

Use of the US Medicare database in HIV epidemiologic and health services research

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Family

Comparative Effectiveness Research on Cancer in Texas (RP210130;

Outline

Background

Introduction to Medicare databases

Questions/discussion

One example for HIV research

Questions/discussion



Background

Former physician in China

Received statistical training (MS 2003, PhD 2015)

Supported CFAR at Baylor College of Medicine (BCM, 2006-2016)

Joined UTMB in 2017

- Continued the collaboration with HIV researchers at BCM
- ✓ Support aging programs at UTMB
- ✓ Interested in collaborative and independent research on HIV and aging
 - BIRCWH training (2020-2022)
 - UCSD STAHR scholar (2021-current)

Why use Medicare data to conduct HIV research?

- People with HIV (PWH) are getting older (53.5% reached 50 in 2021)¹
- Studies from longitudinal HIV cohorts (e.g., MWCCS, VACS, HAILO) provided rich information²⁻⁴
 - Relatively small number of older PWH (especially 65+)
- US Medicare data is a population-based database
 - ✓ 98% of elderly Americans are Medicare enrollees (65M in 2022)⁵

^{1.} CDC. HIV Surveillance Report, 2021; vol. 34. <u>http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html</u>.

^{2. &}lt;a href="https://statepi.jhsph.edu/mwccs/">https://statepi.jhsph.edu/mwccs/;

^{3. &}lt;u>https://www.vacsp.research.va.gov/CSPEC/Studies/INVESTD-R/Veteran-Aging-Cohort-Study.asp</u>

^{4. &}lt;u>https://actgnetwork.org/clinical-trial/a5322-long-term-follow-up-of-older-hiv-infected-adults-in-the-actg-addressing-issues-of-aging-hiv-infection-and-inflammation-hailo-2/;</u>

^{5. &}lt;u>https://data.cms.gov/infographic/medicare-beneficiaries-at-a-glance</u>

Why use Medicare data to conduct HIV research?

In 2020:

- Medicare is the second largest source of federal financing for the care and treatment of PWH
- Covers 28% of adults with HIV per CDC HIV surveillance report



https://www.kff.org/hivaids/issue-brief/medicare-and-people-with-hiv/

CDC MMP 2020 HIV Surveillance Special Report 29. https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html

Growing interest in using Medicare data for HIV research



Introduction to Medicare databases



Medicare population

- Elderly: 65 years and older
- Disability: <65 years old</p>
- End Stage Renal Disease (ESRD)
- Amyotrophic lateral sclerosis
 (ALS) or Lou Gehrig's Disease



Those under 65 years old at enrollment will automatically qualify for old age when turning 65 years old

https://www.cms.gov/Medicare/Eligibility-and-Enrollment/

Center for Medicare & Medicaid Service (CMS) 2020

Medicare population with disability

Definition for disability

The <u>inability to do any substantial gainful activity</u> by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to <u>last for a continuous period of not less than 12 months</u>

Disability benefits

- Wait 5 months before receiving Social Security Disability Insurance (SSDI) benefit
- Enrollment in Medicare: Medicare benefits start <u>24 months after disability</u> <u>benefits start</u>
- □ For ESRD and ALS, Medicare benefit starts at time of diagnosis
- <u>https://www.cms.gov/Medicare/Eligibility-and-Enrollment/</u>
- Social Security Administration. Definition of Disability. <u>https://www.ssa.gov/OP_Home/cfr20/404/404-1505.htm</u>
- Social Security Administration. Disability Benefits. <u>https://www.ssa.gov/benefits/disability/approval.html</u>

Majority of PWH are <65 and aging groups grow faster



Majority of PWH are males



Majority of PWH have a disability



More Black and Hispanic among PWH



Enhanced race/ethnicity designation based on first and last name algorithms developed by Research Triangle Institute

