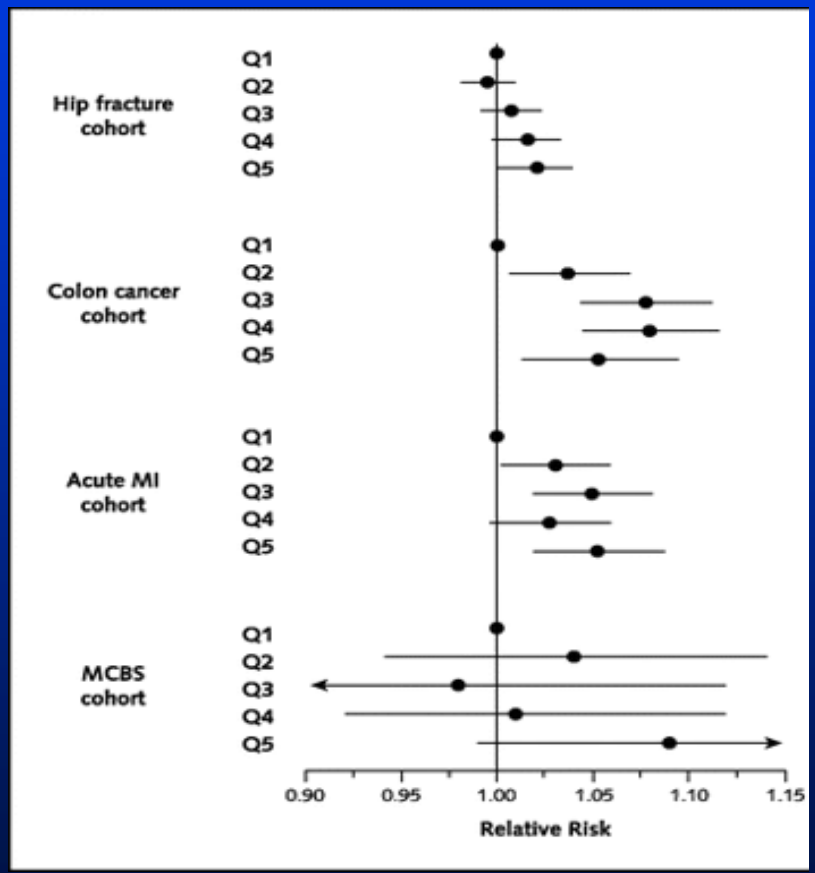
Death	R.R.	95% CL
Hip Fracture	1.019	1.001-1.039
Colon Cancer	1.012	1.018-1.094
Heart Attack	1.052	1.018-1.094

