Secondary Analysis of Existing Data

Presented by the **Biostatistics, Epidemiology, and Research Design (BERD) Core**
of the Center for Clinical and Translational Sciences (CCTS)

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Goals of SDA Seminar Series

- **Education:** To educate investigators about existing data and how that data can be used for research.

- **Collaboration:** To partner with investigators interested in performing SDA and assist them in developing successful research proposals.

- **Promotion:** To increase awareness and visibility of CCTS/BERD members and resources.

Seminars on the 3rd Thursday of every month, from 12:00pm - 1:00pm

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Current Schedule – SDA Series

Date	Topic
February 18, 2021	Women's Health Initiative (WHI) Investigator Data. https://www.whi.org/
March 18, 2021	Center for Medicare and Medicaid Services (CMS) Data. https://www.cms.gov/newsroom/data
April 15, 2021	National COVID Cohort Collaborative (N3C). https://ncats.nih.gov/n3c
May 20, 2021	The National Patient-Centered Clinical Research Network (PCORnet) – PaTH Network. https://pcornet.org/
June 17, 2021	NCTN / NCORP Data Archive - Datasets generated from clinical trials of the National Clinical Trials Network (NCTN) and the NCI Community Oncology Research Program (NCORP). https://nctn-data-archive.nci.nih.gov/
July 15, 2021	National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Central Repository. https://repository.niddk.nih.gov/home/
August 19, 2021	Partners for Kids. https://partnersforkids.org/

For more information and to register: https://ccts.osu.edu/content/secondary-data-analysis-sda-seminar-series
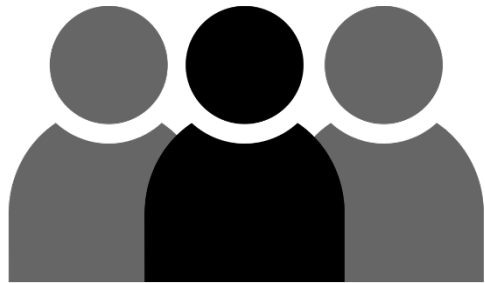
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Biostatistics, Epidemiology, and Research Design (BERD)

Our Mission: To ensure that research conducted under the construct of the CCTS is based on sound and appropriate statistical design and principles.

COLLABORATE (OSU, NCH)

TRAIN

INNOVATE

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The BERD core has a proven RECIPE for success

Rigor	Best practices for rigorous design and analysis. Seasoned reviewers on NIH/PCORI/NSF/DOD panels
Expertise	Broad spectrum covering biostatistics, clinical trials, population studies, genomics, and genetics
Collaboration	Established collaborations with **>300** unique PIs spanning multiple pediatric and adult specialties
Innovation	Funded methodological work in statistical bioinformatics, multiple imputation, Bayesian models, causal inference
Productivity	**300** grant submissions, **50** new awards, **350** peer-reviewed publications since 2018
Experience	Over **100** combined years of continual NIH funding for BERD members

How we can help

- Formulation of research hypotheses
- Complex study design
- Power and sample size calculations
- Statistical plan for grant proposal/IRB protocol
- Clinical trial management and monitoring
- Statistical analysis and modeling
- Datasets for secondary data analysis
- Statistical and epidemiological education

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Data from the Centers for Medicare and Medicaid Services (CMS)

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2021.03.17

Centers for Medicare & Medicaid Services (CMS)

- Centers for Medicare and Medicaid Services is the largest governmental source of health coverage funding.

- The CMS is responsible for administering the Medicare, Medicaid and State Children's Health Insurance Programs, as well as a number of health oversight programs.

- CMS gathers and formats data to support the agency's operations.

- Suitable for **retrospective research studies using secondary data**

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Overview of Medicare & Medicaid Programs

