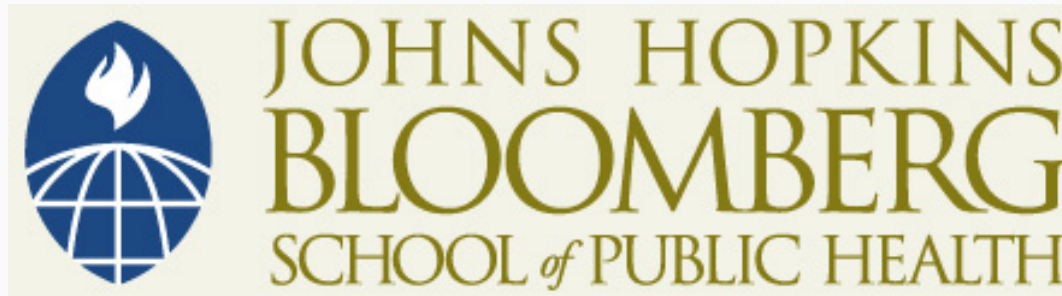


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Research Design: Other Examples

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Section A

Research Design: Other Examples, Part 1

Sources

- *Outcomes and Costs of Care for Acute Low Back Pain among Patients Seen by Primary Care Practitioners, Chiropractors, and Orthopedic Surgeons*, by Carey, R.S., Garrett, J., Jackman, A., et al., *New England Journal of Medicine* 333 (14): 913–17 (1995)

Background

- Patients receive quite different care from different health providers
- Back pain is one of the most frequent reasons for visits to primary care physicians
- Back pain is the second most common reason given for taking time off work

Goals of the Study

- To determine whether the outcomes (health and satisfaction) of, and charges for, care differ among the following:
 - Primary care practitioners
 - Chiropractors (their care had been demonstrated to be effective in earlier randomized trials)
 - Orthopedic surgeons

HSRE Conceptual Framework

- Health services research
- Highly policy relevant
 - \$25 billion annual cost of care
 - Back pain is one of the most frequent reasons for visits to primary care physicians
 - Second most common reason for time taken off from work

Hypothesis of Study

- There will be differences in outcomes and costs, depending on type of practitioner
 - The direction of difference is not hypothesized

Study Design

- Setting—North Carolina, equal urban and rural
- Population—22% black
- 600 chiropractors practice in NC
- Observational
- Prospective
- Compares six strata of practitioners
 - Primary care (urban and rural)
 - Chiropractors (urban and rural)
 - Orthopedic surgeons
 - HMO practitioners

Study Design

Observational, prospective study comparing six strata of practitioners (three types, both urban and rural)

P1	O _{2wk}	O _{4wk}	O _{8wk}	O _{12wk}	O _{24wk}
P6	O _{2wk}	O _{4wk}	O _{8wk}	O _{12wk}	O _{24wk}

P1 & P2 = Primary care (family practice, internal medicine, or general pract.)

P3 & P4 = Chiropractors

P5 = Orthopedic surgeons

P6 = Primary care/HMO

Criteria for Selection of Sample

- Two-staged sampling—by practitioners, then by patients
- Practitioners (n = 208) were eligible to participate if ...
 - They provided ambulatory care more than half the time
 - Saw patients with acute low back pain who had not been referred by other practitioners
- Patients (n = 1633) were selected if ...
 - Back pain of less than 10-week duration
 - No previous care received
 - No history of back pain
 - No pregnancy at the time
 - Have telephone, speak English

Study Variables

- Independent—type of practitioner
- Dependent
 - Date of return to functional status
 - Complete recovery
 - Satisfaction with care
 - Costs of care
 - Use of services during treatment period
- Intervening
 - Demographics
 - Use of health care services prior to acute low back pain
 - Functional status at outset

Sourcing and Collecting Data

- Functional status, use of health care services, demographics, work status obtained by telephone questionnaire
- Patient satisfaction obtained at 24 weeks or when full recovery
- Health care from medical charts

