Referral for Health Care and Support Services (ADAP Enrollment Workers)	Pg
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Non-Adherence to HIV treatment for Cost-Saving Reasons Reported by 8% in American Study - aidsmap.com, March 2019	30

2022-2023 Service Category Definition - DSHS State Services - Rebate

Local Service Category:	Referral for Health Care: ADAP Enrollment Worker
Amount Available:	To be determined
Unit Cost	
Budget Requirements or Restrictions (TRG Only):	Maximum 10% of budget for Administrative Cost. No direct medical costs may be billed to this grant.
DSHS Service Category Definition:	Direct people living with HIV (PLWH) to a service in person or through telephone, written, or other types of communication, including management of such services where they are not provided as part of Ambulatory Outpatient Medical Care or Case Management Services.
Local Service Category Definition:	AIDS Drug Assistance Program (ADAP) Enrollment Workers (AEWs) are co-located at Ryan-White funded clinics to ensure the efficient and accurate submission of ADAP applications to the Texas HIV Medication Program (THMP). AEWs will meet with all potential ADAP enrollees to explain ADAP program benefits and requirements and assist PLWHs with the submission of complete and accurate ADAP applications. AEWs will ensure benefits continuation through timely completion of annual re-certifications by the last day of the PLWH's birth month and attestations six months later to ensure there is no lapse in ADAP eligibility and/or loss of benefits. Other responsibilities will include: • Track the ADAP application process to ensure submitted applications are processed as quick as possible, including prompt follow-up on pending applications to gather missing or questioned documentation as needed. • Maintain ongoing communication with designated THMP staff to aid in resolution of PLWH inquires and questioned applications; and to ensure any issues affecting pending applications and/or PLWHs are mediated as quickly as possible. AEWs must maintain relationships with the Ryan White ADAP Network (RWAN).
Target Population (age, gender, geographic, race, ethnicity, etc.):	People living with HIV in the Houston HDSA in need of medications through the Texas HIV Medication Program.
Services to be Provided:	Services include but are not limited to provision of education on available benefits programs applicable to the PLWH; completion of ADAP application including enrollment/recertification/six-month attestation; aid the PLWH in gathering all required supporting documentation to complete benefits application(s) including ADAP; provide a streamlined process for submission of completed ADAP applications and/or other benefits applications; assist in benefits continuation including six-month attestation and necessary follow-up; liaison with THMP and the PLWH throughout the ADAP application process

2022-2023 Service Category Definition - DSHS State Services - Rebate

Service Unit Definition(s) (TRG Only):	One unit of service is defined as 15 minutes of direct PLWH services or coordination of application process on behalf of PLWH.
Financial Eligibility:	Income at or below 300% of Federal Poverty Guidelines
Eligibility for Service:	People living with HIV in the Houston HDSA
Agency Requirements (TRG Only):	Agency must be funded for Outpatient Ambulatory Medical Care bundled service category under Ryan White Part A/B/DSHS SS.
Staff Requirements:	Not Applicable.
Special Requirements (TRG Only):	The agency must comply with the DSHS Referral to Healthcare Standards of Care and the Houston HSDA Referral for Health Care and Support Services Standards of Care. The agency must have policies and procedures in place that comply with the standards <i>prior</i> to delivery of the service.

FY 2022 RWPC "How to Best Meet the Need" Decision Process

Step in Process: C	ouncil		Date: 06/10/2021
Recommendations:	Approved: Y: No:	If approve	ed with changes list
	Approved With Changes:	changes b	
1.			
2.			
3.			
Step in Process: St	teering Committee		Date: 06/03/2021
Recommendations:	Approved: Y: No:	If approve	ed with changes list
	Approved With Changes:	changes b	
1.	<u> </u>		
2.			
3.			
Step in Process: O	uality Improvement Committe	ee	
wep in Troubble &			Date: 05/18/2021
Recommendations:	Approved: Y: No:	If approve	ed with changes list
	_		ed with changes list
Recommendations:	Approved: Y: No:	If approve	ed with changes list
Recommendations: 1.	Approved: Y: No:	If approve	ed with changes list
Recommendations: 1. 2. 3.	Approved: Y: No:	If approve	ed with changes list
Recommendations: 1. 2. 3.	Approved: Y: No: Approved With Changes:	If approve	ed with changes list elow:
Recommendations: 1. 2. 3. Step in Process: H	Approved: Y: No: Approved With Changes: TBMTN Workgroup #1	If approve	ed with changes list elow:
Recommendations: 1. 2. 3. Step in Process: H Recommendations:	Approved: Y: No: Approved With Changes: TBMTN Workgroup #1	If approve	ed with changes list elow:
Recommendations: 1. 2. 3. Step in Process: H Recommendations: 1.	Approved: Y: No: Approved With Changes: TBMTN Workgroup #1	If approve	ed with changes list elow:

RYAN WHITE PART B/DSHS STATE SERVICES 21-22 HOUSTON HSDA SERVICE-SPECIFIC STANDARDS OF CARE REFERRAL FOR HEALTH CARE AND SUPPORT SERVICES ADAP ENROLLMENT WORKERS

Definition:

Referral for Health Care and Support Services directs a client to needed core medical or support services in person or through telephone, written, or other type of communication. This service may include referrals to assist eligible clients to obtain access to other public or private programs for which they may be eligible (e.g., Medicaid, Medicare Part D, State Pharmacy Assistance Programs, Pharmaceutical Manufacturer's Patient Assistance Programs, and other state or local health care and supportive services, or health insurance Marketplace plans).

#	STANDARD		MEASURE
9.0 Ser	vice-Specific Requirements	<u>.</u>	
9.1	Scope of Services Referral for Health Care and Support Services includes benefits/entitlement counseling and referral to health care services to assist eligible clients to obtain access to other public and private programs for which they may be eligible. **AEW Benefits Counseling*: Services should facilitate a client's access to public/private health and disability benefits and programs. This service category works to maximize public funding by assisting clients in identifying all available health and disability benefits supported by funding streams other than RWHAP Part B and/or State Services funds. Clients should be educated about and assisted with accessing and securing all available public and private benefits and entitlement programs.	•	Program's Policies and Procedures indicate compliance with expected Scope of Services. Documentation of provision of services compliant with Scope of Services present in client files.
	Health Care Services: Clients should be provided assistance in accessing health insurance or Marketplace plans to assist with engagement in the health care system and HIV Continuum of Care, including medication payment plans or programs. Services focus on assisting client's entry into and movement through the care service delivery network such that RWHAP and/or State Services funds are payer of last resort.		