- Established through Social Security Amendments of 1965

- Adds taxpayers to health care financing equation
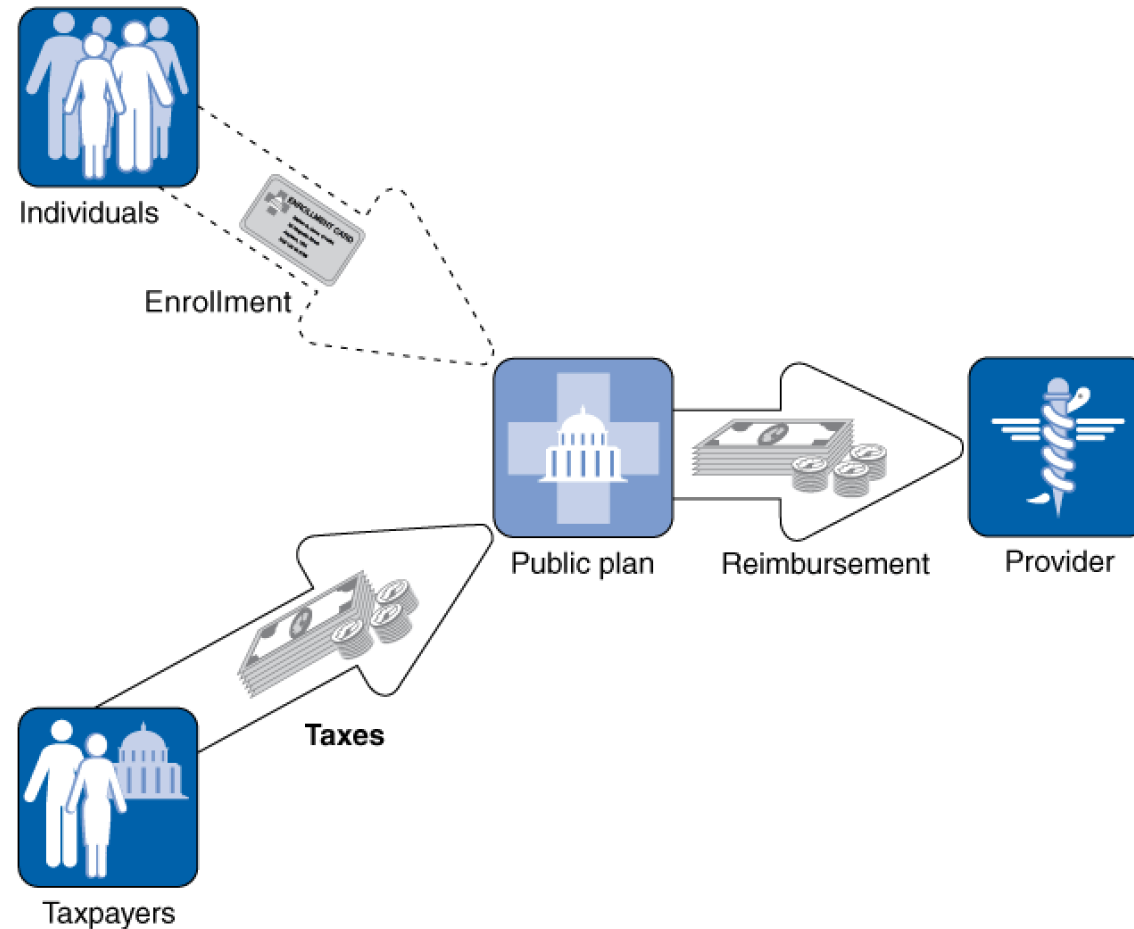
Source: Bodenheimer T, Grumbach K: *Understanding Health Policy: A Clinical Approach, 6th Edition*: www.accessmedicine.com
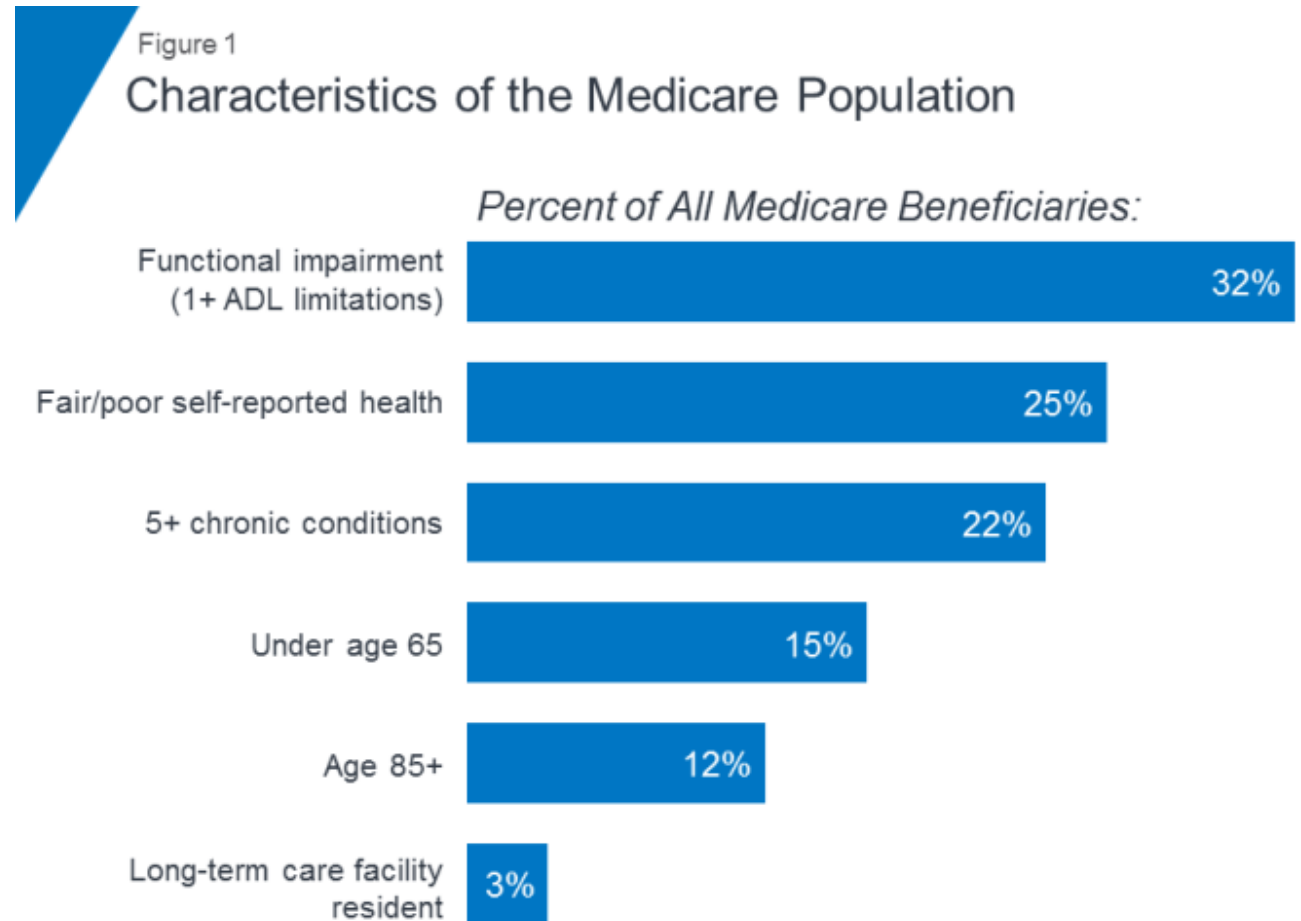
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Eligibility and Enrollment in Medicare