Measurement of Cost

- Office visits
- Radiography and other imaging
- Medication
- Physical therapy
- Other modes of treatment

Standardization of Cost

- Cost of services were based on average statewide charges assigned by a large health insurance carrier
- Medications calculated as the average wholesale cost to the pharmacist plus 40 percent

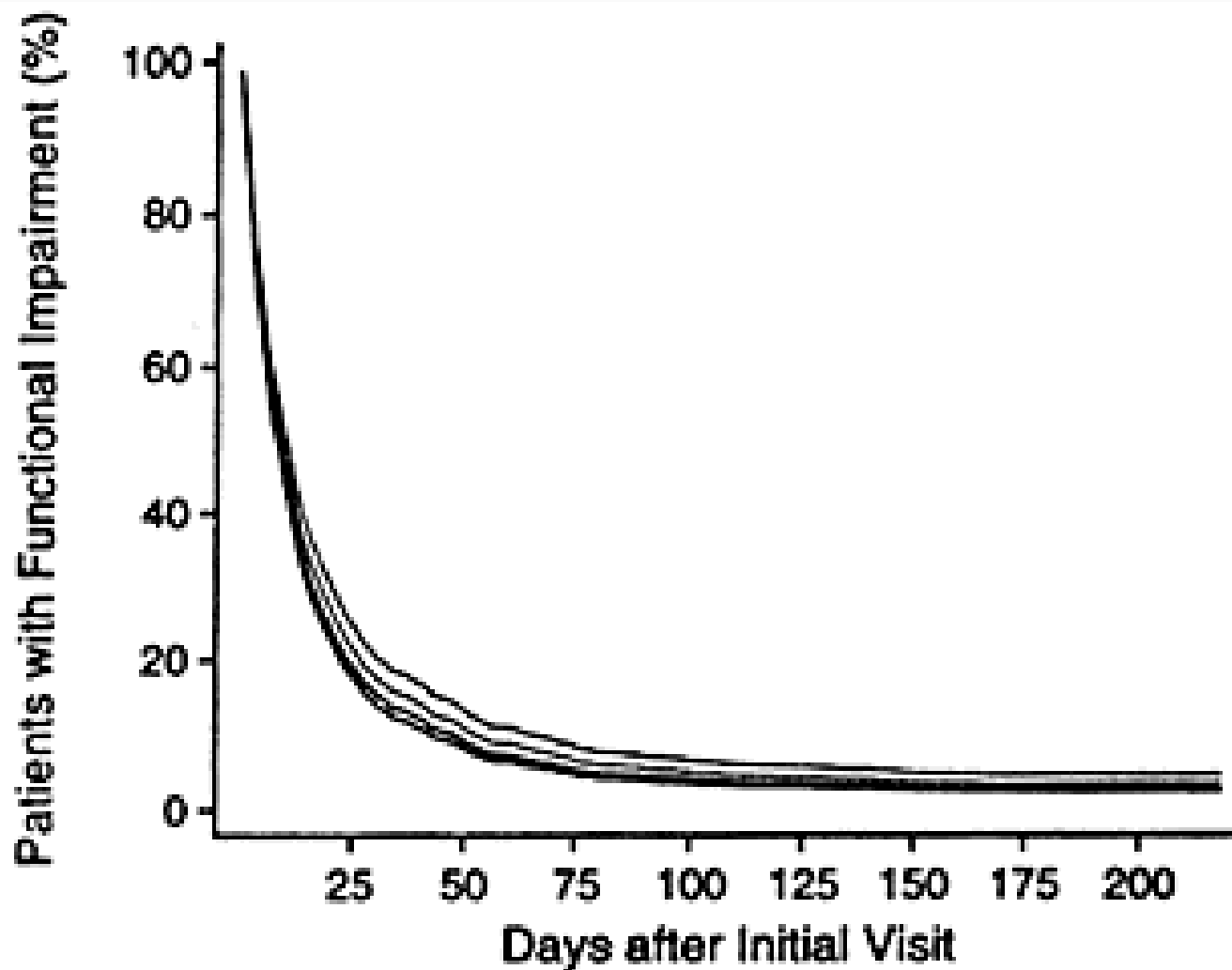
Base-Line Characteristics of Patients with Acute Back Pain Seen by Various Types of Providers