#	STANDARD	MEASURE
9.2	Provision of Services Staff will educate clients about available benefit programs, assess eligibility, assist with applications, provide advocacy with appeals and denials, assist with recertifications and provide advocacy in other areas relevant to maintaining benefits/resources.	
	ADAP Enrollment Workers (AEW) will meet with new potential and established ADAP enrollees to: 1. Explain ADAP program benefits and requirements 2. Assist clients and or staff with the submission of complete, accurate ADAP applications 3. Ensure there is no lapse in ADAP eligibility and loss of benefits, and 4. AEW will maintain relationships through the Ryan White ADAP Network (RWAN).	
9.3	 Staff Qualifications All personnel providing care shall have (or receive training) in the following minimum qualifications: Ability to work with diverse populations in a non-judgmental way Working with Persons Living With HIV/AIDS or other chronic health conditions; Ability to (demonstrate) or learn health care insurance literacy, (Third Party Insurance and Affordable Care Act (ACA) Marketplace plans). Ability to perform intake/eligibility, referral/ linkage and/or basic assessments of client needs preferred. ▶ Data Entry Quickly establish rapport in respectable manner consistent with the health literacy, preferred language, and culture of prospective client. 	 Personnel Qualification on file Documentation of orientation of file
9.4	Staff Education • Education to be defined locally, but must have at minimum a high school degree or equivalency	Documentation of education and/ or certification located in personnel file.

#	STANDARD	MEASURE
9.5	 Staff Training Requirement: THMP Training Modules within 30 days of hire Complete the DSHS ADAP Enrollment Worker (AEW) Regional update at earliest published date after hire DSHS ARIES Document Upload Training (to include TRG upload observation module), completed no later than (45) days after completing ARIES certificate process Data Security and Confidentiality Training Complete all training required of Agency new hires, including any training required by DSHS HIV Care 	 Materials for staff training and continuing education are on file Staff interviews indicate compliance
9.6	AEW Placement AIDS Drug Assistance Program (ADAP) Enrollment Workers will be co-located at Ryan-White Part A funded primary care providers to ensure the efficient and accurate submission of ADAP applications to the Texas HIV Medication Program (THMP).	
9.7	 Initial Provision of Client Education The initial education to clients regarding the THMP process should include, but not limited to: Discussion of confidentiality, specific to the THMP process including that THMP regards all information in the application as confidential and the information cannot be released, except as allowed by law or as specifically designated by the client. Applicants should realize that their physician and pharmacist would also be aware of their diagnosis. Discussion outlining that approved medication assistance through THMP may require a \$5.00 co-payment fee per prescription to the participating pharmacy for each month's supply at the time the drug is dispensed and the availability of financial assistance for the dispensing fee. Discussion outlining the recertification process, specific to THMP eligibility, including birth month recertification, half-birth month attestation and consequences of lapse. 	Documented evidence of education provided on other public and/or private benefit programs in the primary client record.

9.8 Benefits Counseling

Activities should be client-centered facilitating access to and maintenance of health and disability benefits and services. It is the primary responsibility of staff to ensure clients are receiving all needed public and/or private benefits and/or resources for which they are eligible.

Staff will explore the following as possible options for clients, as appropriate:

- AIDS Drug Assistance Program (ADAP)
- Health Insurance Plans/Payment Options (CARE/HIPP, COBRA, OBRA, Health Insurance Assistance (HIA), Medicaid, Medicare, Private, ACA/ Marketplace)
- SNAP
- Pharmaceutical Patient Assistance Programs (PAPS)
- Social Security Programs (SSI, SSDI, SDI)
- Temporary Aid to Needy Families (TANF)
- Veteran's Administration Benefits (VA)
- Women, Infants and Children (WIC)
- Other public/private benefits programs
- Other professional services

Staff will assist eligible clients with completion of benefits application(s) as appropriate within (14) business days of the eligibility determination date.

Conduct a follow-up within 90 days of completed application to determine if additional and/or ongoing needs are present.

- Documented evidence of other public and/or private benefit applications completed as appropriate within (14) business days of the eligibility determination date in the primary client record.
- Eligible clients with documented evidence of the follow-up and result(s) to a completed benefit application in the primary client record.
- Percentage of clients with documented evidence of education provided on other public and/or private benefit programs in the primary client record.

9.9 <u>Health Care Services</u>

Clients should be provided assistance in accessing health insurance or Marketplace plans to assist with engagement in the health care system and HIV Continuum of Care, including medication payment plans or programs.

 Eligible clients will be referred to Health Insurance Premium and Cost-Sharing Assistance (HIA) to assist clients in accessing health insurance or Marketplace plans within one (1) week of the referral for health care and support services intake.

Eligible clients should be referred to other core services (outside of a medical, MCM, or NMCM appointment), as applicable to the client's needs, with education provided to the client on how to access these services.

• Eligible clients are referred to additional support services (outside of a medical, MCM, NMCM appointment), as applicable to the client's needs, with education provided to the client on how to access these services.

Staff will follow-up within (10) business days of an applicable referral provided to HIA, any core or support service to ensure the client accessed the service(s).

- Documented evidence of assistance provided to access health insurance or Marketplace plans in the primary client record.
- Clients who received a referral for other core services who have documented evidence of the education provided to the client on how to access these services in the primary client record.
- Clients who received a referral for other support services who have documented evidence of the education provided to the client on how to access these services in the primary client record.
- Clients with documented evidence of referrals provided for HIA assistance that had follow-up documentation within 10 business days of the referral in the primary client record.
- Clients with documented evidence of referrals provided to any core services that had follow-up documentation within 10 business days of the referral in the primary client record.
- Clients with documented evidence of referrals provided to any support services that had follow-up documentation within 10 business days of the referral in the primary client record.

THMP Intake Process

Staff are expected to meet with new/potential clients to complete a comprehensive THMP intake including explanation of program benefits and requirements. The intake will also include the determination of client eligibility for the ADAP program in accordance with the THMP eligibility policies including Modified Adjusted Gross Income (MAGI).

Staff should identify and screen clients for third party payer and potential abuse

Staff should obtain, maintain, and submit the required documentation for client application including residency, income, and the THMP Medical Certification Form (MCF).

- Documented evidence of THMP education provided to new/potential clients in the primary client record.
- Documentation of acquisition of all required THMP application documentation (including proof of residency, income and MCF)

9.10 Benefits Continuation Process (ADAP)

ADAP Enrollment Workers are expected to meet with new/potential and established ADAP enrollees; explain ADAP program benefits and requirements; and assist clients and or staff with the submission of complete, accurate ADAP applications.