Functional Status: No difference

Satisfaction: No difference

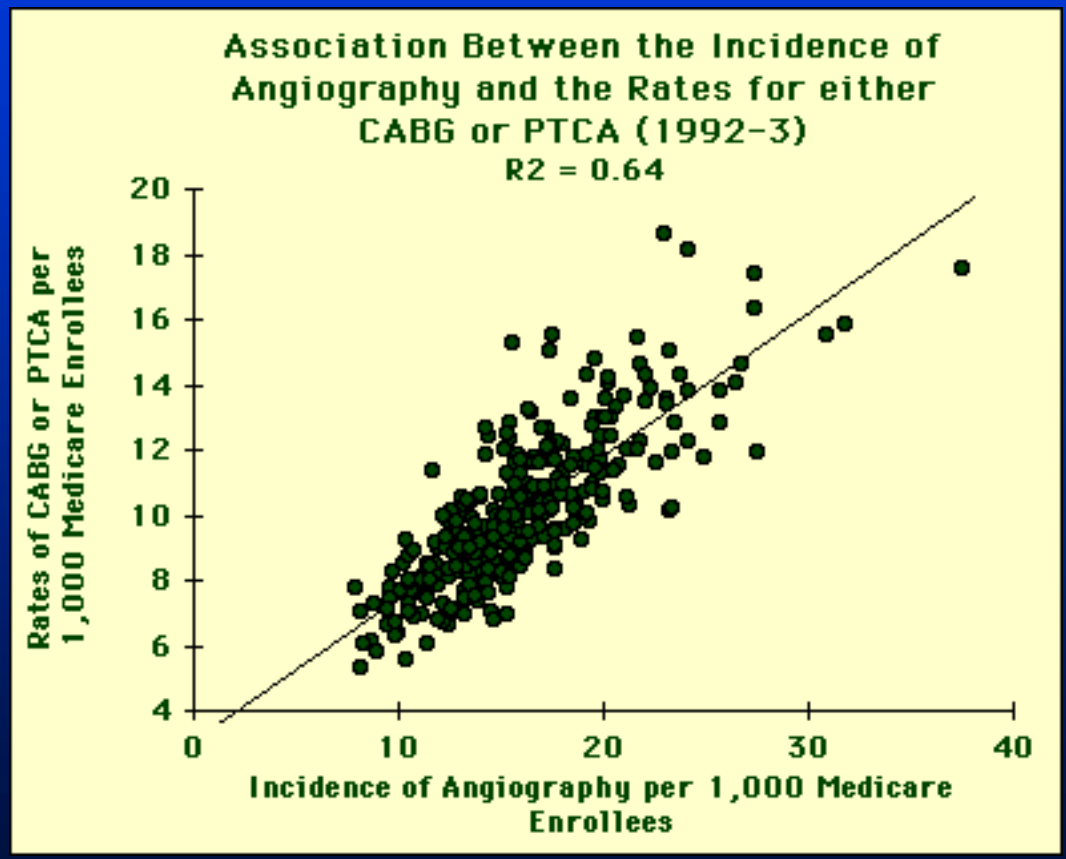
Access: Worse

Adjusted relative risk for death during follow-up across quintiles of Medicare spending (Fisher et al. Ann. Int Med, 2003, 138, 288)



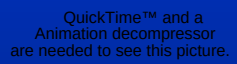
- Circles represent adjusted relative risk for death among residents of hospital referral regions in the specified quintile of the End-of-Life Expenditure Index (EOL-EI) compared to the risk for death among residents of hospital referral regions in quintile 1 of the EOL-EI; bars represent 95% CIs. MCBS = Medicare Current Beneficiary Survey; MI = myocardial infarction; Q1 = quintile 1; Q2 = quintile 2; Q3 = quintile 3; Q4 = quintile 4; Q5 = quintile 5.
- Higher expenditure areas have more, rather then less mortality

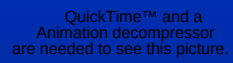
Relationship between angiography and procedures



Angiography US Vs. Canada

Where would you prefer to have your MI. USA or Canada?





Procedures US Vs Canada

Mortality US Vs Canada

Example Policy Problem

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Oregon Medicaid Experiment

- **Initial proposal included prioritization by cost/utility of as an alternative to a more subjective approach**

Oregon Prioritized List, February 1995 (Top)

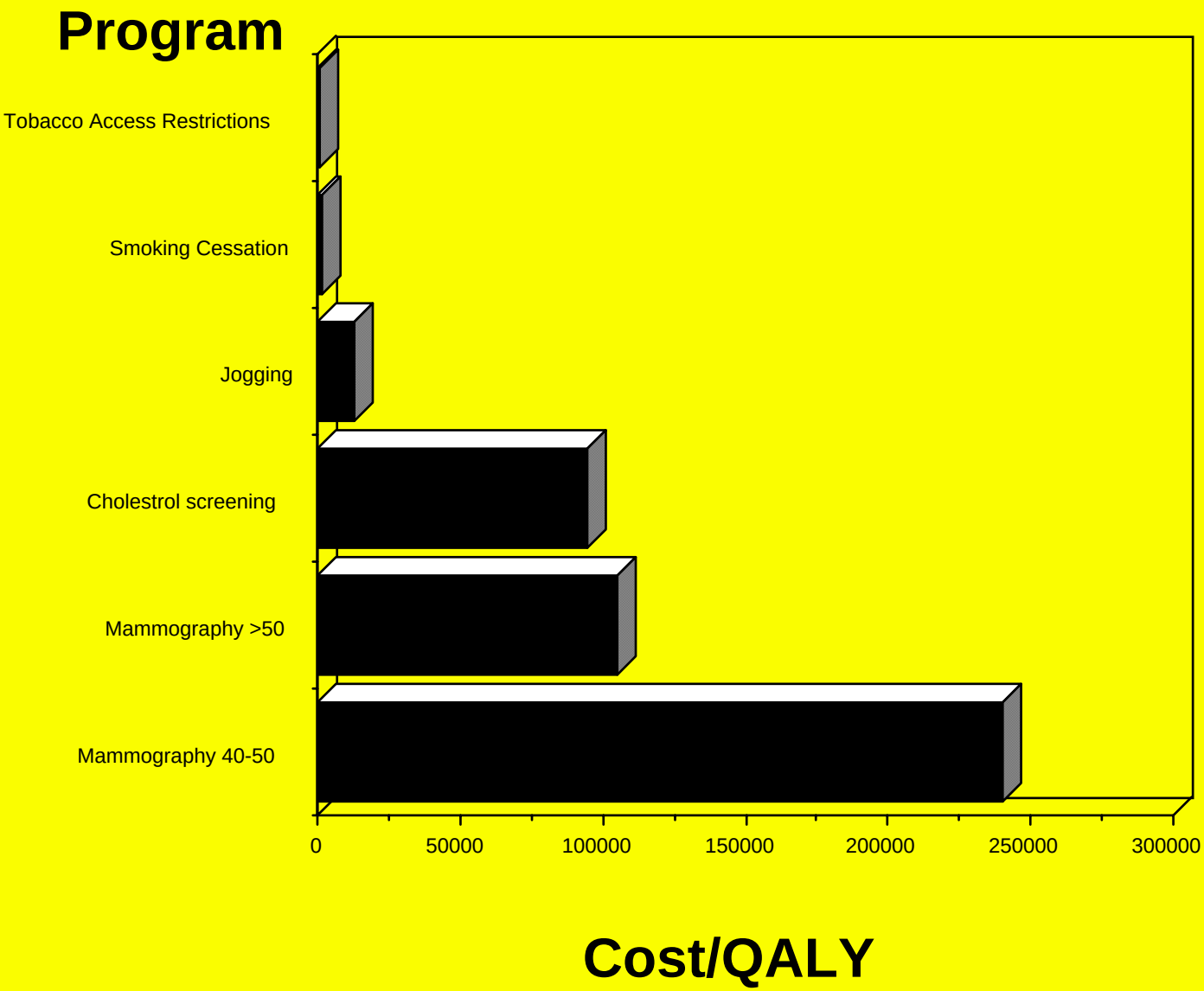
- Medical or surgical treatment for moderate or severe head injury
- Medical therapy, insulin dependent diabetes mellitus
- Treatment of peritonitis
- Therapy (including dialysis) for acute glomerulonephritis