Characteristics	Primary Care Physician		Chiropractor		Orthopedist	HMO Provider	P-Value
	Urban	Rural	Urban	Rural			
No. of Patients	278	366	310	296	181	202	
Mean Age (yr)	41	43	40	44	40	38	< 0.05
White Race (% of Patients)	82	84	84	92	85	65	< 0.05
Male Sex (% of Patients)	44	43	50	55	52	42	< 0.05
Family Income < \$20,000	27	47	27	33	27	19	< 0.05
First Episode of Back Pain Treated by Professional	55	57	54	38	55	50	< 0.05
Sciatica	21	27	28	23	25	15	< 0.05
Duration or Episode < Two Weeks	66	71	64	66	59	68	< 0.05
Mean Functional Loss Score	10.3	12.7	11.7	9.9	11.7	10.4	< 0.05
Workers Comp	34	40	26	23	38	26	< 0.05
Mean Pain Score	5.3	5.6	5.2	5.3	5.4	5.6	< 0.05

* The P-Value are for differences among the strata. Only significant P-values are shown.

Functional loss measured with the Roland-Morris adaptation of the Sickness Impact Profile was measured on a scale of 0 to 23. Pain was assessed on a scale of 1 to 10.

Days Until Return of Function



Patients Satisfaction with and Perception of Care

Variable	Primary Care, Orthopedic, or HMO Provider	Chiropractor	P Value
No. of Patients	1027	606	
Percentage of Patients			
<i>Satisfaction with Care (% Answering Excellent)</i>			
Information Given?	30.3	47.1	< 0.001
Treatment of Back Problem?	31.5	52.1	< 0.001
Overall Results of Treatment?	26.5	42.1	< 0.001
<i>Perception of Care (% Answering Yes)</i>			
Detailed History of Back Pain Taken?	68.4	88.4	< 0.001
Careful Examination of Back Performed?	79.9	95.1	< 0.001
Cause of Problem Clearly Explained?	74.6	93.6	< 0.001

Internal Validity Issues

- History—no problem, over 24 weeks
- Maturation—no problem
- Testing—may have learned from the satisfaction questionnaire
- Instrumentation—no problem

Internal Validity Issues

- Regression—none selected for extreme values
- Selection—could be major problem
 - Do patients select provider based on their level of severity?
- Attrition—not a problem here

External Validity Issues

- Testing treatment interaction—doubtful, but possible
- Selection treatment interaction—to the extent that North Carolina does not represent U. S. patients in other states not as familiar with chiropractors
- Reactive—doubtful, not that much “fuss” about study
- Multiple treatment effects—probably not a problem

Strengths

- 1600 patients enrolled
- 208 providers across six different provider types
- Good measurement techniques
 - Several different observations at 2, 4, 8, 12, 24 weeks
 - Careful measurement of costs
 - Documentation of use of different health services

Weaknesses

- Just an observational study
- May have selection bias

Summary

- Good study, given that it is an observational study
- Could do a more rigorous study
 - Randomized trial
 - Comparison groups that look similar



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Section B

Research Design: Other Examples Part 2

Is This Still a Relevant Question?

- Spending at least some money on medical care is indisputably worthwhile
- But does spending yet more buy still better health?

- "... in this country public health policy has proceeded for more than five decades on the assumption that if some medical care is good, more would be better. The main instrument of this policy has been increased insurance coverage, both public and private."
- "One of the few potential methods for reducing expenditures appears to be to increase the proportion of costs borne by the people who are consuming medical care."

