An Introduction to Medicare and SEER-Medicare Data

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Associate Professor of Medicine, Epidemiology, and Health Policy and Management
Outline

- Medicare data
- SEER-Medicare data
- Brief discussion about Medicaid data
- Detailed examples of use – if you like
Context

- Claims data are tremendously useful for observational research
- Medicare insures virtually all individuals 65 years and older in the U.S., as well as disabled people and people on dialysis
- People do not disenroll except at death
- A lot of people (2011: 47,672,971)

http://www.statehealthfacts.org/comparetable.jsp?yr=200&typ=1&ind=290&cat=6&sub=74&sortc=1&o=a
Medicare

- President Truman advocated for national health insurance
- Strong lobbies against this – particularly the American Medical Association – but Truman didn’t give up
- Oscar Ewing, head of the Federal Security Agency (later the Department of Health, Education, and Welfare and now the Department of Health and Human Services), unveiled a plan in February 1952
- Plan was to cover all Social Security beneficiaries (the elderly, widows, and orphans)
- Still untenable
• The elderly were an appealing group to cover first (ill suited for coverage under voluntary private insurance)

• Goal of the Medicare program was not particularly to reform the practice of medicine – just to pay “reasonable charges” for “medically required services” and to pay for some teaching of medical students
Medicare was enacted in 1965 as the healthcare linchpin of President Lyndon Johnson's Great Society

Medicare Part A

- Finances **inpatient hospital services**, continued treatment or **rehabilitation in a skilled-nursing facility**, and **hospice care** for the terminally ill.

Employees pay into Part A Hospital Insurance Trust Fund during their working years

Medicare Part B

- Enrollment in Part B is voluntary, although the vast majority of beneficiaries sign on.
- Part B pays for **physicians' services** and **outpatient hospital services**, including emergency room visits, ambulatory surgery, diagnostic tests, laboratory services, and **durable medical equipment**.

Financed by individual contribution and federal contributions
Later…

- Medicare Managed Care (1972 – revised legislation in 1985)
  Enrollment of Medicare beneficiaries into managed care plans (HMOs); capitated payments from federal government for their care; often provided drug coverage to enrollees

- Medicare + Choice (Medicare Part C) –Balanced Budget Act of 1997 – allowed different types of payments to other types of plans, like preferred provider organizations (PPOs)

  Prescription drug coverage
Medicare Part D

- A voluntary outpatient drug benefit
- A combination of stand-alone prescription drug plans (PDPs) and Medicare Advantage (MA)–Prescription Drug plans (MA–PDs) delivers the benefit.
- In each of 34 geographic regions, plans compete for enrollees on the basis of annual premiums, benefit structures, specific drug therapies covered, pharmacy networks, and quality of services. Plans bear some risk for their enrollees’ drug spending.
- Medicare subsidizes premiums by about 75 percent and provides additional subsidies for beneficiaries who have low levels of income and assets.
Figure 1  Standard drug benefit in 2010

- **Catastrophic coverage**: 5%
- **No coverage**: $6,440**
- **Partial coverage up to limit**: $2,830
- **Deductible**: $310
- **Approximately $383 per year***

Note: Benefit structure applies for an enrollee who has no supplementary drug coverage.

* Cost sharing above the catastrophic gap is the greater of either 5 percent coinsurance or a copay of $2.50 for generic drugs, or $6.30 for brand name drugs.
** Equivalent to $4,550 in out-of-pocket spending: $310 (deductible) + $630 (25% cost sharing on $2,520) + $3,610 (100% cost sharing in the "coverage gap").
*** There is a base beneficiary premium of $383 per year, which is 25.5% of expected Medicare Part D benefits per person, but the actual premiums that beneficiaries pay vary by plan. Federal subsidies pay for the remainder of covered Part D benefits.

http://medpac.gov/documents/MEDPAC_Payment_Basics_09_PartD.pdf
Chart 1-9. Medicare spending is concentrated in certain services and has shifted over time

Total spending **2000** = $227 billion

- SNF 5%
- Inpatient hospital 39%
- Other hospital 4%
- DME 2%
- Physician fee schedule 18%
- Managed care 18%
- Hospice 1%
- Home health 4%
- Other 10%

Total spending **2010** = $514 billion

- SNF 5%
- Inpatient hospital 27%
- Home health 4%
- Hospice 3%
- Other hospital 5%
- DME 2%
- Physician fee schedule 12%
- Managed care 22%

Prescription drugs provided under Part D 12%
How is Medicare data generated?