Oregon Prioritized List, February 1995 (Middle)

- Medical therapy for rheumatoid arthritis
- Medical/psychotherapy for anxiety disorder
- Surgical repair for cleft palate
- Medical therapy for rheumatic fever

Oregon Prioritized List, February 1995 (Bottom)

- Evaluation of conditions of the eye for which there is no effective treatment
- Evaluation of conditions of the heart for which there is no effective treatment
- In-vitro fertilization for tubal dysfunction
- Radial keratotomy for disorders of refraction


Program
Tobacco Access Restrictions
Smoking Cessation
Jogging
Cholestrol screening
Mammography >50
Mammography 40-50
0
50000
100000
150000
200000
250000
300000
Cost/QALY

NETT Policy Impact

- May 22, 2003. NETT results published in NEJM
- August 10, 2003. CMS announces intent to cover LVRS for groups that benefited in trial
- November 7, 2003. CMS Announces coverages guidelines for LVRS
- January 1, 2004. Coverage begins

Effects of interventions in DPP (DPP Group 2003, Diabetes Care 26: 2518)

Table 2— Health utility scores and QALYs gained by treatment group and year

	Utility scores			QALYs gained		
	Lifestyle	Metformin	Placebo	Lifestyle vs. placebo	Metformin vs. placebo	Lifestyle vs. metformin
Year						
1	0.703 ± 0.118	0.687 ± 0.119	0.686 ± 0.121	0.017	0.001	0.016
2	0.695 ± 0.122	0.680 ± 0.123	0675 ± 0.122	0.020	0.005	0.015
3	0.692 ± 0.125	0.673 ± 0.117	0.657 ± 0.125	0.035	0.016	0.019
Total				0.072	0.022	0.050

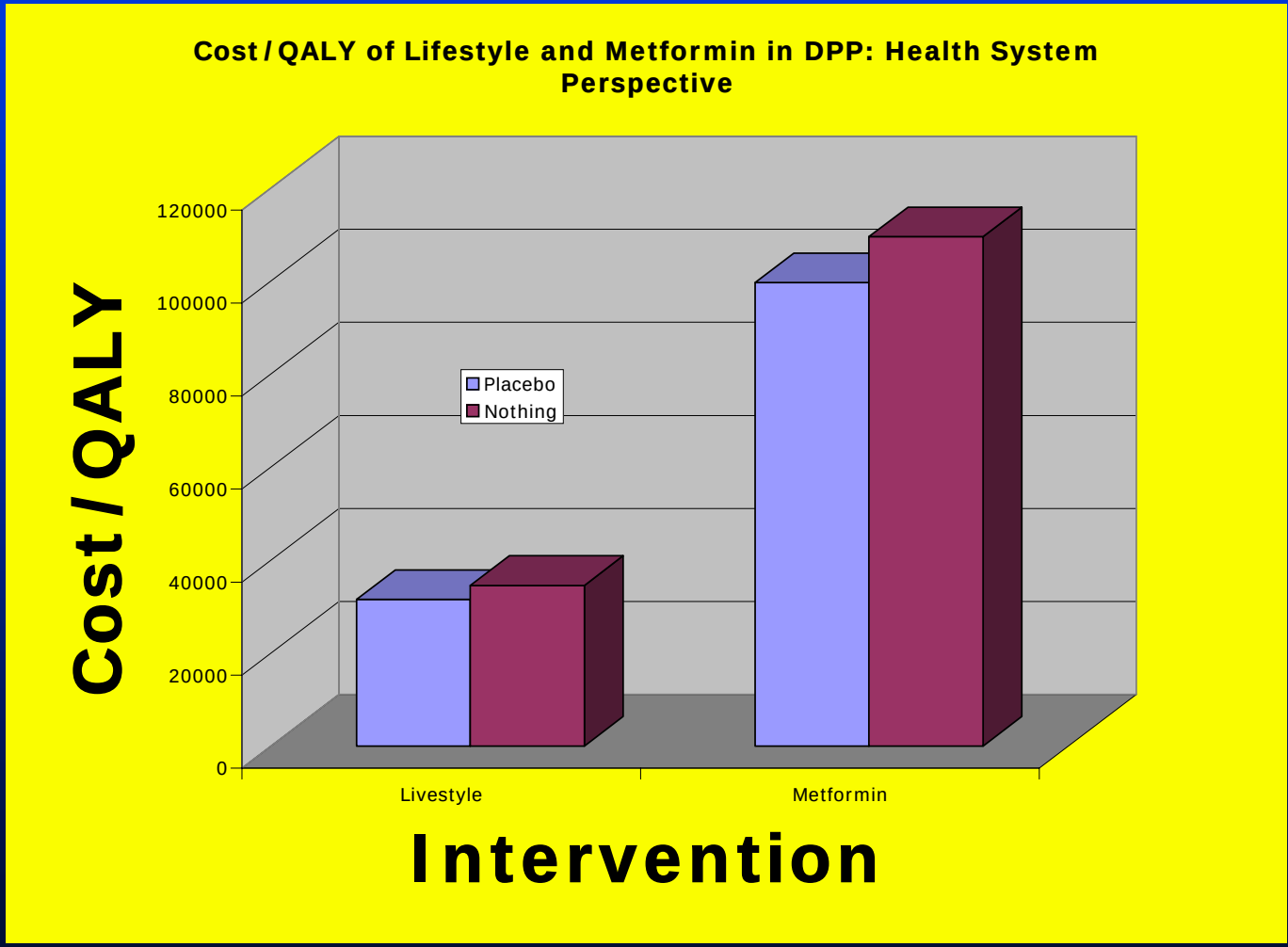
Data are means ± SD.