Birth Month/Recertification

- Staff should conduct annual recertifications for enrolled clients in accordance with THMP policies. Recertification should include completion of the ADAP application, obtaining and verifying all eligibility documentation and timely submission to THMP for approval.
- Recertification process should include screening clients for third party payer to avoid potential abuse.
- Complete ADAP application includes proof of residency, proof of income, and the THMP Medical Certification Form (MCF).
- Staff must ensure Birth Month/Recertifications are submitted by the last day of client's birth month to ensure no lapse in program benefits.
- Proactively contact ADAP enrollees 60-90 days prior to the enrollee's recertification deadline to ensure all necessary documentation is collected and accurate to complete the recertification process on or before the deadline.

Half-Birth Month/ 6-month Self Attestation

- Staff should conduct a 6-month half-birth month/self-attestation for all enrolled clients in accordance with THMP policies. Staff will obtain and submit the client's self-attestation with any applicable updated eligibility documentation.
- Proactively contact ADAP enrollees 60-90 days prior to the enrollee's attestation deadline to ensure all necessary documentation is collected and accurate to complete the attestation on or before the deadline.
- Half-birth/6-month self-attestations must be submitted by the last day of the client's half-birth month to ensure no lapse in program benefits.

• Documentation of lapse benefits due to non-completion of timely recertification/attestation in the client's record.

#	STANDARD	MEASURE
9.11	ARIES Document Upload Process ARIES Document Upload is the uniform practice for submission and approval of ADAP applications (with supportive documentation). This process ensures accurate submission and timely approvals, thereby expediting the ADAP application process. • Completed ADAP Applications (with supportive documentation) must be uploaded into ARIES for THMP consideration. All uploaded applications must be reviewed and certified as "complete" prior to upload. • ADAP applications should be uploaded according to the THMP established guidelines and applicable guidelines as given by AA. • To ensure timely access to medications, all completed ADAP applications must be uploaded into ARIES within one (1) business day of completion • To ensure receipt of the completed ADAP application by THMP, notification must be sent according to THMP guidelines within three (3) business days of the completed upload to ARIES. • Upload option is only available for ADAP applications; other benefits applications should be maintained separately and submitted according to instruction. Houston Only: Medication Certification forms for changes to medication should be faxed to THMP for approval.	Documentation of upload receipt by THMP within (3) business days of application completion.
9.12	Tracking ADAP Applications Track the status of all pending applications and promptly follow-up with applicants regarding missing documentation or other needed information to ensure completed applications are submitted as quickly as feasible Maintain communication with designated THMP staff to quickly resolve any missing or questioned application information or documentation to ensure any issues affecting pending applications are resolved as quickly as possible Case Closure Summary Clients who are no longer in need of assistance through Referral for Health Care and Support Services must have their cases closed with a case closure summary narrative documented in the client primary record. The case closure summary must include a brief synapsis of all services provided and the result of those services documented as 'completed' and/or 'not completed.' A supervisor must sign the case closure summary.	Clients who are no longer in need of assistance through Referral for Health Care and Support Services that have a documented case closure summary in the primary client record.

References

HRSA/HAB Division of Metropolitan HIV/AIDS Programs Program Monitoring Standards – Part A April 2013. p. 43-44.

HRSA/HAB Division of State HIV/AIDS Programs National Monitoring Standards – Program Part B April 2013. p. 42-43.

<u>Virginia Department of Health, Division of Disease Prevention, HIV Care Services Referral for Health Care/Supportive Services (PDF)</u>

<u>HRSA/HAB Ryan White & Global HIV/AIDS Programs, Program & Grants Management, Policy Notices and Program Letters, Policy Clarification Notice 16-02</u>

DSHS Policy 591.000, Section 5.3 regarding Transitional Social Service linkage.



REFERRAL FOR HEALTH CARE SERVICES- ADAP 2019 CHART REVIEW

Preface

DSHS Monitoring Requirements

The Texas Department of State Health Services (DSHS) contracts with The Houston Regional HIV/AIDS Resource Group, Inc. (TRG) to ensure that Ryan White Part B and State of Texas HIV Services funding is utilized to provide in accordance to negotiated Priorities and Allocations for the designated Health Service Delivery Area (HSDA). In Houston, the HDSA is a ten-county area including the following counties: Austin, Chambers, Colorado, Fort Bend, Harris, Liberty, Montgomery, Walker, Waller, and Wharton. As part of its General Provisions for Grant Agreements, DSHS also requires that TRG ensures that all Subgrantee's comply with statutes and rules, perform client financial assessments, and delivery service in a manner consistent with established protocols and standards.

As part of those requirements, TRG is required to perform annual quality compliance reviews on all Subgrantee's. Quality Compliance Reviews focus on issues of administrative, clinical, data management, fiscal, programmatic and quality management nature. Administrative review examines Subgrantee operating systems including, but not limited to, non-discrimination, personnel management and Board of Directors. Clinical review includes review of clinical service provision in the framework of established protocols, procedures, standards and guidelines. Data management review examines the Subgrantee's collection of required data elements, service encounter data, and supporting documentation. Fiscal review examines the documentation to support billed units as well as the Subgrantee's fiscal management and control systems. Programmatic review examines non-clinical service provision in the framework of established protocols, procedures, standards and guidelines. Quality management review ensures that each Subgrantee has systems in place to address the mandate for a continuous quality management program.

QM Component of Monitoring

As a result of quality compliance reviews, the Subgrantee receives a list of findings that must be address. The Subgrantee is required to submit an improvement plan to bring the area of the finding into compliance. This plan is monitored as part of the Subgrantee's overall quality management monitoring. Additional follow-up reviews may occur (depending on the nature of the finding) to ensure that the improvement plan is being effectively implemented.

Scope of Funding

TRG contracts with five Subgrantees to provide referral for health care services in the Houston HSDA.

Introduction

<u>Description of Service</u>

Referral for Health Care and Support Services directs a client to needed core medical or support services in person or through telephone, written, or other type of communication. This service may include referrals to assist eligible clients to obtain access to other public or private programs for which they may be eligible (e.g., Medicaid, Medicare Part D, State Pharmacy Assistance Programs, Pharmaceutical Manufacturer's Patient Assistance Programs, and other state or local health care and supportive services, or health insurance Marketplace plans).

Benefits Counseling: Services should facilitate a client's access to public/private health and disability benefits and programs. This service category works to maximize public funding by assisting clients in identifying all available health and disability benefits supported by funding streams other than RWHAP Part B and/or State Services funds.

Health Care Services: Clients should be provided assistance in accessing health insurance or Marketplace plans to assist with engagement in the health care system and HIV Continuum of Care, including medication payment plans or programs. Services focus on assisting client's entry into and movement through the care service delivery network such that RWHAP and/or State Services funds are payer of last resort.