- **An entitlement**
- **Most common eligibility pathways:**
  - Age≥65: ~85% of Medicare beneficiaries
  - Disability: ~15%
  - End Stage Renal Disease (ESRD)

Figure 1

Characteristics of the Medicare Population

Percent of All Medicare Beneficiaries:

|	
Functional impairment (1+ ADL limitations)	32%
Fair/poor self-reported health	25%
5+ chronic conditions	22%
Under age 65	15%
Age 85+	12%
Long-term care facility resident	3%

NOTE: ADL is activity of daily living.
SOURCE: KFF analysis of the Centers for Medicare & Medicaid Services 2016 Medicare Current Beneficiary Survey.

KFF
HENRY J KAISER
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Structure of Medicare Program

- **Part A** covers inpatient hospital stays, skilled nursing facility (SNF) stays, some home health visits, and hospice care.

- **Part B** covers physician visits, outpatient services, preventive services, and some home health visits.

- *We typically refer Part A and Part B combined as traditional* **Medicare fee-for-service** *program*.

- **Part C** refers to the **Medicare Advantage** program, through which beneficiaries can enroll in a private health plan and receive all Medicare-covered services.
  - ~40% Medicare beneficiaries in 2020

- **Part D** covers outpatient prescription drugs through private plans that contract with Medicare.

Sources of Medicare Funding
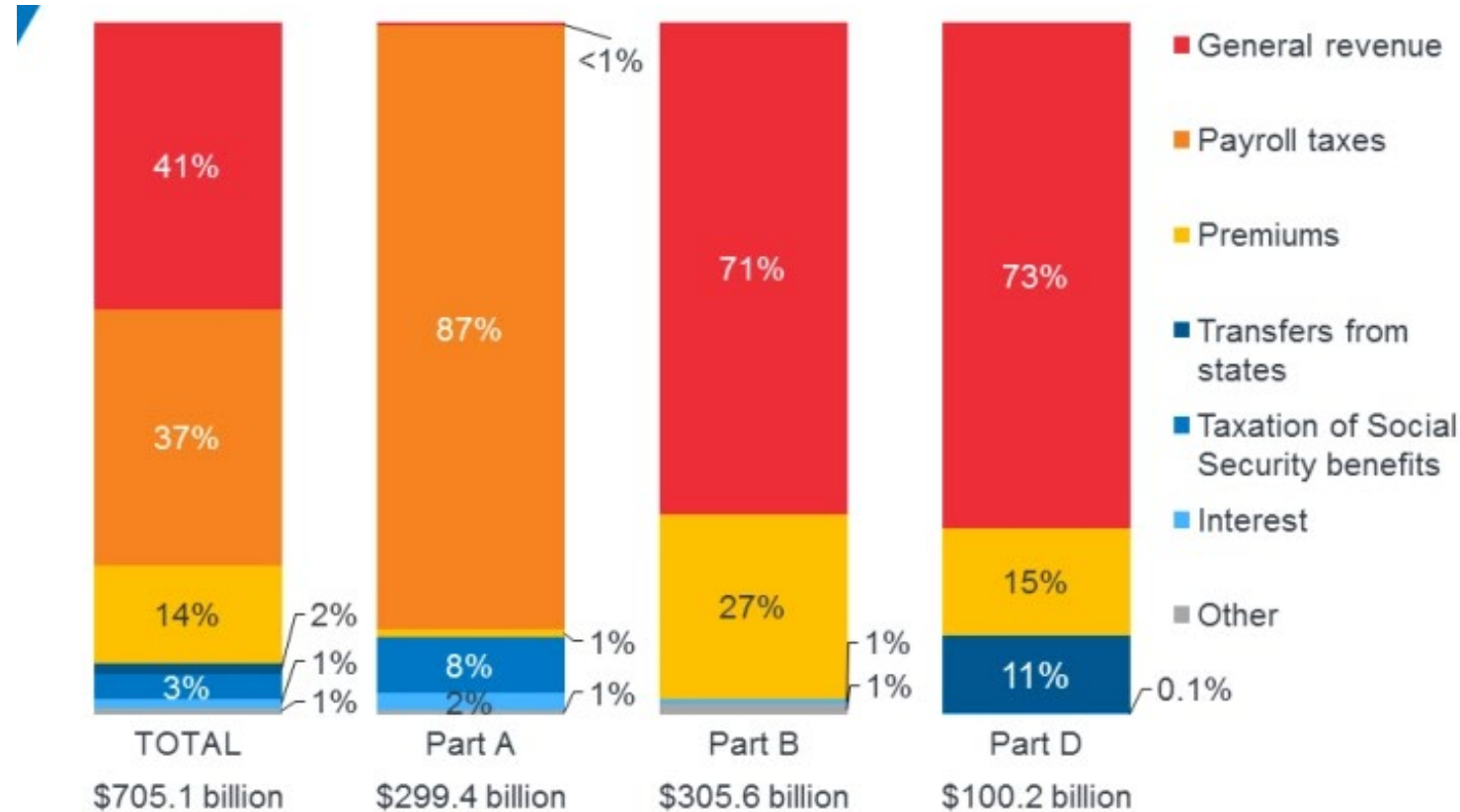
NOTE: Data are for the calendar year.
SOURCE: KFF analysis of Medicare spending data from 2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, Table II.B1.