Costs of interventions in DPP (DPP Group 2003, Diabetes Care 26: 2518)

Table 1— Summary of total and incremental costs of the lifestyle, metformin, and placebo interventions in year-2000 U.S. dollars

	Lifestyle	Metformin	Placebo	Lifestyle vs. placebo	Metformin vs. placebo	Lifestyle vs. metformin
Direct medical costs						
Case finding	139	139	139	0	0	0
Intervention	2,780	2,542	79	2,701	2,463	238
Care outside DPP	4,579	4,739	5,011	-432	-272	-160
Total costs from health system perspective	7,498	7,420	5,229	2,269	2,191	78
Direct nonmedical costs	17,137	15,683	15,692	1,445	-9	1,455
Indirect costs	2,430	2,834	2,604	-174	230	-404
Total costs from societal perspective	27,065	25,937	23,525	3,540	2,412	1,128

Cost/QALY in DPP (DPP Group 2003, Diabetes Care 26: 2518)



What has held us back?

- Distractions
  - Disagreements on which measure is best
  - Disagreements on general philosophy of outcome measurement
    - » Generic vs disease specific
    - » Psychometric vs. utility based
    - » Disciplinary differences – statistics, economics, medicine, psychology, anthropology….

We do agree on some of the core issues

- Most measures can be traced back to Sullivan (1966)
  - Sullivan rarely cited
- Content of items is remarkably similar
- Most measures combine measures of life length and life quality
- Most quality of life measures are hybrid health status/utility measures
  - Health states and health weights (Erickson)