Tool Development

The DSHS Referral for Healthcare Review tool is based upon the established local and DSHS standards of care.

Chart Review Process

All charts were reviewed by Masters-level Social Worker experienced in programmatic requirements and guidelines for the THMP program. The collected data for each site was recorded directly into a preformatted computerized spreadsheet. The data collected during this process is to be used for service improvement.

File Sample Selection Process

File sample was selected from a provider population of 6,098 clients who accessed oral healthcare services in the measurement year. The records of 200 clients were reviewed, representing 3.3% of the unduplicated population. The demographic makeup of the provider was used as a key to file sample pull.

Demographics- Referral for Healthcare Services-ADAP

2019 Annual

Total UDC: 6098

A go	Number of	% of	
Age	Clients	Total	
Client's age as of the end of the reporting period			
Less than 2 years		0.00%	
02 - 12 years		0.00%	
13 - 24 years 25 - 44 years	319	5.23%	
25 - 44 years	3355	55.02%	
45 - 64 years	2260	37.06%	
65 years or older	164	2.69%	
Unknown	0	0.00%	
	6098	100%	
Gender	Number of Clients	% of Total	
	'Refused" are cour	nted as	
Female	"Unknown" 1433	23.50%	
Male	4577	75.06%	
Transgender			
FTM	1	0.02%	
Transgender MTF	86	1.41%	
Unknown	1	0.02%	
	6098	100%	
Race/Ethnicity	Number of Clients	% of Total	
Includes	Multi-Racial Clier	nts	
White	741	12.15%	
Black	2758	45.23%	
Hispanic	2468	40.47%	
Asian	90	1.48%	
Hawaiian/Pacific Islander	3	0.05%	
Indian/Alaskan Native	10	0.16%	
Unknown	28	0.46%	
	6098	100%	

From 01/01/19 - 12/31/19

2020 Annual

Total UDC:

Age	Number of Clients	% of Total
Client's age as	of the end of the reperiod	eporting
Less than 2 years		
02 - 12 years		
13 - 24 years		
25 - 44 years		
45 - 64 years		
65 years or older		
Unknown		
		100%
Gender	Number of Clients	% of Total
"Other" and '	'Refused" are cour "Unknown"	nted as
Female		
Male		
Transgender FTM		
Transgender MTF		
Unknown		
		100%
Race/Ethnicity	Number of Clients	% of Total
Includes	Multi-Racial Clier	nts
White		
Black		
Hispanic		
Asian		
Hawaiian/Pacific		
Islander		
Indian/Alaskan		
Native Market Aller Street		
Multi/Unknown		1000
		100%

From 01/01/20 - 12/31/20

RESULTS OF REVIEW- BASELINE YEAR

Benefits Counseling

Documented evidence of education provided on public and/or private benefit programs in the primary client record.

	Yes	No	N/A
Number of client records that showed evidence of the measure	108	92	ı
Number of client records that were reviewed.	200	200	-
Rate	54%	46%	-

Documented evidence of public and/or private benefit applications completed as appropriate within (14) business days of the eligibility determination date in the primary client record.

	Yes	No	N/A
Number of client records that showed evidence of the measure	117	83	ı
Number of client records that were reviewed.	200	200	-
Rate	58.5%	41.5%	-

Health Care Services

Documented evidence of assistance provided to access health insurance or Marketplace plans in the primary client record.

	Yes	No	N/A
Number of client records that showed evidence of the measure	118	82	1
Number of client records that were reviewed.	200	200	-
Rate	59%	41%	-

Documented evidence of a referral for other core or support services who have documented evidence of the education provided to the client on how to access these services in the primary client record.

	Yes	No	N/A
Number of client records that showed evidence of the measure	9	83	108
Number of client records that were reviewed.	92	92	200
Rate	10%	90%	54%

Documented evidence of referrals provided to any core or support services that had follow-up documentation within (10) business days of the referral in the primary client record.

	Yes	No	N/A
Number of client records that showed evidence of the measure	9	83	108
Number of client records that were reviewed.	92	92	200
Rate	10%	90%	54%

ARIES Documentation

Documented evidence of ADAP application being uploaded onto ARIES within one (1) business day of completion.

	Yes	No	N/A
Number of client records that showed evidence of the measure	95	62	43
Number of client records that were reviewed.	157	157	200
Rate	60.5%	39.5%	21.5%

Documented evidence of THMP being notified within three (3) business days of completed ADAP application upload into ARIES.

	Yes	No	N/A
Number of client records that showed evidence of the measure	104	53	43
Number of client records that were reviewed.	157	157	200
Rate	66.2%	33.8%	21.5%

Documented evidence of completed secondary review of ADAP application indicated before application submission to THMP.

	Yes	No	N/A
Number of client records that showed evidence of the measure	115	42	43
Number of client records that were reviewed.	157	157	200
Rate	73.2%	26.8%	21.5%

Case Closure Summary

Documentation of case closure summary in client primary client record.

	Yes	No	N/A
Number of client records that showed evidence of the measure	0	84	116
Number of client records that were reviewed.	84	84	200
Rate	0%	100%	58%

CONCLUSIONS

The ADAP Enrollment Worker (AEW) program funded under the Referral for Healthcare service category is a new program. In 2019, there were 6098 unduplicated clients served, with 848 new clients. AEW workers provided assistance with 4035 applications, 1797 attestations, and 2446 recertifications during the calendar year. They also entered 18,928 service encounters! Review year 2019 was a baseline year to assess all Houston HSDA programs with a revised review tool. Six (6) of the ten (10) indicators reviewed were above the established threshold of 50%, however follow-up needs to occur with four (4) indicators below the threshold. Due to this program(s) being newly established, documentation of activities was inconsistent. Technical assistance was provided and outcomes for 2020 review should reflect training on documenting service activities.