- Hospitals and doctors offices and service providers generate claims that are submitted to the insurers for payment.
- Providers that “accept assignment” submit the bill to Medicare for their reimbursement and bill the patient for the difference.
May submit up to eight diagnosis codes
This diagnosis “pointer” points back to the diagnoses listed in item 20.

<table>
<thead>
<tr>
<th></th>
<th>DATE(S) OF SERVICE</th>
<th>PLACE OF SERVICE</th>
<th>PROCEDURES, SERVICES, OR SUPPLIES</th>
<th>DIAGNOSIS POINTER</th>
<th>CHARGES</th>
<th>DAYS OR UNITS</th>
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<th>RENDERING PROVIDER ID. #</th>
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<td>6</td>
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</tbody>
</table>

25. FEDERAL TAX I.D. NUMBER: NPI
26. PATIENT'S ACCOUNT NO.
27. ACCEPT ASSIGNMENT?
YES  NO
28. TOTAL CHARGE
29. AMOUNT PAID
30. BALANCE DUE

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS
'I certify that the statements on the reverse apply to this bill and are made a part thereof.'

32. SERVICE FACILITY LOCATION INFORMATION

33. BILLING PROVIDER INFO & PH # ( )

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-0999 FORM CMS-1500 (08-05)
Therefore ... 

- Expect to see **demographic information** about the beneficiary
- Expect to see information about the **service provider** (the clinician and the hospital or laboratory)
- Expect to see **diagnoses**
- Expect to see **procedures** and the **dates of service**
- Expect to see the **charges** associated with those procedures
What is in Medicare data?

**Beneficiary Summary File:** demographic and enrollment information about each beneficiary enrolled in Medicare during a calendar year: the beneficiary unique identifier, state and county codes, zipcode, date of birth, date of death, sex, race, age, monthly entitlement indicators (A/B/C/D), reasons for entitlement, state buy-in indicators, and monthly managed care indicators (yes/no). They include a derived race/ethnicity code…

(used to be called the Denominator File, now called the Master Beneficiary Summary File)
Outpatient claim file: final action claims data submitted by institutional outpatient providers (hospital outpatient departments, rural health clinics, renal dialysis facilities, outpatient rehabilitation facilities, comprehensive outpatient rehabilitation facilities, and community mental health centers).

Includes **diagnosis** and **procedure** (ICD-9 diagnosis, ICD-9 procedure code, CMS Common Procedure Coding System (HCPCS) codes-CPT), **dates of service**, **reimbursement amount**, outpatient (facility) **provider number**, revenue center codes and **beneficiary demographic information**. Each observation in this file is at the claim level.

“outpatient space charges”
**Carrier claim file:** final action claims data submitted by non-institutional providers (physicians, physician assistants, clinical social workers, nurse practitioners, independent clinical laboratories, ambulance providers, and free-standing ambulatory surgical centers.)

Includes **diagnosis** and **procedure** (ICD-9 diagnosis, CMS Common Procedure Coding System (HCPCS) codes), **dates of service**, **reimbursement amount**, non-institutional **provider numbers** (e.g., UPIN, PIN, NPI), and **beneficiary demographic information**. Each observation in this file is at the claim level (includes inpatient and outpatient provider claims)

“professional fees”
**MedPAR File:** inpatient hospital and skilled nursing facility (SNF) final action stay records. Each MedPAR record represents a stay in an inpatient hospital or SNF.