Medicare programs

	Part A		Part B		Part D
Original Medicare	Fee-for-Service Home Health Agency Hospice Inpatient Skilled Nursing Facility	+	Fee-for-Service Carrier Curable Medical Equipment Home Health Agency Outpatient	+/-	 Event/Drug Characteristics Formulary Medication Therapy Management Pharmacy Characteristics
Part C	Encounter Home Health Agency Inpatient Skilled Nursing Facility	+	Encounter Carrier Carrier Durable Medical Equipment Home Health Agency Outpatient	+	 Plan Election Type Beneficiary Summary Plan Characteristics Prescriber Characteristics

Fee-for-Service (FFS)

- Providers submit bills to CMS for services provided
- Payments are based on standard fee schedules

Part C – Medicare Advantage

- Pay extras not covered in FFS
- Encounter data reported to CMS
- Payments to provider are on a capitated basis
- Data for research was released since 2015
- <u>https://www.youtube.com/watch?v=eMFn3BmBarM</u>
- <u>https://resdac.org/videos/overview-history-and-</u> structure-medicare-advantage-and-comparison-ffsand-ma-enrollees

Medicare programs





Center for Medicare & Medicaid Service (CMS) 2020



Assistance to people with low income

State buy-in

State Medicaid programs can pay Medicare premiums for certain dual eligibles (this action is called "buying in")

Part D low-income subsidy (LIS)

Covers some or all of those costs for certain low income individuals, including deductibles and cost-sharing during the coverage gap (74% of PWH in 2020)

• CMS 101 Medicare Data workshop: Introduction to the Use of Medicare Data for Research

https://www.kff.org/hivaids/issue-brief/medicare-and-people-with-hiv/

Research files (Yearly)	Type of information	Available fields (selected, all files can be linked by BENE_ID)
Master beneficiary Summary files (MBSF base & NDI)	Demographics and enrollment	Age, date of birth , sex, race, place of residence (state, county and zip code), date of death and cause of death (available through NDI segment), and indicators in enrollment in part A, B, C, D, Medicaid, and LIS
MBSF chronic conditions segments	Chronic/disabling conditions	Indicators of 62 chronic conditions or potentially disabling conditions (65, 2017 forward): first ever occurrence date and flags of condition in the calendar year based on the CCW algorithms
Part A files	Diagnosis and service (hospital)	Admission date, discharge date, diagnosis codes (DRG, ICD-9/ICD-10 codes, procedure codes (CPT/HCPCS), physician/provider codes (UPIN, NPI), charge data
Part B files	Diagnosis and service (Physician)	Date of service, diagnosis codes (ICD-9/ICD-10 codes, procedure codes (CPT/HCPCS), physician codes, charge data
Part D event file (2006-2021)	Prescription filled	fill date, NDC codes , quantity dispensed, days supply, gross drug cost, out- of-pocket cost, benefit phase, prescriber identifiers, pharmacy identifier

NDI: National Death Index; CCW: Chronic Conditions Data Warehouse; DRG: Diagnosis-related group; UPIN: Unique Physician Identifier; NPI: National Provider Identifier; NDC: National Drug Code

Check data availability for the year and data dictionary: <u>https://www2.ccwd/guest/data-dictionaries</u>

Chronic Conditions Data Warehouse

	My CCW Login (Authorized Users Only)	FAQ	Help			
Chronic Conditions Date Warehouse						
Your source for national CMS Medicare and Medicaid research data						
Home Medicare Data - Medicaid Data - Data Dictionaries Condition Categories - Analytic Guidance -	Pricing 👻					

Chronic Conditions Data Warehouse » Home

- Provides researchers with Medicare and Medicaid beneficiary, claims, and assessment data linked by beneficiary across the continuum of care
- A research database designed to make Medicare, Medicaid, Assessments, Part C, and Part D Prescription Drug Event data more readily available to support research designed to improve the quality of care and reduce costs and utilization

https://www2.ccwdata.org/web/guest/home/

Overview of file difference by privacy level

	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

The inclusion of patient identifiers linkable to outside data requires CMS approval. Without this approval, the RIF patient identifiers are not linkable to outside data.
 More detailed information about the runoff periods and availability are found in the articles, "<u>RIF Medicare Quarterly Data</u>" and "<u>Medicare Limited Data Set (LDS) Quarterly Claims and Enrollment Data</u>".