RAND Health Insurance Experiment

- A large scale study, which took place in the 1970s, tested the effect of health insurance on the use of services and health outcomes
- There was expectation that national health insurance would be passed in the near future and this demonstration would give policy makers some understanding of the effect

Goals of the Study

- There were a large number of goals
- The primary goals were to study the effect of ...
 - Cost-sharing on the use of outpatient medical care
 - Insurance on health status

HSR&E Conceptual Framework

- Health Services Research
- High policy relevant

Hypotheses Study

- Demand for health services is sensitive to price
- Reduced coverage will not affect medical outcomes

- Sample
 - Population-based
 - Six sites representing four U.S. Census regions
 - 2,005 families, 5,814 individuals
 - Exclusions

- Selection of sites
 - Represented census regions
 - Various city size and diversity of medical delivery systems
 - Varied by existing levels of excess demand
 - Northern and southern rural areas

The 16 Experimental Plans Include ...

- x_1 One plan in which care is free to the family
- x_2 Three plans with 25% coinsurance (i.e., the family pays 25% of its medical bills)
- x_3 Three plans with 50% coinsurance (two of these only in Dayton)
- x_4 Three plans with 50% coinsurance for dental and outpatient mental health services and 25% for all others (all sites except Dayton)

The 16 Experimental Plans Include ...

- x_5 Three plans with 95% coinsurance (100% in Dayton during the experiment's first year)
- x_6 One plan with 95% coinsurance (100% in Dayton during the first year) up to a maximum expenditure of \$150 per individual (or \$450 per family) per year and no coinsurance above that (in this plan only, the coinsurance applies solely to outpatient expenditures; inpatient expenditures are not subject to coinsurance)

Health Status Variables

- Physical functioning
- Role functioning
- Mental health
- Social contacts
- General health ratings
- Bed days
- Serious symptoms

Health Status Variables

- Smoking (risk of death due to)
- Weight
- Serum cholesterol
- Diastolic blood pressure
- Functional far vision
- Risk of dying from any cause related to systolic blood pressure, serum cholesterol, and cigarette smoking

Health Status Data Sources

- Baseline interview
- Enrollment medical history questionnaire
- Health reports
- Health questionnaire
- Exit medical history questionnaire
- Multi-phasic screening examination

Approaches to Measurement and Measurement Reliability and Validity

- Episodes of care
- General health questionnaire

Internal Validity Issues

- History—could be different health services experiences in different cities
- Maturation—possible
- Testing—no
- Instrumentation—did same technicians take measurements in different cities?
 - If not, was training adequate?

Internal Validity Issues

- Selection—inevitable to some degree in a study with 2000 families
 - Different acceptance rates depending on plans
 - ▶ In Seattle, 93% accepted free FFS
 - ▶ 75% accepted HMO
 - Families chosen to assure optimal variation in explanatory variables in order to estimate equations

Internal Validity Issues

- Regression to the mean—possible for some of the outcome variables, where there were extreme values initially
- Attrition—did people drop out of high co-pay plans sooner?

External Validity Issues

- Selection-treatment interaction—income-related ceiling on out-of-pocket medical expenses
- Testing-treatment interaction—unlikely
- Situational—possible that people behaved differently under study conditions
- Multiple treatment effects—possible, but unlikely to be consistent in multiple sites

Strengths of Study

- Importance of question to health policy both in the 1970s and currently
- Very large number of participants and variables collected
- Multiple sites strengthened generalizability
- Multiple subgroups by proportion of co-pays
- Countless papers have been published from the data collected

Weaknesses of Study

- Finding that reduced coverage (higher copay) will not affect medical outcomes may not hold for small subgroups that were too small to analyze
- There could have been different “history” effects in different cities that were masked when data were collapsed
- In reality, no one lost money by being in the study so true effect of higher co-pay may be masked

Cost Sharing

- When cost sharing was higher, use of medical care (visits to physicians, adult hospitalizations) and accordingly expenditures were lower . . . people enrolled in cost sharing plans made only about two thirds as many outpatient visits as those receiving free care