By Jamie R. Daw and Michael R. Law

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Compared With Other Countries, Women In The US Are More Likely Than Men To Forgo Medicines Because Of Cost

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Michael R. Law is the Canada Research Chair in Access to Medicines and director of the Centre for Health Services and Policy Research, School of Population and Public Health, at the University of British Columbia, in Vancouver, British Columbia, Canada

ABSTRACT Cost-related nonadherence to prescription medicines is a common problem with important implications for population health. Relative to men, women may be more vulnerable to cost-related nonadherence because of higher health needs and lower financial resources. Using data from the Commonwealth Fund International Health Policy Survey, we compared cost-related nonadherence among younger (ages 18-64) and older (ages 65 and older) women and men in eleven high-income countries. Among younger adults, the unadjusted female-male disparity was larger in the US compared with other countries: One in four younger women reported cost-related nonadherence compared with one in seven younger men. This large disparity persisted after adjustment for age, income, and chronic conditions. We also found smaller but significant female-male differences among younger women in Australia and Canada. We did not find significant female-male differences among older adults in adjusted analyses in any country. Higher rates of cost-related nonadherence among younger women, and US women in particular, may produce important sex-related disparities in health outcomes that should be further explored.

ost-related nonadherence to prescription medicines is a common problem with important implications for the management of chronic disease and population health outcomes.¹ Patients who do not fill prescriptions because of cost or who decrease their medication costs by skipping medication doses, delaying refills, or splitting pills may compromise the therapeutic benefit of their treatment, with negative consequences including increased rates of health care use, health care costs, morbidity, and mortality.²⁻⁶

In the US, women are more likely than men to report cost-related barriers to health care, including prescription medicines.⁷⁻⁹ Higher rates of cost-related nonadherence among women

than among men may relate to women's higher health needs and higher overall prescription medicine use: 41 percent of US males reported receiving one or more prescription drugs from 2015 to 2016 compared with 50 percent of US females in the same time frame. Further, financial contributions to health care such as insurance premiums, copayments, and deductibles are more burdensome for women, who have lower wages, fewer financial assets and wealth, and higher rates of poverty than men, on average. A large body of studies has found that low-income people, of whom women constitute a greater proportion than men, are more sensitive to changes in the price of health care.

The extent to which sex-related disparities in cost-related nonadherence are a uniquely US

phenomenon or persist across comparable highincome countries has not been explored. Differences in social policies, including health insurance schemes and required patient cost sharing for prescription drugs, may mitigate or exacerbate female—male differences in cost-related nonadherence, resulting in variation in this disparity across countries. In contrast, female—male differences could be persistent across different health and social policy schemes, reflecting intrinsic differences in health needs, health behaviors, and preferences between women and men.

To explore this variation, this study assessed differences in cost-related nonadherence between women and men in the US and ten other high-income countries. Because health insurance arrangements differ by age in many nations, we examined international differences separately for younger and older adults.

Study Data And Methods

This was a cross-sectional study based on a secondary analysis of three rounds (2014, 2016, and 2017) of the Commonwealth Fund International Health Policy Survey. Each survey year, the stratified survey samples a representative sample of adults within specific age ranges from eleven high-income countries: Australia, Canada, France, Germany, the Netherlands, New Zealand, Norway, Sweden, Switzerland, the United Kingdom, and the United States.

POLICY CONTEXT Health insurance access may mitigate the relationship between sex and costrelated barriers to medicines by lowering the direct charges faced by patients at the time of care. Indeed, the World Health Organization has recommended universal health coverage as a policy measure to reduce the disproportionate financial burden of health care placed on women relative to men.12 The rationale for this recommendation is that without universal coverage, access to insurance often depends on formal employment, which may reduce women's ability to gain coverage compared with men. However, the potential for universal insurance to reduce sexrelated disparities in cost-related barriers to care depends largely on patient cost-sharing arrangements. Many countries with universal coverage schemes require out-of-pocket payments that can lead to barriers to health care or catastrophic levels of health spending.^{13,14} Coverage schemes that require higher out-of-pocket contributions when filling a prescription through annual deductibles (a fixed dollar amount that the patient must pay before the insurer will pay any expenses), copayments (a fixed dollar amount paid by the patient per prescription), or coinsurance (a percentage of the total prescription drug

charge paid by the patient) may result in wider female-male differences in cost-related nonadherence than those that require nominal or no out-of-pocket payments.¹²

Online appendix A provides a broad overview of prescription drug coverage in the sampled countries.15 In eight of the eleven countries, government and compulsory insurance schemes (funded via general tax revenues or social insurance) are the dominant source of pharmaceutical financing, and all citizens are covered by universal, comprehensive prescription drug coverage. In most of these countries, patient charges are low to moderate and are often subject to annual out-of-pocket maximums. However, there is notable variation; for example, per capita out-ofpocket spending on prescribed medicines is much higher in Switzerland (\$314; all dollar amounts are in 2015 US dollars) compared with France (\$94).¹⁶ In some countries cost-sharing rules change directly after age sixty-five (for example, the copayment exemption in England), or universal indirect exemptions disproportionally reduce cost sharing for older adults (for example, chronic condition exemptions in France and Germany).

In Australia, Canada, and the US, private sources (including private insurance and out-of-pocket charges) make up the dominant source of pharmaceutical financing. In Australia, out-of-pocket spending represented 51.3 percent of retail pharmaceutical spending in 2015 despite a publicly financed universal drug coverage scheme. This may partly reflect the relatively large copayments required for nonelderly adults (AU\$39.50/US\$28 in 2018). Significant copayment reductions are available for older adults and low-income adults (AU\$6.40/US\$4.50 in 2018).

Canada and the US are unique among the studied countries in the large role that private insurance plays in prescription drug financing (30.5 percent of financing in Canada and 34.4 percent in the US). ¹⁶ In Canada, nonelderly adults can either obtain employer-sponsored private drug coverage or purchase private insurance directly. Patient contributions vary across private plans but generally require moderate deductibles and copayments, coinsurance, or both. An estimated 20 percent of Canadians are uninsured or underinsured for prescription drugs, concentrated among part-time and low-wage workers. 18 In most provinces, public drug plans provide high-deductible catastrophic coverage as a safety net for nonelderly uninsured and underinsured people. For older adults, comprehensive coverage is offered with low copayments in many provinces. In others, public coverage for older adults is limited to high-deductible catastrophic coverage.19

In the US, low-income nonelderly adults in the majority of states are eligible for Medicaid, which requires nominal patient cost sharing for medicines. Other nonelderly adults can obtain private insurance either from the individual market (subsidized for lower incomes) or from an employer, school, or spouse. In 2018, 10.3 percent of the nonelderly US population was uninsured and thus was required to pay the entire cost of prescribed medication out of pocket.²⁰ Among employer-sponsored plans in 2018, the average individual deductible was \$1,573 for non-high-deductible plans and \$2,245 for highdeductible plans (which cover 30 percent of workers).21 Among covered workers, average copayments for nonspecialty drugs range from \$11 to \$105, and average coinsurance ranges from 19 percent to 31 percent, depending on drug class.²¹ At age sixty-five, people have the option of enrolling in Medicare Part D drug coverage, which covered 72 percent of older adults in 2018.²² Part D plans require monthly premiums (average, \$41 in 2018), an annual deductible (average, \$405), and low-to-moderate copayments (median \$1 for preferred generics, \$37 for preferred brands).²² Premium and cost-sharing subsidies are available for low-income older adults, who account for about a third of Part D enrollees.22

pata The surveys were conducted on nationally representative samples of adults of different age groups living in the community in each country and year: 2014 (ages fifty-five and older), 2016 (ages eighteen and older), and 2017 (ages sixty-five and older). The surveys were administered by telephone (mobile and landline), as well as online in Switzerland. The surveys were based on a common questionnaire that was translated and adjusted for country-specific wording, as required.