An inpatient "stay" record summarizes all services rendered to a beneficiary from the time of admission to a facility through discharge. Each MedPAR record may represent one claim or multiple claims, depending on the length of a beneficiary's stay and the amount of inpatient services used throughout the stay. The record unit of MedPAR file is the hospital or SNF stay (includes beneficiaries, diagnoses, procedures, dates, providers, charges).

“inpatient charges”
Hospice claim file: final action claims data submitted by Hospice providers. Some of the information contained in this file includes the level of hospice care received (e.g., routine home care, inpatient respite care), terminal diagnosis (ICD-9 diagnosis), the dates of service, reimbursement amount, Hospice provider number, and beneficiary demographic information. Each observation in this file is at the claim level.
**Home Health Agency claim file:** final action claims data submitted by HHA providers. Some of the information contained in this file includes the number of visits, type of visit (skilled-nursing care, home health aides, physical therapy, speech therapy, occupational therapy, and medical social services), diagnosis (ICD-9 diagnosis), the dates of visits, reimbursement amount, HHA provider number, and beneficiary demographic information. Each observation in this file is at the claim level.

**Skilled Nursing Facility claim file:** final action claims data submitted by SNF providers. Some of the information contained in this file includes diagnosis and procedure (ICD-9 diagnosis and ICD-9 procedure code), dates of service, reimbursement amount, SNF provider number, and beneficiary demographic information. Each observation in this file is at the claim level.

**Durable Medical Equipment claim file:** The Durable Medical Equipment (DME) claim file contains final action claims data submitted by Durable Medical Equipment suppliers. Some of the information contained in this file includes diagnosis, (ICD-9 diagnosis), services provided (CMS Common Procedure Coding System (HCPCS) codes), dates of service, reimbursement amount, DME provider number, and beneficiary demographic information. Each observation in this file is at the claim level.
Part D Drug Event (PDE) File: The PDE data contain prescription drug costs and payment data that enable CMS to make payments to the plans and otherwise administer the Part D benefit. When a beneficiary fills a prescription under Medicare Part D, a prescription drug plan sponsor must submit a summary record to CMS. The PDE data are not the same as individual drug claim transactions but are summary extracts using CMS-defined standard fields.
Medicare Identifiable Data File Descriptions
(http://www.resdac.org/Medicare/file_descriptions.asp#inpatient)

Note: there are also limited data sets and non-identifiable data sets that are easily attainable and inexpensive or free from the CMS site.
SEER-Medicare
Linkage of Two Large Population-based Data Sources

Surveillance, Epidemiology, and End Results (SEER) Cancer Registries
• Cancer Site
• Stage
• Histology

Medicare Claims for Covered Health Services
• Hospital
• Physician
• Outpatient
• Home Health
• Hospice

SEER-MEDICARE
• 3.5 million cancer cases
• Random sample of non-cancer controls from SEER Regions

http://healthservices.cancer.gov/seermedicare/
Population-based Sample Representing Approximately 28% of the U.S. Population
(http://seer.cancer.gov/registries/data.html)
SEER-Medicare Allows Studies Across the Cancer Continuum

<table>
<thead>
<tr>
<th>Cancer Control Continuum</th>
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<tbody>
<tr>
<td><strong>Diagnosis/Treatment</strong></td>
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<tr>
<td>Patterns of care</td>
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<tr>
<td>Perioperative complications</td>
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<tr>
<td>Volume outcomes studies</td>
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<tr>
<td>Extent of staging</td>
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<tr>
<td>Comorbidities</td>
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<td><strong>Survivorship</strong></td>
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<td>Late effects of treatment</td>
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<td>Post-diagnostic surveillance</td>
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<td>Treatment of prevalent cancers</td>
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<tr>
<td>Survival</td>
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<tr>
<td><strong>Second Occurrence</strong></td>
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<tr>
<td>Rates of second primaries</td>
</tr>
<tr>
<td>Relationship of initial treatment to second primaries</td>
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<tr>
<td><strong>Terminal</strong></td>
</tr>
<tr>
<td>Use of hospice services</td>
</tr>
<tr>
<td>Patterns of care during the last year of life</td>
</tr>
</tbody>
</table>