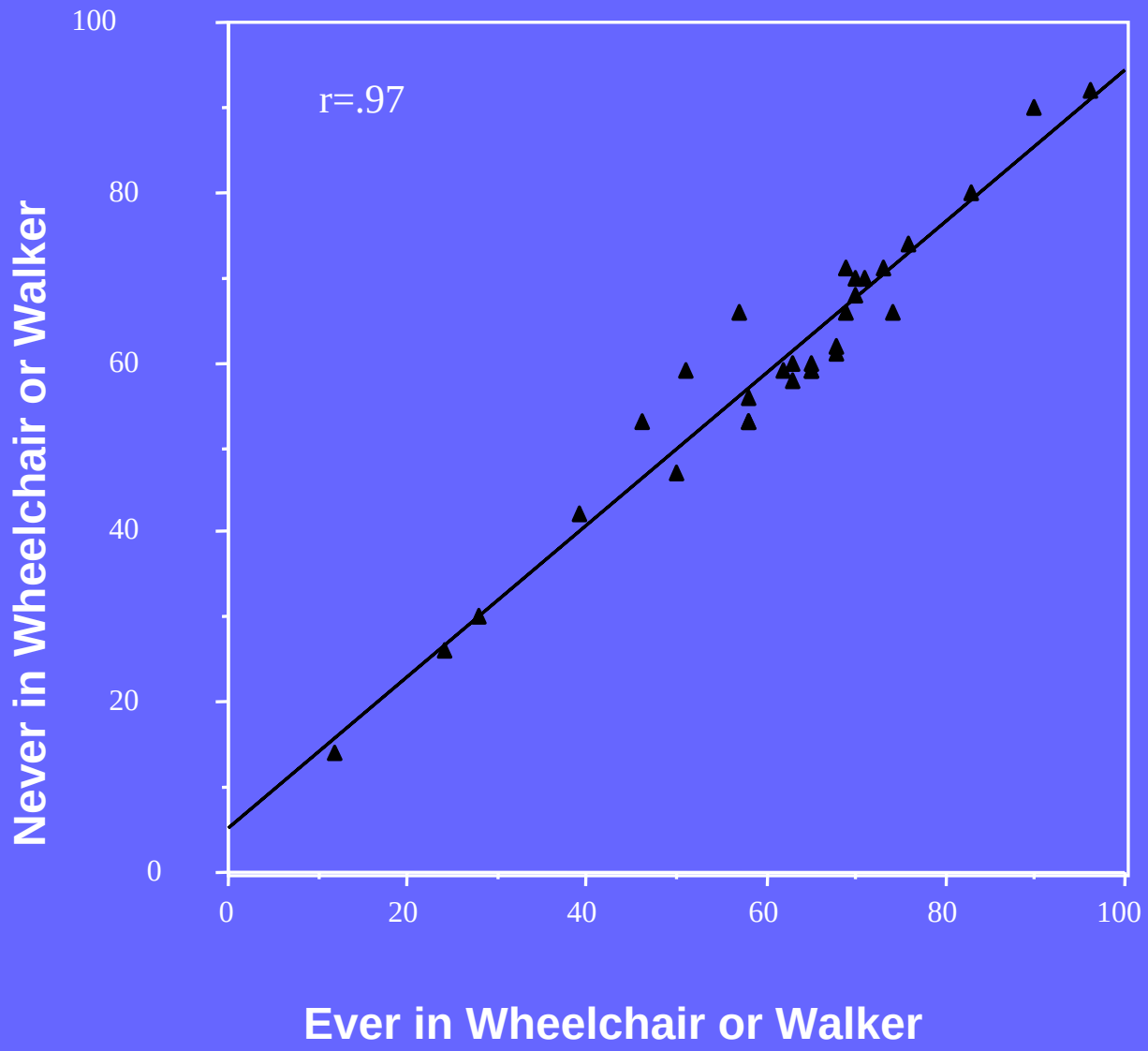
John Ware

- Think of different approaches as brand names of products designed to measure the same underlying construct… health