We pooled three survey years to increase the sample size and our ability to detect differences between men and women in each country. To produce pooled estimates that were representative of each country's younger adult (ages 18–64) and older adult (ages 65 and older) populations, we calculated survey weights based on UN population estimates for each survey year, country, age group, and sex (details are in appendix B). 15 All main results shown are weighted using these pooled weights. We also present the results for the unpooled analysis for each age group and survey year, using the original weights provided by the Commonwealth Fund (see appendix D).15 The original weights account for the sample design and systematic nonresponse across known population parameters, including region, sex, age, education, and other demographics, depending on each country's standards.

VARIABLES The primary outcome variable was cost-related nonadherence to prescription medicines, defined as respondents reporting that they "did not fill/collect a prescription for medicine or skipped doses because of the cost" in the past twelve months. Demographic variables included sex, age, number of chronic conditions (one, two, three, or more), and household income (categorized as below, at, or above average in each country). The selection of these covariates was based on availability in the data set and hypotheses about factors that could potentially confound sex disparities observed between countries. These covariates can also be considered in the context of Ron Andersen's health behavior model of the determinants of health care use: predisposing factors (sex, age), enabling factors (income), and needs (chronic disease burden).²³ We included only respondents with complete data for the outcome and study covariates (90 percent of the total survey sample).

STATISTICAL ANALYSIS We calculated unadjusted rates of self-reported cost-related nonadherence among survey respondents for men and women ages 18-64 and ages 65 and older. We also estimated unadjusted and adjusted logistic regression models for each age group. Adjusted models include age, number of chronic conditions, relative household income, and survey year. On the basis of each model, we calculated the average marginal effect of being female in each country—that is, the difference in the predicted probability of reporting cost-related nonadherence, assuming that the entire sample was female in country X compared with male in country X, with all other covariates held as observed in the data set across all countries in each age group (younger adults and older adults). Analyses were performed using Stata, version 15.0.

LIMITATIONS This study had several limitations that should be considered when interpreting the results. First, small sample sizes in some countries (for example, Norway and the United Kingdom) may have limited the statistical power to detect sex disparities in cost-related nonadherence. Second, response rates varied across countries, which could have introduced participation bias. The direction of the bias is unknown, however, and would only affect estimates of sex disparities if the characteristics of male and female nonrespondents were differential across nations. As other studies have noted, the overall cost-related nonadherence rates reported in the Commonwealth Fund surveys are reasonably similar to those of country-specific studies that draw on surveys with greater response rates.24

Third, the pooled survey weights did not take into account all demographic (for example, education or race) and geographic (for example, subregion) factors used to weight respondents by some countries. Thus, we included unpooled results using the original survey weights by year in appendix D,¹⁵ and we highlight any notable discrepancies in the results. Fourth, the survey only measured sex as a binary variable, which does not recognize nonbinary gender identities. More research is needed to explore differences in access and affordability of health care for gender minorities.

Fifth, the survey contained limited sociodemographic variables. We were not able to adjust for several variables that could be correlated with both sex and cost-related nonadherence, either because they were not collected (for example, marital status) or because the survey questions were incomparable across countries (for example, household size). Variable availability and sample size also limited exploration of variation in sex disparities across subgroups, defined by race, ethnicity, income, or other characteristics.

Study Results

YOUNGER ADULTS We identified 24,724 survey respondents ages 18–64. In seven countries a significantly higher proportion of younger women reported two or more chronic conditions compared with men. In six countries younger women were significantly more likely than men to report below-average incomes (exhibit 1).

Among younger adults there was wide varia-

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tion in the overall unadjusted rate of cost-related nonadherence across countries, ranging from 2.7 percent in Germany to 19.6 percent in the US (exhibit 2). There was also variation in the unadjusted difference in cost-related nonadherence among women and men (exhibit 3): Younger women reported significantly higher unadjusted rates of cost-related nonadherence compared with men in Australia (+1.8 percentage points; 95% confidence interval: 0.6, 3.0), Canada (+3.6 percentage points; 95% CI: 1.8, 5.5), New Zealand (+3.8 percentage points; 95% CI: 1.0, 6.7), and the US (+9.6 percentage points; 95% CI: 5.9, 13.4). In France younger women reported significantly lower cost-related nonadherence than men (-4.0 percentage points; 95% CI: -6.5, -1.6).

In the adjusted model, younger women were more likely than men to report cost-related non-adherence in Australia (+1.2 percentage points; 95% CI: 0.01, 2.4), Canada (+2.5 percentage points; 95% CI: 0.7, 4.3), and the US (+7.9 percentage points; 95% CI: 4.3, 11.5) (exhibit 4).

Results for the unpooled analysis using the original survey weights are reported in appendix D.¹⁵ In the 2014 survey of adults ages 55–64, the unadjusted and adjusted female–male difference in cost-related nonadherence was significant only in the US (adjusted estimate, +12.7 percentage points; 95% CI: 4.9, 20.5). In the 2016 survey of adults ages 18–64, a significantly higher proportion of women reported cost-related nonadherence in unadjusted and adjusted analyses in Canada, New Zealand, Norway, Sweden, and the US. The magnitude of the difference was

EXHIBIT 1

Characteristics of male and female respondents to the Commonwealth Fund International Health Policy Surveys in eleven countries, 2014-17