Health disparities, quality of care, and cost of care

http://healthservices.cancer.gov/seermedicare

April 2011
### SEER-Medicare Data

-- Data is Requested Per Body Part (examples)

<table>
<thead>
<tr>
<th>Body Part</th>
<th>Cancer Cases</th>
<th>Claims</th>
<th>Part D</th>
<th>5% Sample</th>
</tr>
</thead>
</table>


Medicare Current Beneficiary Survey (MCBS)

- The Medicare Current Beneficiary Survey (MCBS) is a continuous, multipurpose survey of a representative national sample of the Medicare population, conducted by the Center for Strategic Planning of the Centers for Medicare & Medicaid Services (CMS) through a contract with Westat.

- Goal of survey are to determine expenditures and sources of payment for all services used by Medicare beneficiaries, including co-payments, deductibles, and non-covered services; to ascertain all types of health insurance coverage and relate coverage to sources of payment.
Two data files in MCBS

a. MCBS Access to Care
The Access to Care file contains information on beneficiaries' access to health care, satisfaction with care, and usual source of care.

b. MCBS Cost and Use Files
The MCBS Cost and Use files link Medicare claims to survey-reported events and provides complete expenditure and source of payment data on all health care services, including those not covered by Medicare.

Survey-reported data include information on the use and cost of all types of medical services, as well as information on supplementary health insurance, living arrangements, income, health status, and physical functioning.
Medicaid

**Health Insurance Coverage**
- 31 million children & 16 million adults in low-income families;
- 16 million elderly and persons with disabilities

**Assistance to Medicare Beneficiaries**
- 9.4 million aged and disabled — 20% of Medicare beneficiaries

**Long-Term Care Assistance**
- 1.6 million institutional residents; 2.8 million community-based residents

**Support for Health Care System and Safety-net**
- 16% of national health spending;
- 40% of long-term care services

**State Capacity for Health Coverage**
- Federal share can range from 50 - 83%;
- For FFY 2012, ranges from 50 - 74.2%
Medicaid

- **Eligibility** Medicaid and CHIP provide health coverage to nearly 60 million Americans, including children, pregnant women, parents of young children, seniors and individuals with disabilities. Federal law requires States to cover certain population groups (mandatory eligibility groups) and gives them the flexibility to cover other population groups (optional eligibility groups). Medicaid is jointly funded by the Federal government and the States.

- For many eligibility groups, income is calculated in relation to a percentage of the Federal Poverty Level (FPL). For example, 100% of the FPL for a family of four is $22,350 in 2011.
• **Benefits** States establish and administer their own Medicaid programs, and determine the type, amount, duration, and scope of services within broad federal guidelines. States are required to cover certain “mandatory benefits,” and can choose to provide other “optional benefits” including prescription drugs. States receive federal matching funds to provide these benefits.

• **Cost Sharing** States have the option to charge premiums and to establish out of pocket spending (cost sharing) requirements for Medicaid enrollees. Out of pocket costs may include copayments, coinsurance, deductibles, and other similar charges.
Medicaid Expenditures by Service, 2010

**Total = $389.1 billion**

NOTE: Total may not add to 100% due to rounding. Excludes administrative spending, adjustments and payments to the territories.