Eligibility in Medicaid

- Medicaid is the nation's public health insurance program for people with low income.
  - Federal and state governments share costs
- Medicaid covers:
  - **Adults ages 19-64** with incomes ≤138% FPL: 34%
  - **Children**: ~43%
  - **Disable**d: 14%
  - **Medicare beneficiaries**: dual-eligible: 9%

Percent of People Covered By Medicaid/CHIP, 2017

Click below to download US fact sheet

United States: 21%

10-14% (8 states) 15%-19% (19 states) 20%-23% (12 states) Greater than 24% (11 states and DC)
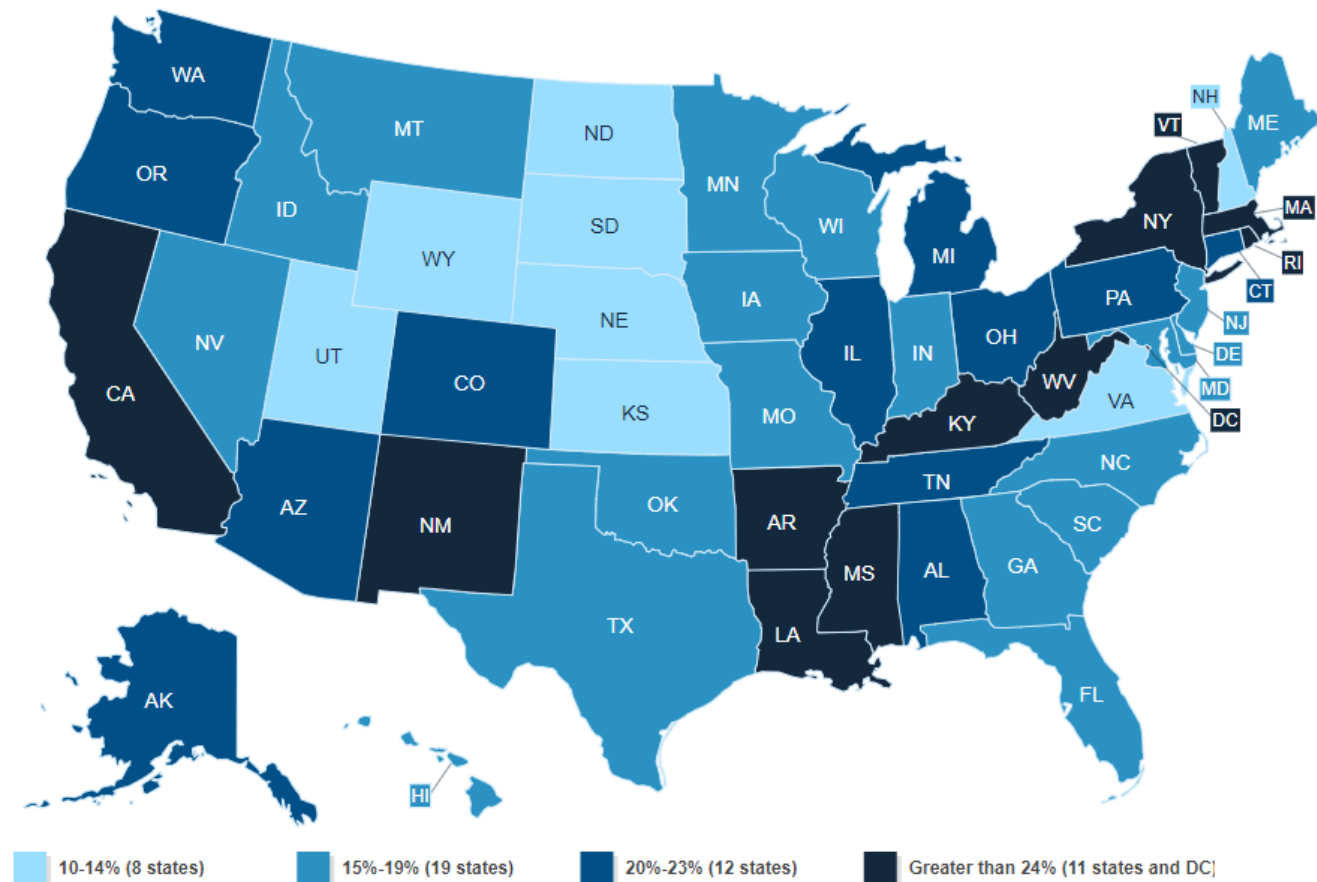
Medicaid Benefits and Spending