Ages 18-64					Age 65+							
	Sample	size		more chronic ons (%)	Below-	-average e (%)	Sample size		Two or more chronic conditions (%)		Below-average income (%)	
Country	Men	Women	Men	Women	Men	Women	Men	Women	Men	Women	Men	Women
Australia	2,320	2,369	14.8	21.2**	34.0	37.5**	2,152	2,495	50.4	52.3	43.3	50.7**
Canada	1,966	2,806	25.4	31.0**	28.9	32.9**	3,072	5,265	57.2	60.9**	41.5	55.0**
France	599	632	13.5	18.4**	32.4	33.1	752	887	41.0	45.5	43.5	52.7**
Germany	468	573	15.1	15.1	40.1	32.9**	598	790	52.8	53.8	50.6	63.8**
The Netherlands	628	578	15.3	17.9	21.7	27.2**	710	765	39.2	43.5	30.1	47.2**
New Zealand	493	572	19.7	21.9**	23.0	34.0**	459	554	42.8	44.2	51.3	47.4
Norway	466	546	19.5	21.4	30.3	33.9	774	858	43.5	40.6	53.2	65.0**
Sweden	2,362	2,797	18.3	23.7**	27.5	29.1	6,429	8,270	49.1	52.1**	36.6	56.3**
Switzerland	862	891	15.8	20.8**	43.8	46.9	1,784	2,154	48.4	44.4	44.0	54.3**
United Kingdom	452	487	14.6	18.6	23.6	30.3**	549	761	42.1	46.6	35.9	45.8**
United States	876	981	32.8	38.6**	34.4	37.5	1,119	1,714	67.3	69.6	31.3	52.5**

source Authors' analysis of data from the 2014, 2016, and 2017 Commonwealth Fund Health Policy Surveys. **NOTES** Unweighted sample sizes and sample-weighted prevalence. Asterisks indicate p values for test of difference between women and men (based on two-sided t-test). **p < 0.05

EXHIBIT 2

Unadjusted rates and adjusted differences in the predicted probability of self-reported cost-related nonadherence to prescription medicines (CRNA) for women and men in eleven countries, by age group, 2014-17

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	Overall	Men	Women	Unadjusted difference in predicted probability of CRNA	Adjusted difference in predicted probability of CRNA
AGES 18-64 (N = 2	4,724)				
Australia Canada France Germany The Netherlands New Zealand Norway Sweden Switzerland United Kingdom	7.6 9.4 3.6 2.7 5.2 5.4 3.5 4.9 7.9 2.8	6.7 7.6 5.6 2.9 4.0 3.4 2.6 4.3 7.7 2.3	8.5 11.2 1.6 2.4 6.5 7.3 4.5 5.6 8.1 3.3	1.8** 3.6** -4.0** -0.5 2.5 3.8** 2.0 1.3 0.5	1.2*** 2.5*** -4.4*** -0.4 1.8 2.4 1.5 0.6 -0.4 0.7
United States	19.6	14.8	24.4	9.6**	7.9**
AGE 65+ (N = 42,9					
Australia Canada France Germany The Netherlands New Zealand Norway Sweden Switzerland United Kingdom United States	4.1 4.7 2.0 4.0 2.2 4.3 1.6 1.4 3.7 1.2	3.8 4.5 2.2 4.0 2.5 2.8 1.4 1.3 3.4 1.0 9.4	4.4 4.8 1.8 4.0 1.9 5.6 1.7 1.5 3.9 1.3	0.6 0.3 -0.3 0.0 -0.7 2.9 0.3 0.2 0.5 0.4 3.4***	0.3 -0.3 -0.5 -0.4 -1.0 2.7 0.2 -0.1 0.3 0.3 1.7

SOURCE Authors' analysis of data from the 2014, 2016, and 2017 Commonwealth Fund Health Policy Surveys. **NOTES** Differences in predicted probabilities (expressed in percentage points) represent average marginal effects and are calculated based on an unadjusted or adjusted logistic regression model with covariates at sample observed values within each age group. The unadjusted model includes survey year. The adjusted model includes age, income, number of chronic conditions, and survey year. Asterisks indicate p-values for marginal difference in the predicted probability for women and men (based on two-sided t-test). **p < 0.05

largest in the US (adjusted estimate, +5.8 percentage points; 95% CI: 0.8, 10.7).

OLDER ADULTS We identified 42,911 survey respondents ages sixty-five and older. In Canada and Sweden a higher proportion of older women reported two or more chronic conditions compared with men (exhibit 1). Older women were more likely than men to report below-average incomes in all countries except New Zealand.

Compared with younger adults, overall unadjusted cost-related nonadherence rates were generally lower among adults ages sixty-five and older, ranging from 1.2 percent in the UK to 11.3 percent in the US (exhibit 2). Differences in unadjusted cost-related nonadherence between men and women were also of smaller magnitude for older adults and were not statistically significant in any country except the US (exhibits 2 and 3). Older women in the US reported 3.4 percentage points (95% CI: 0.9, 6.0) higher unadjusted cost-related nonadherence rate compared with older men. After adjustment for

income, age, and chronic conditions, the difference in the predicted probability of cost-related nonadherence between older women and men in the US decreased by 50 percent and was not statistically significant (+1.7 percentage points; 95% CI: -0.8, 4.2).

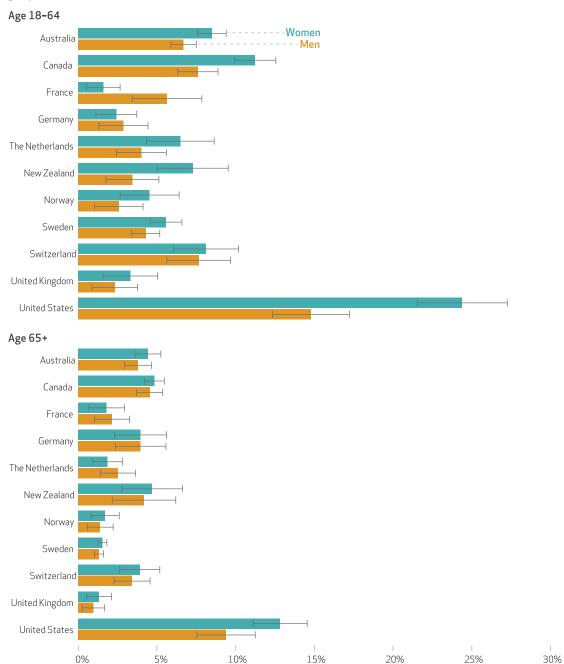
In the unpooled unadjusted and adjusted analyses of adults ages sixty-five and older in the 2014 and 2016 surveys, no significant sex differences in cost-related nonadherence were identified (appendix D).¹⁵ In the 2017 survey, women reported a higher unadjusted and adjusted rate of cost-related nonadherence in Sweden (adjusted estimate, +0.7 percentage points; 95% CI: 0.01, 1.4) and the US (adjusted estimate, +5.1 percentage points; 95% CI: 0.2, 10.0).