SOURCE: Urban Institute estimates based on data from CMS (Form 64), prepared for the Kaiser Commission on Medicaid and the Uninsured.
Percent of Nonelderly Residents Covered by Medicaid, by State, 2007-2008

US Average = 14%

Dual eligible beneficiaries account for a substantial share of Medicaid spending

Medicaid Enrollment, 2009

- Children: 49%
- Adults: 26%
- Other Aged & Disabled: 10%
- Duals: 15%

Total = 63 Million

Medicaid Spending, 2009

- Children & Adult Spending: 34%
- Other Aged & Disabled Spending: 28%
- Long-Term Care: 25%
- Prescribed Drugs: 0.4%
- Medicare Acute: 7%
- Other Acute: 2%
- Premiums: 3%

Total = $359 Billion

SOURCE: KCMU/Urban Institute estimates based on data from FY 2009 MSIS and CMS-64, 2012. MSIS FY 2008 data were used for MA, PA, UT, and WI, but adjusted to 2009 CMS-64.
Medicaid Enrollees are Sicker and More Disabled Than the Privately-Insured

Note: Adults 19-64.
Challenges of using Medicaid data

- State data -- need to get data from individual states
- Different eligibility criteria so that the patient populations are all different
- Individual have Medicaid as their insurance for short times – cycle on and off

- Poor, childless woman
- Pregnant
- Married
- Divorced, poor, has dependent children
- Employed
Medicare Data Core (MDC) helps investigators access and use the rich claims data from the Centers for Medicare and Medicaid Services (CMS).

Data use agreements with CMS must be in place for their use.

Successful analysis of the data involves expertise in manipulating claims, clinical knowledge, and advanced programming skills.

The MDC can offer these services to researchers.
## Medicare Data Holdings (as of January 2012)

<table>
<thead>
<tr>
<th>Year</th>
<th>Description</th>
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<tbody>
<tr>
<td>1999-2009</td>
<td>100% MedPAR</td>
</tr>
<tr>
<td>1999-2009</td>
<td>100% Beneficiary Summary file</td>
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<tr>
<td>1999-2009</td>
<td>5% Beneficiary Annual Summary File</td>
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<tr>
<td>1999-2009</td>
<td>5% Outpatient SAF</td>
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<tr>
<td>1999-2009</td>
<td>5% Carrier SAF</td>
</tr>
<tr>
<td>1999-2009</td>
<td>5% DME SAF</td>
</tr>
<tr>
<td>1999-2009</td>
<td>5% HHA SAF</td>
</tr>
<tr>
<td>1999-2009</td>
<td>5% Hospice SAF</td>
</tr>
<tr>
<td>2007</td>
<td>Medicare Part D</td>
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<td>1999-2006</td>
<td>Medicare Current Beneficiary Survey (MCBS)-Cost and Use file</td>
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<td>2003-2006</td>
<td>Base ID to HIC crosswalk from the MCBS</td>
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<tr>
<td>2002-2002</td>
<td>RDDC crosswalk</td>
</tr>
<tr>
<td>2003-2006</td>
<td>HIC – RDDC conversion</td>
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</tbody>
</table>

*CCW=Chronic Conditions Warehouse, SAF=Standard Analytic File, DME=durable medical equipment, RDDC=Research Data Distribution Center, HHA=Home Health Agency, HIC=Health Insurance Claims numbers, MedPAR=Medicare Provider Analysis and Review*
Let’s Look at a CER Study Using Medicare Data

Original Research
Assessing the Impact of Screening Colonoscopy on Mortality in the Medicare Population


Cary P. Gross, Pamela R. Soulos, Joseph S. Ross, Laura D. Cramer, Christopher Guerrero, Mary E. Tinetti and R. Scott Braithwaite
DATA REQUEST
Data request comes in to Segal or Snyder (S/S)
S/S meet with client by phone to review:
-- financial structure
-- services offered
-- brief review of data needs

DATA USE AGREEMENT INITIATION
Investigator meets with Debra Moffitt and they walk through the material needed to complete a DUA

Investigator prepares the proposal and additional documentation as needed for the DUA and for the IRB (mostly will be Exempt or Expedited)

Debra Moffitt submits the DUA request to CMS and purchases data as needed

Up to 4 months elapse

DUA is granted. D.M. notifies the investigator, S/S, and A.B. S/S authorize the release of data to the investigator.