- Routine outpatient and inpatient care
- State enhanced benefits
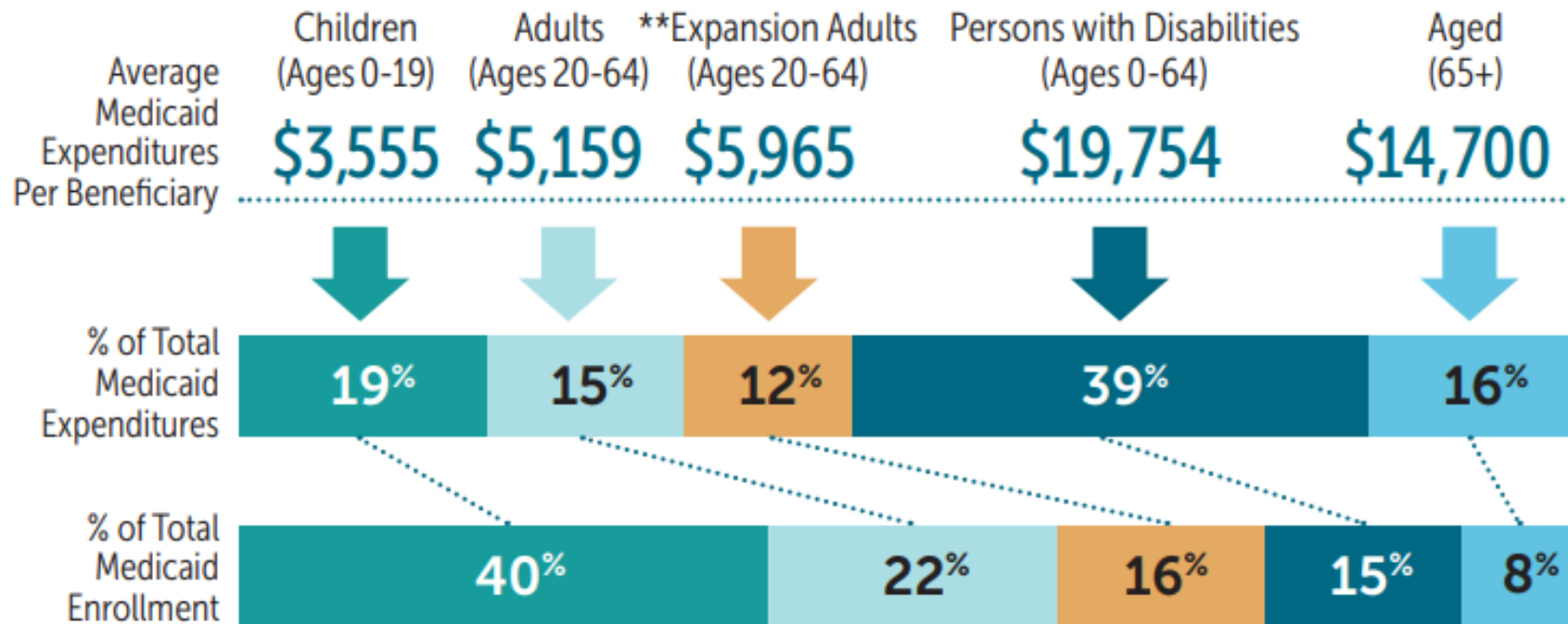- Long-term care in nursing home facilities
  - Account for 50% of LTC finance
- Support local health system and safety-network hospitals
- Assistance to 18% Medicare beneficiaries

Figure 5

Medicaid's benefits reflect the needs of the population it serves.

Low-Income Families	•Pregnant Women: Pre-natal care and delivery costs •Children: Routine and specialized care for childhood development (immunizations, dental, vision, speech therapy) •Families: Affordable coverage to prepare for the unexpected (emergency dental, hospitalizations, antibiotics)
Individuals with Disabilities	•Child with Autism: In-home therapy, speech/occupational therapy •Cerebral Palsy: Assistance to gain independence (personal care, case management and assistive technology) •HIV/AIDS: Physician services, prescription drugs •Mental Illness: Prescription drugs, physicians services
Elderly Individuals	•Medicare beneficiary: help paying for Medicare premiums and cost sharing •Community Waiver Participant: community based care and personal care •Nursing Home Resident: care paid by Medicaid since Medicare does not cover institutional care

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Medicare Average Cost, Enrollment and Expenditures

	Children (Ages 0-19)	Adults (Ages 20-64)	**Expansion Adults (Ages 20-64)	Persons with Disabilities (Ages 0-64)	Aged (65+)
Average Medicaid Expenditures Per Beneficiary	$3,555	$5,159	$5,965	$19,754	$14,700
% of Total Medicaid Expenditures	19%	15%	12%	39%	16%
% of Total Medicaid Enrollment	40%	22%	16%	15%	8%

Note: Children and adults with disabilities as their basis for eligibility are included in the category of persons with disabilities.