https://resdac.org/articles/differences-between-rif-lds-and-puf-data-files#:~:text=The%20difference%2C%20however%2C%20between%20RIF,or%205%25%20random%20sample%20file

Medicare standard analytic files (SAFs)

5% or 20% sample of Medicare beneficiaries

- Beneficiaries are selected for inclusion in the database based on the last 2 digits of their health insurance claim number, which, in the vast majority of cases, is their social security number
- 100% of Medicare beneficiaries (generally limited to specific disease cohorts, for example, all people with HIV)
- 100% of Medicare beneficiaries for a state

Disease-specific Medicare datasets and linkages

Additional survey data, disease-specific databases, and linked databases with access to more detailed information regarding health care utilization and clinical characteristics of Medicare beneficiaries

- Medicare Current Beneficiary Survey
- United States Renal Data System
- ✓ SEER-Medicare

https://www.cms.gov/research-statistics-data-and-systems/research/mcbs https://resdac.org/articles/data-resources-studying-end-stage-renal-disease-esrd https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/usrds https://healthcaredelivery.cancer.gov/seermedicare/overview/

Strengths of the Medicare data

- Nearly complete coverage for older population: 98% of US individuals aged ≥65 years receive Medicare (65M+ US individuals as of 2022)
- Longitudinal information on health care services: Once individuals are enrolled in Medicare, they are typically followed until death
- Reflect near-complete capture of <u>health care services</u> across all settings of care: The data can be used to answer a wide range of health care-related questions
- Demographic data, such as age, date of birth, race, place of residence and date of death are considered <u>largely reliable and valid</u>: Can serve as denominator file
- Convenient <u>linkage to external data sources</u>: US Census, survey, cancer registries, other providers, etc.

https://resdac.org/articles/strengths-and-limitations-cms-administrative-data-research Turrini G et al. PLoS One. 2020. doi: 10.1371/journal.pone.0241833.

Limitations of the Medicare data

- Contain record of cares received and conditions can be underdiagnosed
- Lack information on behavioral characteristics, physiological measures, laboratory tests and results of diagnostic tests and disease severity indicators
- Diseases are typically defined in Medicare data by the presence of a diagnostic code and prone to misclassification
- Impact of changes in CMS policy (ex., ICD-9-CM code switched to ICD-10-CM in October 2015)
- It is difficult to conduct longitudinal studies on the entire Medicare population (data availability on beneficiaries covered by Medicare Advantage plans)
- Medicare data for beneficiaries aged <65 years are not representative of the age-matched national population</p>

https://resdac.org/articles/strengths-and-limitations-cms-administrative-data-research Turrini G et al. PLoS One. 2020. doi: 10.1371/journal.pone.0241833.

Example questions relevant to HIV research

- Understanding the epidemiology of HIV and chronic conditions (prevalence, incidence, trend over time)
- Describing treatment utilization patterns and the delivery of HIV health care services
- Comparing the effectiveness, safety, and costs of HIV medications and treatments
- Studying the effects of policy changes on prescribing patterns and clinical outcomes for PWH

Challenges for HIV research

It is challenging to ascertain the timing of first HIV diagnosis and incident conditions

 \rightarrow Apply an 'observation' period

Lack of information on risk behaviors among PWH and lab test results such as, CD4 counts and viral load data

 \rightarrow Link external datasets (e.g., census data) to the Medicare by zip code

- PWH can receive medications outside the Medicare program. Non-FDA approved drugs were not covered
 - \rightarrow Interpret your results appropriately

Challenges for HIV research

It is challenging to understand what services/treatments/drugs are covered by Medicare and policy changes