DATA SPECIFICATION
Investigator schedules an in depth meeting with S/S and Amanda Blackford to discuss specific data needs

Amanda discusses the data request with S/S for confirmation that it is within scope.

DATA RELEASE
Amanda cuts the data and releases it to the investigator. Data lives encrypted on a server in BIOSTATISTICS.

Amanda meets with investigator if requested.

BILLING
Amanda tracks hours spent in post-delivery analytic consulting. If investigators needs exceed the fifteen house, she can negotiate separately with the investigator.

Investigator reviews the delivered data and schedules analytic consulting as needed with Amanda.

Investigator completes project and notifies D. M. to terminate the DUA

Investigator notifies S/S about any publications that result from use of this data
Fees

- One cut of data costs $5,000.
- A cut is an analytic file that is created in response to defined inclusion/exclusion criteria.
- Each cut comes with 15 hours of post-delivery analytic consulting per cut.
# Key People

<table>
<thead>
<tr>
<th>Person</th>
<th>Role</th>
<th>Contact</th>
</tr>
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<tbody>
<tr>
<td>Jodi Segal</td>
<td>Medicare</td>
<td><a href="mailto:jsegal@jhmi.edu">jsegal@jhmi.edu</a></td>
</tr>
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<td>Claire Snyder</td>
<td>SEER-Medicare</td>
<td><a href="mailto:csynder@jhsph.edu">csynder@jhsph.edu</a></td>
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<tr>
<td>Amanda Blackford</td>
<td>Analyst</td>
<td><a href="mailto:ablackf1@jhmi.edu">ablackf1@jhmi.edu</a></td>
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<tr>
<td>Debra Moffitt</td>
<td>Data Use Agreements</td>
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<tr>
<td>Albert Wu</td>
<td>Overseer</td>
<td><a href="mailto:awu@jhsph.edu">awu@jhsph.edu</a></td>
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<tr>
<td>Rachel Jones</td>
<td>Budget</td>
<td><a href="mailto:rajones@jhsph.edu">rajones@jhsph.edu</a></td>
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</tbody>
</table>
CER Question

Are there mortality benefits to receiving screening colonoscopy compared to receiving colonoscopy only when symptomatic?
(if we were to do a trial)

Randomize

Screening colonoscopy

Colonoscopy only for symptoms

10-years

Outcomes of death from colorectal cancer,
Injury from colonoscopy
Population

- We used the Surveillance, Epidemiology, and End Results (SEER)-Medicare database.
- Selected patients 67–94 years old, diagnosed with initial invasive primary CRC from 1993 through 2002.
- Only included patients who had fee-for-service and Part B coverage in the 24 months preceding diagnosis.
- Randomly selected a subset of 50,000 non-cancer patients who met the same age and administrative criteria as the cancer patients for each year from 1993–2002.
- Randomly selected a month during that year to serve as the patient’s index date, which served as “time zero” for subsequent survival analyses.
Variables

- Chronic conditions were identified by searching Medicare claims during the 24 through 3 months prior to cancer diagnosis/index date (*for risk adjustment*)

- Used ICD-9 codes recommended by Elixhauser to identify chronic conditions
Exposure

Used the Medicare claims to identify patients who had undergone an outpatient screening colonoscopy (*HCPCS CODES (CPT) G0105, G0121*) and all other colonoscopies that were not preceded by claims that were consistent with gastrointestinal symptoms (abdominal pain, weight loss, gastrointestinal bleeding, anemia, altered bowel habits, positive FOBT) during the previous 90 days (*HCPCS codes 44388–44389, 44392–4, 45378, 45379, 45380, 45382–45385; ICD-9 codes 45.23, 45.25, 45.41-45.43, 48.36*).
Could they have validated how they operationalized “screening colonoscopy?  ---- Yes

Validation procedure might be to get the claims data from one hospital and apply the algorithm that they used to identify presumptive screening colonoscopies, and then CALL the patient or review the MEDICAL RECORD to learn what the real indication of the test was (was it screening or was it for something else)
Other methods ...