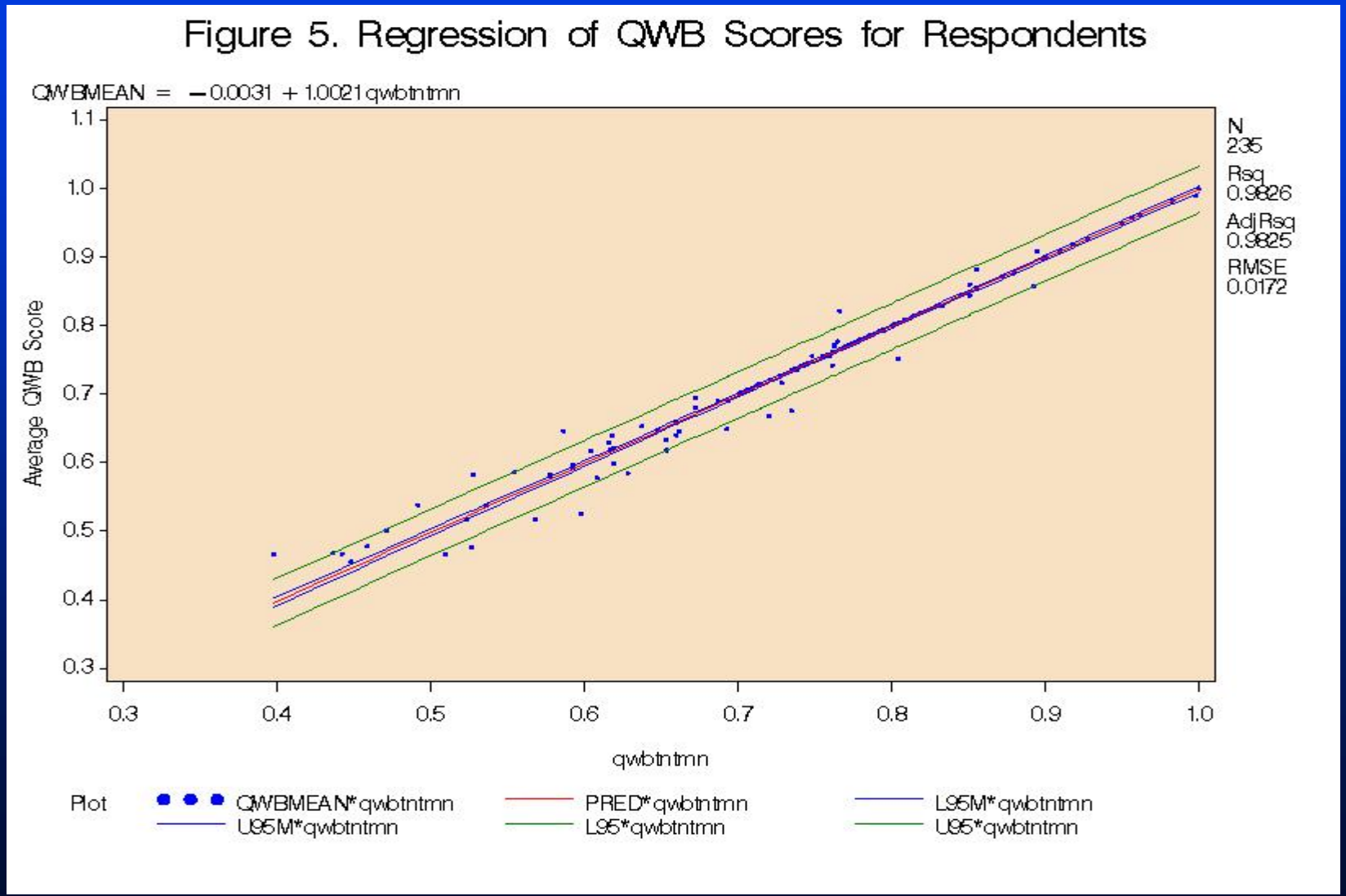
Response Shift

- Preferences of patients and non-patients differ
- As a result, preferences weights have no meaning
- But, is this supported by evidence?

Comparison between ever and never in wheelchair or walker for 31 items:
Data from Oregon Health Services Commission



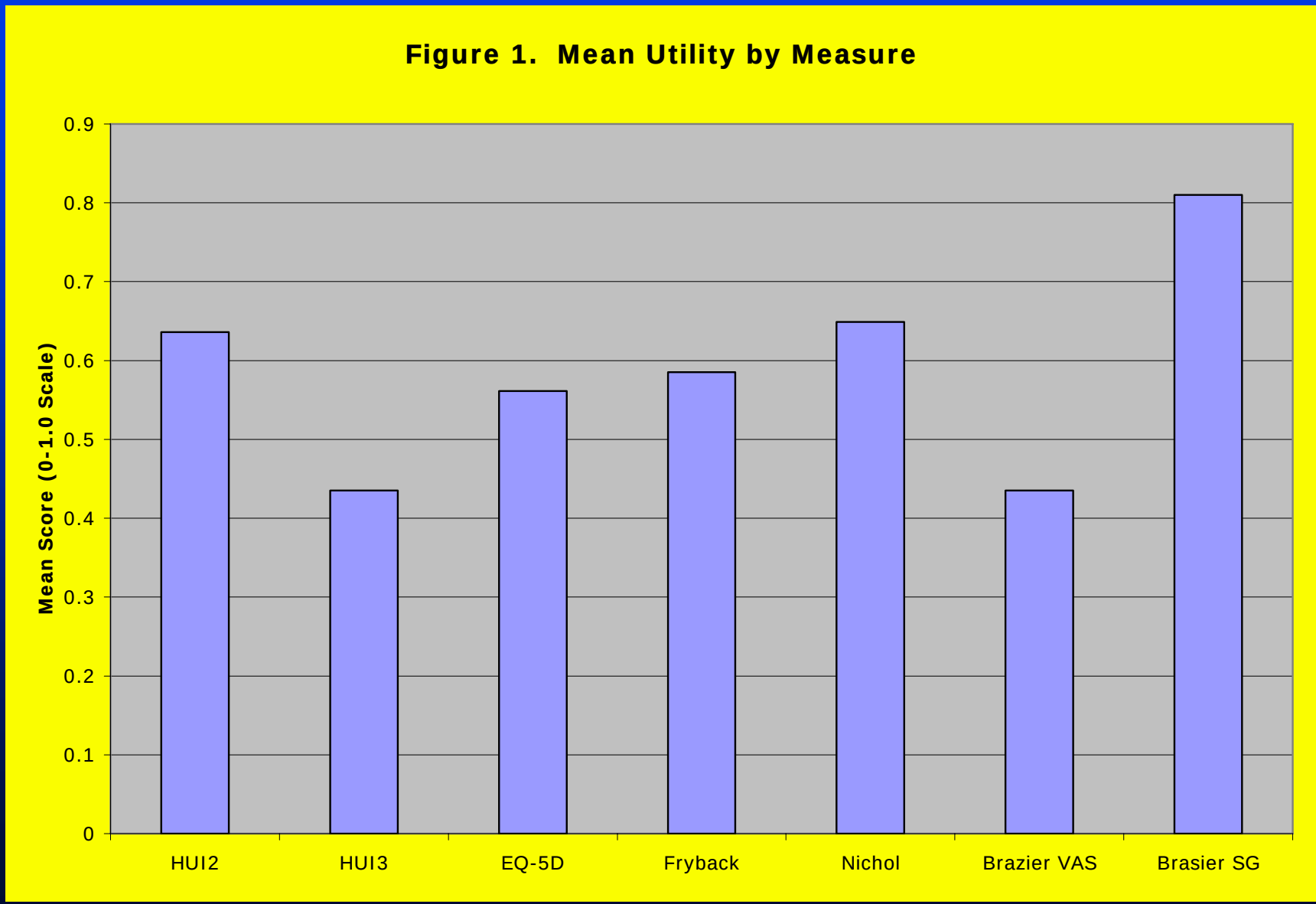
QWB Weights US- 1975 vs Trinidad-Tobago 2000 (from Hector 2007)