→ Consult with clinician and who are familiar with billing and policies

Need advanced statistical methods to handle complex analytical issues

- → Control measured confounding (e.g., matching, propensity methods)
- → Address unmeasured confounding (e.g., instrumental variable methods)
- → Address misclassification (e.g., sensitivity analysis using various algorithms)



Process to get access to the data

 \checkmark

Process data

Data access

Researcher (1,3,6) Proposal 🗸 DUA **ResDAC** submits final packet to CMS Submit payment ✓ Payment Privacy Board **ResDAC** team for data and 620 reviews packet notify CMS ResDAC (2,4) 2 6 4 ✓ Technical support \mathbf{O} for the submission 3 5 Estimate the cost Submit draft Complete edits **CMS (5)** Data is processed CMS emails request packet and return **Privacy Board** to ResDAC Review and final signed decision documents to approve the ResDAC application **ResDAC** forwards **ResDAC** obtains cost data management invoice **CCW (7)** plan for review

= Steps to be completed by researcher

https://resdac.org/cms-research-identifiable-request-process-timeline

Access format and cost

Туре	Cost
Physical files*	Fees are per year of data and vary based on beneficiary count and file type
CCW Virtual Research	Based on seat access, project fee, software, space/usage cost
Data Center (VRDC)	Ex., 1 seat, 1 project, SAS only, and no extra space → \$35,000 (initial), \$23,000 (renewal), for one-year access

Institution needs to complete a Data Management Plan Self-Attestation Questionnaire (DMP SAQ)
 to demonstrate compliance and preparedness with CMS security and privacy requirements

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

Support needed to be able to manage and analyze Medicare data

- Administrate support for data access requests and revisions, need designated custodian
- Institution IT support, IRB (NOT exempt research)
- Training on Medicare data (ResDAC) and utilization of VRDC (CCW)
- Data management (combine complex files, construct the cohort and create all analytical variables)
- Statistical support to employ advanced analytical methods



Questions/Comments...

Example to use Medicare data for HIV research



HHS Public Access

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Assessing comorbidities and survival in HIV-infected and uninfected matched Medicare enrollees

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Background

- People with HIV experience excessive mortality compared with people without HIV (PWOH)^{1,2}
- Age-related comorbidities have become more prevalent in PWH
- Only one large study used the Medicare dataset to extensively examine the comorbidities and mortality of all older PWH (≥65 years old between 2011-2016, N=43,708) and compared them to a 1% sample of PWOH³
- It is unclear whether the impact of HIV infection on mortality varies by comorbidities or whether sex difference exists in this relationship
- There are limited data on enrollees who qualify for Medicare because of disability despite they comprise majority of the PWH in Medicare program

^{1.} de Coninck Z, et al. AIDS Patient Care STDS 2018; 32(8):297-305.; 2. Legarth RA, et al.. J Acquir Immune Defic Syndr 2016; 71(2):213-218.; 3. Turrini G et al. PLoS One 2020; 15(11):e0241833.

Objective

Assess the effect of newly diagnosed HIV infection on overall mortality among Medicare enrollees who qualify for disability and old age (≥65)

Examined sex differences in baseline comorbidities and the impact of HIV infection on mortality

Explore baseline comorbidities interacting with HIV infection on outcomes

Data source and HIV cohort

5% national sample of Medicare beneficiaries between 1995 and 2015 (Master Beneficiary Summary Files and claim files for each year)

- Newly diagnosed HIV patients by ICD-9-CM/ICD-10-CM (1 on inpatient claim, or 2 outpatient/Carrier claims)
- Have at least 1 year of continuous enrollment in Medicare parts A and B with no HMO enrollment (FFS) prior to 1st HIV diagnosis





Statistical analysis

Outcome: All-cause mortality and time to death/censoring (beneficiaries were censored at the end of the study period (December 31, 2015) or final loss of coverage)