- Not so important to this discussion
- Modeled life expectancy
- Modeled outcomes for the “screened” patients and the unscreened patients
Try doing this with a trial ...

<table>
<thead>
<tr>
<th>Age at diagnosis/ index date</th>
<th>Cancer sample (N = 68,073)</th>
<th>Non-cancer sample (N = 226,868)</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>N (%)</td>
<td>% survived 5-yrs</td>
<td>N (%)</td>
<td>% survived 5-yrs</td>
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<tr>
<td>67-69</td>
<td>8,004 (11.8)</td>
<td>57.7</td>
<td>52,846 (23.3)</td>
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<tr>
<td>70-74</td>
<td>16,301 (24.0)</td>
<td>53.4</td>
<td>66,591 (29.4)</td>
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<td>75-79</td>
<td>17,259 (25.4)</td>
<td>47.7</td>
<td>48,305 (21.3)</td>
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<td>80-84</td>
<td>14,351 (21.1)</td>
<td>38.5</td>
<td>32,388 (14.3)</td>
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<td>85-94</td>
<td>12,158 (17.9)</td>
<td>25.2</td>
<td>26,738 (11.8)</td>
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<tr>
<td>Race/ethnicity</td>
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<td>White</td>
<td>59,819 (87.9)</td>
<td>44.7</td>
<td>193,147 (85.1)</td>
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<td>Black</td>
<td>5,006 (7.4)</td>
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<td>37,401 (54.9)</td>
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<td>0</td>
<td>35,200 (51.7)</td>
<td>50.5</td>
<td>125,748 (55.4)</td>
</tr>
<tr>
<td>1-2</td>
<td>23,459 (34.5)</td>
<td>42.7</td>
<td>74,685 (32.9)</td>
</tr>
<tr>
<td>≥3</td>
<td>9,414 (13.8)</td>
<td>25.2</td>
<td>26,435 (11.7)</td>
</tr>
</tbody>
</table>
### Decision Aid

#### Life-Years Saved -- Males

<table>
<thead>
<tr>
<th>COMORBIDS</th>
<th>67-69</th>
<th>70-74</th>
<th>75-79</th>
<th>80-84</th>
<th>85-94</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1128</td>
<td>852</td>
<td>459</td>
<td>232</td>
<td>65</td>
</tr>
<tr>
<td>1-2</td>
<td>519</td>
<td>382</td>
<td>139</td>
<td>12*</td>
<td>0</td>
</tr>
<tr>
<td>≥3</td>
<td>81</td>
<td>28*</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>AGE</strong></td>
<td><strong>67-69</strong></td>
<td><strong>70-74</strong></td>
<td><strong>75-79</strong></td>
<td><strong>80-84</strong></td>
<td><strong>85-94</strong></td>
</tr>
</tbody>
</table>

#### Life-Years Saved -- Females

<table>
<thead>
<tr>
<th>COMORBIDS</th>
<th>67-69</th>
<th>70-74</th>
<th>75-79</th>
<th>80-84</th>
<th>85-94</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>989</td>
<td>823</td>
<td>509</td>
<td>287</td>
<td>111</td>
</tr>
<tr>
<td>1-2</td>
<td>549</td>
<td>388</td>
<td>151</td>
<td>34</td>
<td>0</td>
</tr>
<tr>
<td>≥3</td>
<td>130</td>
<td>73</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>AGE</strong></td>
<td><strong>67-69</strong></td>
<td><strong>70-74</strong></td>
<td><strong>75-79</strong></td>
<td><strong>80-84</strong></td>
<td><strong>85-94</strong></td>
</tr>
</tbody>
</table>

*Indicates that colonoscopy was not found to be beneficial for patients in this stratum, if they had undergone prior colonoscopy (see Appendix Table 2 for full results of sensitivity analysis)