** Expansion adults = Adults made newly eligible for Medicaid under the Affordable Care Act beginning in 2014.

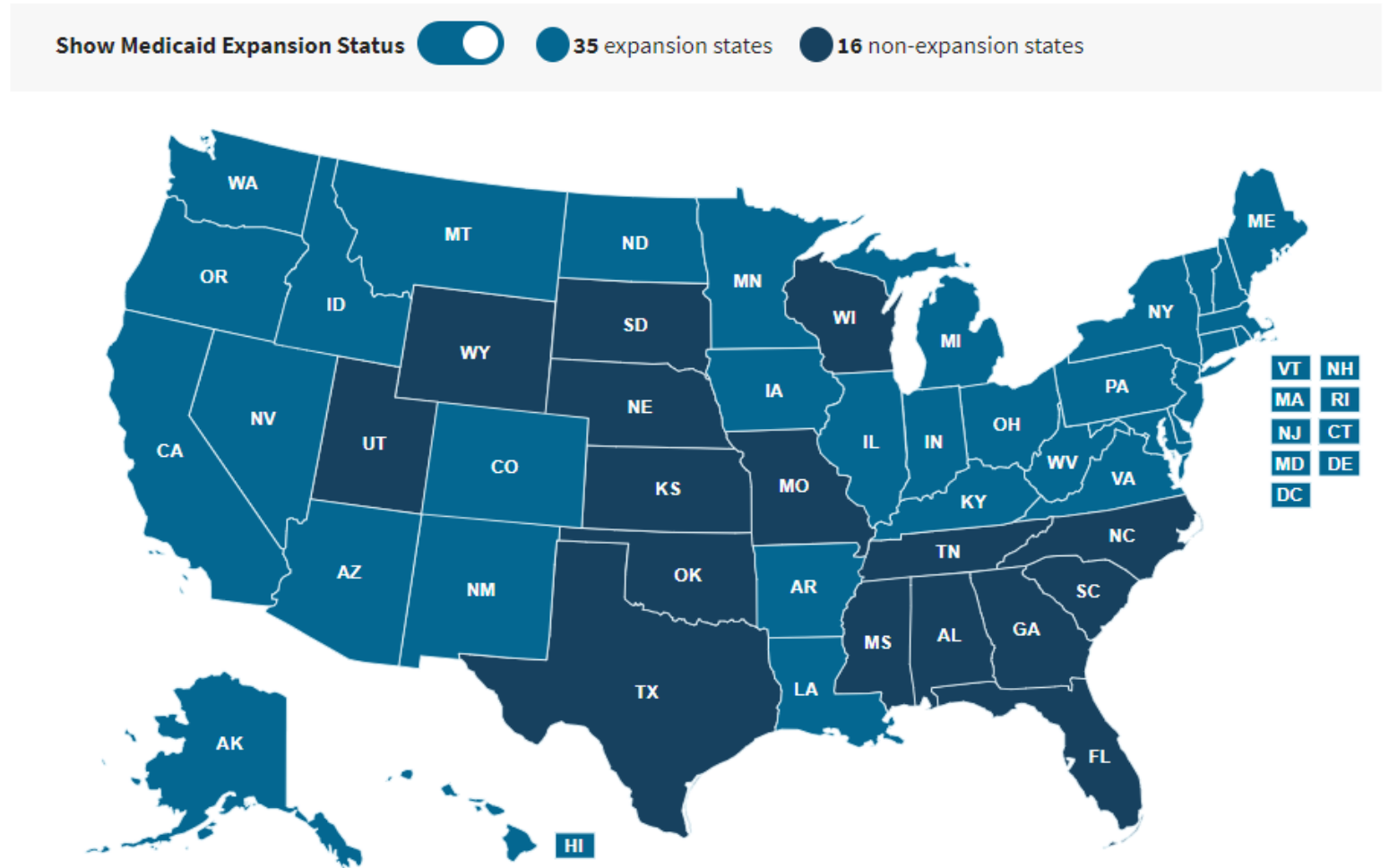# A Complication in Medicaid

- Not all states allow childless adults to enroll in Medicaid

Show Medicaid Expansion Status ⬤ **35** expansion states ⬤ **16** non-expansion states

Map represents data from September 2020, last updated January 15, 2021

Medicare and Medicaid Programs Generate Data!