All analyses were stratified by disability status and sex

- Baseline comorbidities included in Elixhauser comorbidity index.
 Hypertension and diabetes were examined as two individual covariates (High prevalence and individual effect has been under-studied)
- Unadjusted survival curves by HIV status were obtained using the Kaplan-Meier method
- Hazard ratio (HR) and 95% confidence intervals (CI), stratified results by comorbidity levels

Demographics

- Only PWH were presented due to individual matching on these variables
- Females were older than males, especially among 65+
- Race make up was similar except for more Black persons among older males, fewer
 Black persons among males with disability
- More females had Medicaid
 Dual Eligibility

Medicare or	iginal entitlement	nent Disabled		Older Age		
Sex	Level	Male N (%)	Female N (%)	Male N (%)	Female N (%)	
Sample size		3,313	1,558	1,064	930	
	Mean (SD)	47.4 (11.7)	48.3 (12.9)	73.3 (6.3)	76.7 (7.4)	
	18-39	888 (26.8)	417 (26.8)			
A ac at	40-49	1,097 (33.1)	439 (28.2)			
Age at Index Date	50-59	773 (23.3)	400 (25.7)			
index Date	60-69	443 (13.4)	221 (14.2)	370 (34.8)	194 (20.9)	
	70-79	97 (2.9)	64 (4.1)	516 (48.5)	437 (47.0)	
	80+	15 (0.5)	17 (1.1)	178 (16.7)	299 (32.2)	
	Black	1,487 (44.9)	811 (52.1)	289 (27.2)	204 (21.9)	
Paca	Hispanic	212 (6.4)	89 (5.7)	57 (5.4)	82 (8.8)	
Nace	Other/Unknown	150 (4.5)	64 (4.1)	39 (3.7)	41 (4.4)	
	White	1,464 (44.2)	594 (38.1)	679 (63.8)	603 (64.8)	
	East North Central	335 (10.1)	183 (11.7)	139 (13.1)	132 (14.2)	
	East South Central	190 (5.7)	71 (4.6)	43 (4.0)	38 (4.1)	
	Middle Atlantic	636 (19.2)	300 (19.3)	216 (20.3)	174 (18.7)	
	Mountain	91 (2.7)	31 (2.0)	34 (3.2)	26 (2.8)	
Division	New England	173 (5.2)	54 (3.5)	31 (2.9)	20 (2.2)	
Division	Pacific	480 (14.5)	175 (11.2)	157 (14.8)	95 (10.2)	
	South Atlantic	969 (29.2)	538 (34.5)	314 (29.5)	325 (34.9)	
	West North Central	88 (2.7)	37 (2.4)	32 (3.0)	30 (3.2)	
	West South Central	351 (10.6)	169 (10.8)	98 (9.2)	90 (9.7)	
Medicaid Dual Eligibility (Yes)		2,020 (61.0)	1,141 (73.2)	268 (25.2)	341 (36.7)	
	1995-2000	1,056 (31.9)	367 (23.6)	231 (21.7)	206 (22.2)	
Index Vear	2001-2005	800 (24.1)	341 (21.9)	215 (20.2)	179 (19.2)	
Index Year	2006-2010	837 (25.3)	463 (29.7)	375 (35.2)	354 (38.1)	
	2011-2015	620 (18.7)	387 (24.8)	243 (22.8)	191 (20.5)	

Baseline comorbidities

In general, older age group has higher prevalence except for obesity, depression and drug abuse

The order of prevalence:

- 1 Female PWH (highest)
- 2 Male PWH
- 3 Female PWOH
- 4 Male PWOH (lowest)

Exceptions:

 Males had more alcohol/drug abuse, cancer/tumor



Survival

- Lower survival for PWH
- Lower survival among males
- Larger difference in males especially among older age group (HIV-sex interaction p=0.004) by Cox proportional hazard models adjusting for the baseline covariates and comorbidities.