Zhang J, Xie F, Delzell E, Chen L, Winthrop KL, Lewis JD, Saag KG, Baddley JW, Curtis JR.
CER Question

What is the comparative effectiveness of the herpes zoster vaccine (compared to no vaccination) for people with immune-mediated diseases?
(if we were to do a trial)

Randomize

- Shingles vaccine
- No shingles vaccine

Shingles

Image description: The diagram illustrates a trial design with two branches: Randomize. One branch leads to 'Shingles vaccine', and the other to 'No shingles vaccine'. The right side of the diagram shows an image of shingles on the back.
Exposure

The administration of zoster vaccine was identified by Current Procedural Terminology (CPT) code 90736; or a combination of the National Drug Code (NDC) for the zoster vaccine (representing the purchase of the vaccine) followed by either the Health Care Common Procedure Coding System (HCPCS) code G0377 or the CPT code 90471 in the subsequent 7 days (representing its administration).

The vaccination administration date was defined as the date when the vaccine injection procedure was identified.
Outcomes

Incident HZ cases were identified by the first HZ diagnosis code occurring during follow-up (ICD-9 code 053) in an inpatient or physician office visit claim that was accompanied by a pharmacy claim for antiviral treatment (acyclovir, famciclovir, valacyclovir) within 7 days before or after.

Cite a validation study!

The positive predictive value (PPV) of the HZ diagnosis code alone to identify a new case of HZ (using medical record review as a gold standard) has been shown to range between 85% and 100%. The additional requirement for antiviral drug use was applied to further improve the PPV to better distinguish incident HZ from a history of, or prevalent, HZ. In a sensitivity analysis, we used a case definition that required only an HZ diagnosis code from inpatient or physician office visit claims and not antiviral drug use. In this sensitivity analysis, the exclusion for prior antiviral use was not applied so as to be methodologically consistent.
Other Safety Outcomes of Interest

Prespecified safety outcomes within 42 days after vaccination were examined, including varicella/chickenpox (ICD-9-CM code 052.X) and non–HZ-specific hospitalization for meningitis and encephalitis (ICD-9-CM codes 047.8, 047.9, 049.9, 321.2, 321.8, 322.0-322.2, and 322.9)
Table 3. Herpes Zoster Incidence Rate for Unvaccinated and After Vaccinationa

<table>
<thead>
<tr>
<th>Mediation, mutually exclusive groupsb</th>
<th>&gt;42 Days Since Vaccination</th>
<th>Unvaccinated</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HZ Cases, No.</td>
<td>HZ IR</td>
</tr>
<tr>
<td>Overall</td>
<td>138</td>
<td>6.7 (5.7-7.9)</td>
</tr>
<tr>
<td>Medications, regardless of concomitant DMARDs or oral glucocorticoids</td>
<td>14</td>
<td>8.5 (5.1-14.4)</td>
</tr>
<tr>
<td>Anti-TNF therapies</td>
<td>12</td>
<td>8.5 (4.8-15.0)</td>
</tr>
<tr>
<td>DMARDs, without biologics but regardless of oral glucocorticoids</td>
<td>25</td>
<td>7.0 (4.7-10.3)</td>
</tr>
<tr>
<td>Oral glucocorticoids alone</td>
<td>21</td>
<td>10.3 (6.7-15.8)</td>
</tr>
</tbody>
</table>
Results supporting the safety and efficacy of vaccination were consistent regardless of which outcome definition was used. When the more sensitive case definition requiring only an HZ diagnosis code was applied, no cases of HZ or varicella were observed during the 42 days following vaccination in the group exposed to anti-TNF or other biologics.

The adjusted hazard ratio for vaccination was 0.67 (95% CI, 0.59-0.75) using this more sensitive definition.
In Conclusion

- Medicare data is a good example of claims data with some benefits and drawbacks
- Patients don’t disenroll (+)
- National data (+)
- Generalizable (+)
- Patients are primarily old (+/-)
- All the problems with using claims data for research are present (-)