- Topics
  - Enrollment
  - Spending
  - Claims and managed care data
    - Procedures
    - Diagnosis
  - Survey of provider quality and patient satisfaction
  - Death

Data Available for Research

http://www.resdac.org
https://www.cms.gov/Research-Statistics-Data-and-Systems/Research-Statistics-Data-and-Systems

- Research Identifiable data files (IDFs or referred to as RIFs): PHI and PII data included.
    - Medicare claims with zip code, provider NPIs, and patient birth/death date
    - Can be expensive!
- Limited Data Set Files (LDSs): data elements can be similar to RIFs but stripped of PHI and PII data. No direct HIPPA identifiers.
    - Medicare Current Beneficiary Survey (MCBS)
    - LDS version of Medicare claims

Data Available for Research

- Public Use Files (PUFs): Non-Identifiable Data Files.
    - PUF version of MCBS
    - Part D Plan-level prescription drug plan formulary and drug price
    - MA plan-level enrollment and demographics
    - PUF Medicare claims (synthetic)
    - Hospital cost reports

- Other Examples of Public Data
    - Health and Retirement Study (by NIA)
    - National Health Interview Survey
    - Medical Expenditure Panel Survey
    - Behavioral Risk Factor Surveillance System (BRFSS)

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Medicaid Data

- Data maintained by Medicaid:
    - Transformed Medicaid Statistical Information System (T-MSIS)
    - https://www.medicaid.gov/medicaid/data-systems/macbis/transformed-medicaid-statistical-information-system-t-msis/index.html
- State Medicaid Data:
    - E.g. Ohio Colleges of Medicine Government Resource Center
- Public Data
    - State Drug Utilization Data (SDUD)

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Privacy Level and IRB by ResDAC

	Public Use File	Limited Data Sets	Research Identifiable
Requires Privacy Board Review?	No	No	Yes
Requires a Data Use Agreement?	No	Yes	Yes
Files include beneficiary-level data?	No	Yes	Yes
Researchers may request customized cohorts (e.g. Diabetics residing in MN)?	No	No	Yes
Data can be linked at beneficiary level to non-CMS data using a beneficiary identifier?	No	No	Yes[1]
Claim run off period[2]	NA	Annual file: 6-month run off	Annual file: 12-month run off
		Quarterly file: 3-month run off	Quarterly file: 3-month run off

Table 1. Overview of file difference by privacy level

In light of the evolving COVID-19 situation, we want to assure you that **ResDAC is open for business**. We are actively responding to all phone and email inquiries.

Find, Request and Use **CMS Data**

GETTING STARTED

New to
CMS data

How to begin

Who is in the data?   →
What is in the data?   →
What type of data is right for me?   →

SUBMITTING A REQUEST

Find the documents you
need & submit a request

How to request identifiable data

Timeline and process   →
CMS data fee information   →
Get the documents you need   →

LEARN ABOUT CMS DATA

Get answers about
CMS data

How to understand & use the data

CMS data training   →
Articles about the data   →
Medicaid data quality resources   →

VIEW ALL NEWS >

NEWS UPDATES FROM CMS

2019 Preliminary Medicaid and CHIP Data Now Available

Costs to Obtain Data

- The fees for RIF and LDS data are determined by:
    - Files Requested
    - Number of People Included
    - Whether a Finder File is needed
    - Whether it is physical delivery of data or via virtual servers

https://resdac.org/cms-fee-information-research-identifiable-data

https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/StandardAnalyticalFiles

Medicare Administrative Claims Data

- Data derived from reimbursement or the payment of bills
- Data contains information about:
  - Procedures performed (services to be paid)
  - Providers of care (who gets paid)
  - Diagnoses codes (why service was performed so provider can be paid)
  - Care location (where the service happened, with whom)
  - Area characteristics (where the patient and care provider is located)
  - Other useful information (e.g. admission date)
- Claims can be linked to enrollment data
  - Enrollment details, age, sex, race…

Major Strengths and Limitations of Claims Data

- Data is largely reliable and valid, with rich clinical details
- Large population base
- Can easily be combined with data from other sources
  - Census data
  - Cancer registries (e.g., SEER/Medicare)
  - Vital statistics
  - Surveys (e.g,. MCBS and Health and Retirement Study) □
  - Other Provider Information
- Major limitations:
  - Disease stage and severity cannot be identified in most cases
  - Services paid entirely out-of-pocket cannot be known

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What Types of Questions May Be Answered?

- Baxter NN, Habermann EB, Tepper JE, Durham SB, Virnig BA. **Risk of pelvic fractures in older women following pelvic irradiation**. *JAMA*, 294:2587-2593, 2005.

- Bradley C, Given C, Luo Z, Dahman B, Virnig BA. **Diagnosis of advanced cancer among elderly Medicare and Medicaid Patients**. Medical Care, 45(5):410- 419, 2007.

- Jung J, Xu WY, Kalidindi Y. **Impact of the 340B Drug Pricing Program on Cancer Care Site and Spending in Medicare**. Health Serv Res. 2018 Oct;53(5):3528-3548.

- Xu WY, Jung K. **Socioeconomic Differences in Use of Low-Value Cancer Screenings and Distributional Effects in Medicare**. Health Services Research. 2017;52(5):1772-1793.

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Example 1: "Risk of pelvic fractures in older women following pelvic irradiation"

Context: Pelvic fractures, including hip fractures, are a major source of morbidity and mortality in older women. Although therapeutic pelvic irradiation could increase the risk of such fractures, this effect has not been studied.