A difference of 4-5 years in median survival time among the older age groups



Impact of comorbidities (adjusted hazard ratio)

		Disabled				Older Age				
Comorbidities	1	Male		Female		Male		Female		
	Level	HR (95% CI)	р	HR (95% CI)	р	HR (95% CI)	р	HR (95% CI)	р	
Hypertension	No	2.43 (2.21, 2.68)	<0.0001	2.44 (2.03, 2.94)	<0.0001	1.91 (1.59, 2.29)	0.06	1.42 (1.11, 1.82)	0.38	
	Yes	1.37 (1.23, 1.53)		1.42 (1.22, 1.65)		1.55 (1.36, 1.76)		1.25 (1.11, 1.42)		
Diabetes	No	2.26 (2.08, 2.46)	<0.0001	1.89 (1.62, 2.19)	0.08	1.69 (1.49, 1.92)	0.48	1.31 (1.13, 1.51)	0.66	
	Yes	1.13 (0.99, 1.29)		1.54 (1.29, 1.84)		1.57 (1.32, 1.87)		1.25 (1.05, 1.48)		
Elixhauser Comorbidity Count	0	3.10 (2.70, 3.56)	<0.0001	2.91 (2.17, 3.90)	<0.0001	2.08 (1.63, 2.66)	0.14	1.40 (0.98, 2.00)	0.88	
	1	2.26 (1.89, 2.70)		2.42 (1.71, 3.42)		1.45 (1.07, 1.95)		1.31 (0.95, 1.82)		
	2-3	1.87 (1.62, 2.16)		1.75 (1.38, 2.21)		1.79 (1.45, 2.21)		1.19 (0.95, 1.47)		
	4-5	1.41 (1.17, 1.68)		1.98 (1.52, 2.56)		1.49 (1.17, 1.90)		1.29 (1.01, 1.66)		
	6-8	1.14 (0.94, 1.38)		0.95 (0.73, 1.23)		1.35 (1.04, 1.74)		1.41 (1.10, 1.81)		
	9+	0.90 (0.69, 1.17)		1.45 (1.03, 2.05)		1.87 (1.26, 2.77)		1.11 (0.73, 1.68)		

Higher HIV impact on survival among those without comorbidity, especially for males and those with disability

Discussion

- More prevalent chronic conditions among PWH, and among females
 - Possible some individuals had HIV infection, but delayed diagnosis impacted their general health conditions
 - ✓ Women live longer, and seek more care/service thus more diagnoses?
- Risk of death due to HIV infection was amplified in males and individuals with disabilities
 - ✓ Differences in health utilization between sex?
 - Disadvantages in individuals with HIV and disabilities
- PWH with chronic conditions had a less pronounced increase in risk of death than those without conditions compared to controls
 - Increase in care utilization might improve the management of their HIV and comorbidities and thus decrease their impact on other outcomes

Limitations and future work

- Did not examine ART treatment as a covariate. The Medicare Prescription Drug Benefit program became available in 2006
- Did not assess HIV-related death
- Consider time-varying covariates for comorbid conditions would be incorporated in future studies
- Further analysis could include more conditions including HIVrelated conditions and additional sex-specific conditions

Conclusions

- Older Medicare enrollees with newly diagnosed HIV had more prevalent baseline comorbidities and were at higher risk of death following diagnosis
- The impact of HIV infection was less pronounced among beneficiaries with more chronic conditions
- Older females with HIV had more baseline comorbidities, but HIV infection had less impact on their survival compared to males with HIV

Summary

- Medicare data is valuable to conduct HIV and aging research at population level and provide real-world evidence to guide decision-makers
- It is important to consider its limitations and use the data appropriately to address relevant questions

References and resources

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Thank You and Questions Comments...

Contact: xiyu@utmb.edu

Questions? Have ideas? Need support? Let us help you propose new projects and find resources for your work!

Contact us: <u>CFARClinicalCore@mednet.ucla.edu</u> or Stephanie Buchbinder, CSC Program Manager, <u>sbuchbinder@mednet.ucla.edu</u>