Preference and Utility Assessment

- Standard Gamble
- Time Trade-off
- Rating Scales
- Think scoring systems

Mean Utility by Measure



All measures captured clinical change

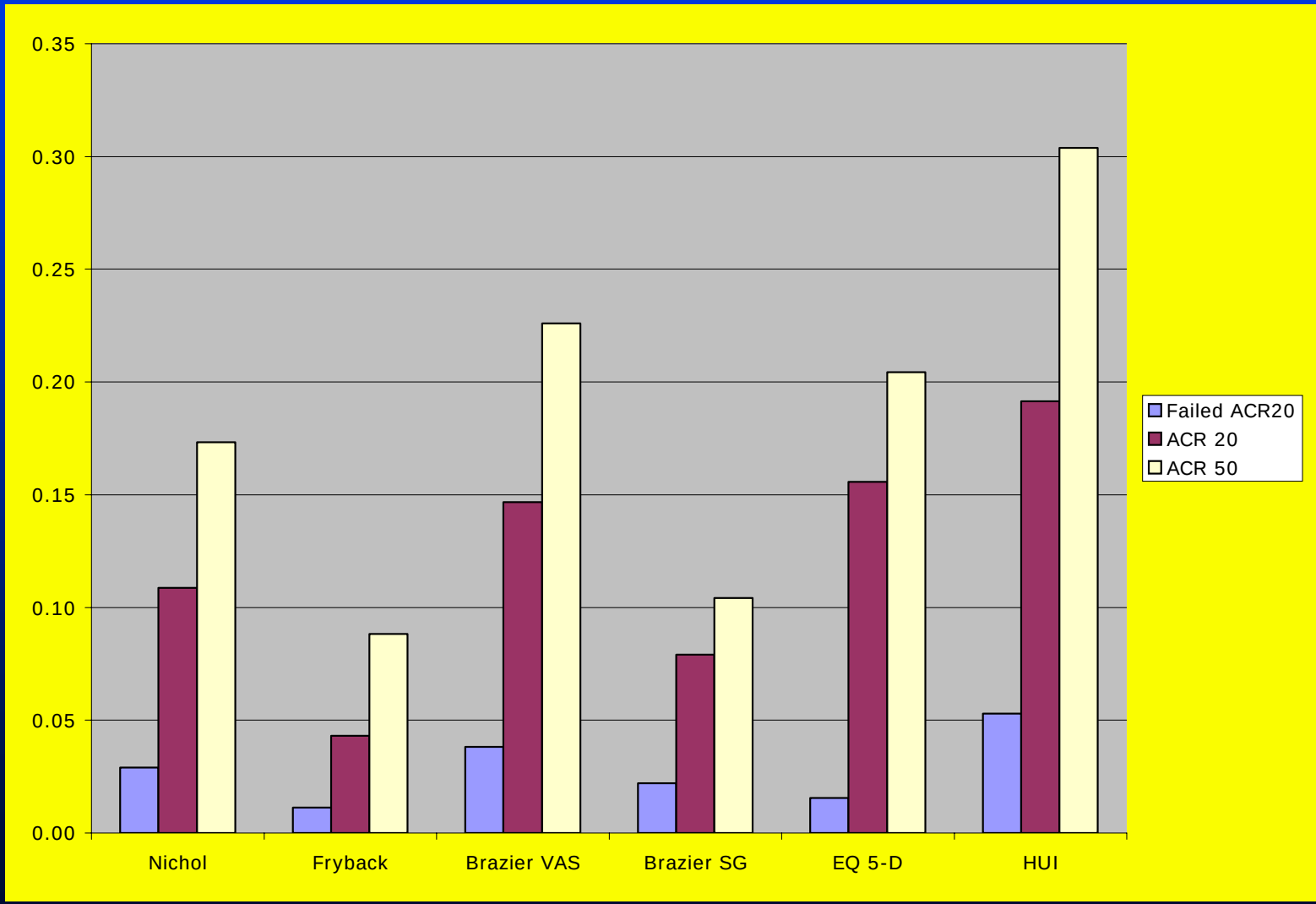
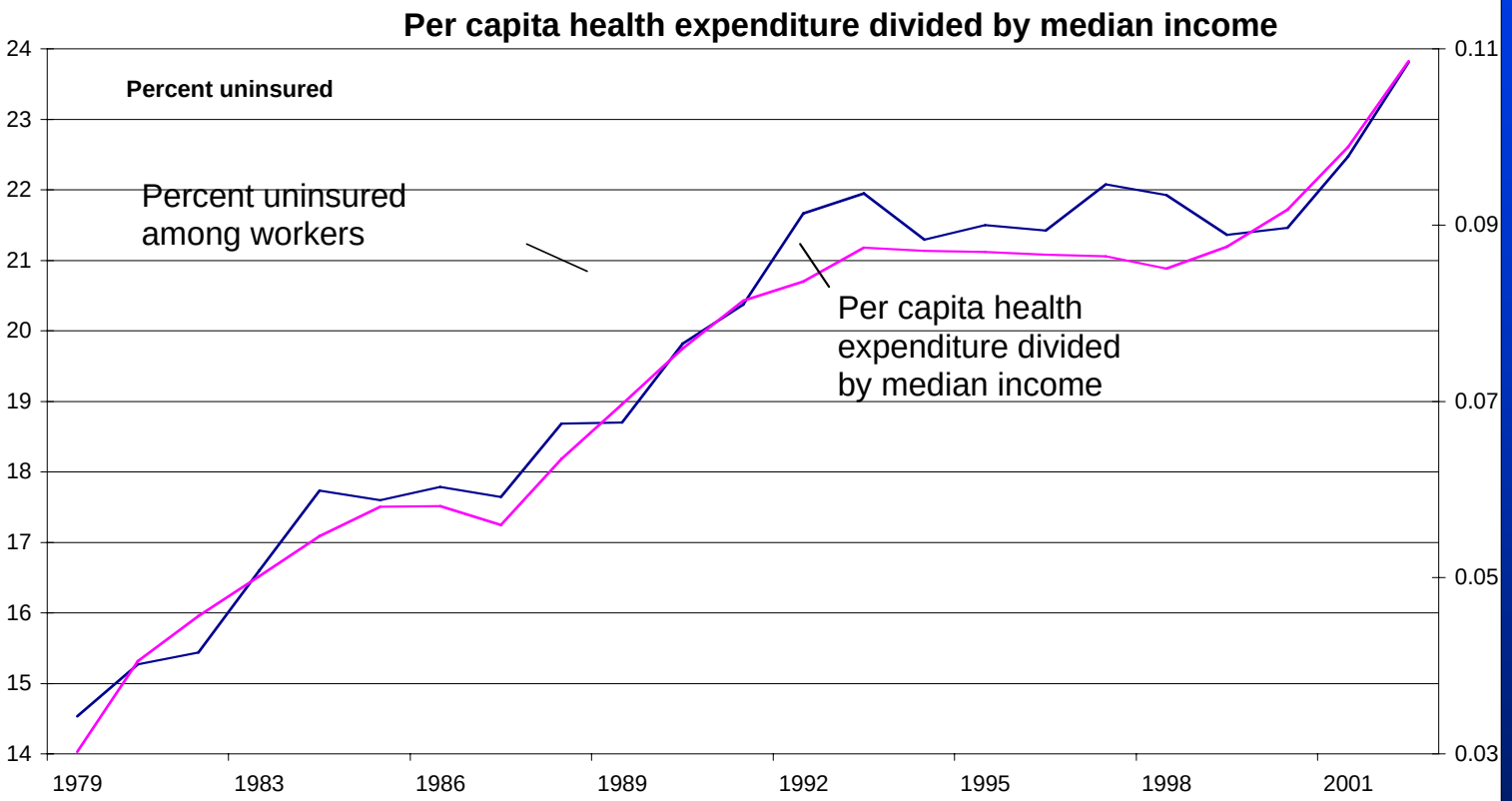


EXHIBIT 2
Percentage Uninsured Among Workers And Per Capita Health Expenditure Divided by Median Income, 1979-2002



SOURCES: Authors' Analysis of Current Population Survey, March Supplements, Annual Demographics Files, 1980-2003, except 1981; and Health Care Financing Administration, National Health Accounts, 1979-2002.

NOTE: Percentage uninsured is scaled on the left axis and per capita health expenditure divided by median income is scaled on the right axis. Results from 1979-1999 have been adjusted to make them consistent with the insurance verification question that was added to the CPS in 2001. The series for workers is restricted to those not covered as a dependent or by a public program.

Summary

- Utility-based measures are available to estimate the impact of pharmaceutical products
- Generic methods allow the comparison of investments in drugs with investments in other aspects of health care
- There are very few applications at present
- We look forward to the development of these methods for studies on pharmaceutical regulation.