Objective: To determine if women who undergo pelvic irradiation for pelvic malignancies (anal, cervical, or rectal cancers) have a higher rate of pelvic fracture than women with pelvic malignancies who do not undergo irradiation.

Design, setting, and participants: We conducted a retrospective cohort study using Surveillance, Epidemiology, and End Results (SEER) cancer registry data linked to Medicare claims data. A total of 6428 women aged 65 years and older diagnosed with pelvic malignancies from 1986 through 1999 were included. We compared results for women who did (n = 2855) vs did not (n = 3573) undergo radiation therapy. To assess the influence of selection bias, we also evaluated the effect of irradiation on osteoporotic fractures in nonirradiated sites (arm and spine).

Main outcome measure: We evaluated the effect of irradiation on the incidence of pelvic fractures over time, and adjusted for potential confounders using a proportional hazards model.

Baxter NN, Habermann EB, Tepper JE, Durham SB, Virnig BA. Risk of pelvic fractures in older women following pelvic irradiation. *JAMA*, 294:2587-2593, 2005.

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Example 2. The Impact of Mental Illness on Postoperative Outcomes Among Medicare Beneficiaries. A Missed Opportunity to Help Surgical Patients?

Objective:

The aim of this study was to define the prevalence of preexisting mental illness, as well as characterize the impact of a preexisting mental illness diagnosis on postoperative outcomes.

Summary Background Data:

Preoperative surgical evaluation and risk stratification have traditionally centered on optimizing physical health. The influence of mental health on postoperative surgical outcomes has not been investigated.

Methods:

Medicare beneficiaries who underwent elective colectomy, coronary artery bypass grafting, abdominal aortic aneurysm repair, abdominal aortic aneurysm repair, total hip arthroplasty, total knee arthroplasty, and lung resection were identified. Patients were classified as having mental illness using *International Classification of Diseases, 9th and 10th Revisions Procedures codes* (*ICD9/10CM*) codes for anxiety, depression, bipolar disorder, schizophrenia, or other psychotic disorder.

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Example 3: "Impact of the 340B Drug Pricing Program on Cancer Care Site and Spending in Medicare"

Objective: To examine the impact of the 340B drug discount program on the site of cancer drug administration and cancer care spending in Medicare.

Data sources/study setting: 2010-2013 Medicare claims data for a random sample of Medicare Fee-for-Service beneficiaries with cancer.

Study design: We identified the 340B effect using variation in the availability of 340B hospitals across markets. We considered beneficiaries from markets that newly gained a 340B hospital during the study period (new 340B markets) as the treatment group. Beneficiaries in markets with no 340B hospital were the control group. We used a difference-in-differences approach with market fixed effects.

Data collection: Secondary data analysis.

Principal findings: The probability of a patient receiving cancer drug administration in hospital outpatient departments (HOPDs) versus physician offices increased 7.8 percentage points more in new 340B markets than in markets with no 340B hospital. Per-patient spending on other cancer care increased $1,162 more in new 340B markets than in markets with no 340B hospital.

Conclusions: The 340B program shifted the site of cancer drug administration to HOPDs and increased spending on other cancer care. As the program expands, continuing assessment of its impact on service utilization and spending would be needed.

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Example 4. "Socioeconomic Differences in Use of Low-Value Cancer Screenings and Distributional Effects in Medicare"

Objective: Consuming low-value health care not only highlights inefficient resource use but also brings an important concern regarding the economics of disparities. We identify the relation of socioeconomic characteristics to the use of low-value cancer screenings in Medicare fee-for-service (FFS) settings, and quantify the amount subsidized from nonusers and taxpayers to users of these screenings.

Data sources: 2007-2013 Medicare Current Beneficiary Survey, Medicare FFS claims, and the Area Health Resource Files.

Study design: Our sample included enrollees in FFS Part B for the entire calendar year. We excluded beneficiaries with a claims-documented or self-reported history of targeted cancers, or those enrolled in Medicaid or Medicare Advantage plans. We identified use of low-value Pap smears, mammograms, and prostate-specific antigen tests based on established algorithms, and estimated a logistic model with year dummies separately for each test.

Data collection/extraction methods: Secondary data analyses.

Principal findings: We found a statistically significant positive association between privileged socioeconomic characteristics and use of low-value screenings. Having higher income and supplemental private insurance strongly predicted more net subsidies from Medicare.

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Is higher privacy level better for research?

- Hernandez I, Good CB, Shrank WH, Gellad WF. **Trends in Medicaid Prices, Market Share, and Spending on Long-Acting Insulins, 2006-2018**. *JAMA*. 2019;321(16):1627–1629. doi:10.1001/jama.2019.2990
  - Using Medicaid state drug utilization data, quarterly
  - Examined changes in reimbursement and market share of long-acting insulins in Medicaid following the approval of these new products. Additionally, they estimated savings associated with the use of certain Rx

Use of CMS Data for Research

- Finding the right data for your research will depend on several factors:
  - The research question
  - Level of detail needed
  - Level of customization
  - Budget available
  - Time to obtain
  - Storage capacity

Questions?

- Make sure to first contact BERD researchers!
- My contact: xu.1636@osu.edu