Discussion

In this study of eleven high-income countries, we found that the United States is an outlier in terms of the overall magnitude of cost-related nonad-

EXHIBIT 3

Unadjusted rates of self-reported cost-related nonadherence to prescription medicines in eleven countries, by sex and age group, 2014–17

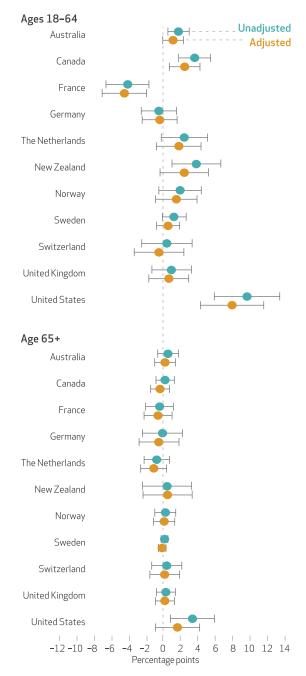


SOURCE Authors' analysis of data from the 2014, 2016, and 2017 Commonwealth Fund Health Policy Surveys. **NOTE** Error bars represent 95% confidence intervals.

herence to prescription medications reported among both younger and older adults, as well the relative difference in cost-related nonadherence between younger women and men. We found that the adjusted rate of cost-related nonadherence was 54 percent higher among younger women than men in the US. We also found higher rates of adjusted cost-related nonadherence among younger women compared with men in Canada (33 percent higher) and Australia (17 percent higher), although the differences were smaller in magnitude than those observed in the US. We found lower overall rates of costrelated nonadherence among older adults in all

EXHIBIT 4

Adjusted difference in the predicted probability of self-reported cost-related nonadherence to prescription medicines between female and male respondents in eleven countries, 2014–17



SOURCE Authors' analysis of data from the 2014, 2016, and 2017 Commonwealth Fund Health Policy Surveys. **NOTES** Differences in predicted probabilities (expressed in percentage points) represent average marginal effects and were calculated on the basis of an unadjusted or adjusted logistic regression model with covariates at sample observed values within each age group. The adjusted model included age, income, number of chronic conditions, and survey year. A negative value indicates that more men than women reported cost-related nonadherence to prescription medicines; a positive value indicates that more women than men did so. Error bars represent 95% confidence intervals.

countries and no evidence of significant femalemale differences, except in unadjusted analyses in the US (exhibit 2).

COMPARISON WITH PRIOR RESEARCH Our findings are consistent with previous research that has found higher overall rates of cost-related nonadherence in countries where patients face higher cost sharing (for example, US, Canada, and Australia) compared with those that require only nominal patient contributions (for example, the UK). 24,25 Our study is also consistent with US studies that have found that women face a higher out-of-pocket spending burden than men for prescription drugs or are more likely to report cost-related nonadherence in the nonelderly population⁷ and in the elderly population^{26,27} and for specific populations such as cancer survivors,28 people with disabilities,29 stroke patients,³⁰ and patients with cardiovascular disease.31 Our estimates of the magnitude of cost-related nonadherence overall and by sex between nonelderly men and women in the US are similar to those in an analysis of the 2015 National Financial Capability Study, which found that 26.2 percent of women reported cost-related nonadherence compared with 19.8 percent of men, and a 2018 survey analysis that found that 17 percent of nonelderly women reported costrelated nonadherence compared with 12 percent of men. 9,32 Our findings for Canada are also consistent with a 2016 study that found that nonelderly Canadian women reported significantly higher cost-related nonadherence compared with men.33 To our knowledge, there has been limited research on sex differences in cost-related nonadherence in other high-income countries.

POTENTIAL DRIVERS OF CROSS-NATIONAL VAR-**IATION** This was a cross-sectional study, and thus we could not draw causal conclusions about the impact of any particular factor in a given country and overall cost-related nonadherence or sex disparities in cost-related nonadherence. There are several possible explanations for the variation in sex disparities seen across nations. First, our results support the hypothesis that health insurance schemes that are tied to employment or that require greater out-of-pocket contributions have a greater impact on medication adherence among women compared with men. Canada and the US had the largest female-male differences in cost-related nonadherence and are also the only two countries studied that do not have universal prescription drug coverage for nonelderly adults and for which private insurance plays a major role in pharmaceutical financing. The US, Canada, and Australia also rank in the top four countries studied in terms of out-of-pocket spending on prescribed medicines per capita (appendix table A2).15 The larger magnitude of the female-male disparity in the US may reflect the relatively high premiums, deductibles, and other out-of-pocket payments that patients face,

particularly privately insured and uninsured nonelderly adults.

Further, we found lower rates of overall costrelated nonadherence and little to no evidence of sex disparities among adults ages sixty-five and older across nations, which could be a result of policies that provide more generous prescription drug coverage for the older populations in all the countries studied.

Beyond the availability and structure of health insurance, social and economic policies differ across nations, including welfare assistance, minimum wage laws, poverty alleviation programs, family leave, and childcare support. These differences could relate to female-male disparities in labor-force participation and socioeconomic status and, in turn, to the production of sex-related disparities in cost-related nonadherence. For example, of the countries studied, labor-force participation among nonelderly women is lowest and the female-male wage gap is the highest in the US (appendix table A3).15 Our findings in Switzerland also suggest that sex disparities in cost-related nonadherence are determined by more than health insurance design. Although Switzerland has the highest per capita out-of-pocket spending on prescribed medicines among the studied countries (both crude and as a percentage of mean disposable household income) and a relatively high rate of overall cost-related nonadherence among younger adults (7.9 percent; exhibit 2), we found no significant sex differences in cost-related nonadherence.

Female-male differences in cost-related nonadherence may also relate to differences in relative health status as well as health beliefs and attitudes between women and men in different countries. We explored whether sex disparities were sensitive to adjustment for a limited set of factors: age, chronic disease burden, and income. In most countries the magnitude of the sex disparity decreased after adjustment. Future research should further consider how the interactions among health status, beliefs, socioeconomic status, and sex affect how patients modify medicine use in response to out-of-pocket expenses and the subsequent impacts on health outcomes and health disparities. Understanding the drivers of cost-related nonadherence and the

extent to which they differ for women and men (and across therapeutic settings) is critical for developing policy approaches to mitigate sexrelated disparities.

Policy Implications

Canada and the US, the only studied countries without universal coverage for prescribed medicines, had the highest rates of reported cost-related nonadherence and the largest female-male disparities among younger adults. Proposals to expand insurance options for prescription medicines are high on the policy agenda in both countries (that is, Medicare-for-all or a public option in the US and universal pharmacare in Canada). These proposals would weaken or break the tie between access to prescription drug insurance and employment, which disproportionally limits women's access to private coverage. These public plans would also offer lower patient cost sharing relative to average private plans in both countries. Expansions of affordable insurance could serve not only to reduce overall cost-related nonadherence but also to mitigate sex-related disparities. Further, policy proposals to reduce the list prices of medicines in the US—such as by using external reference pricing to benchmark list prices to those paid in other countries-could also lower cost-related nonadherence for the uninsured, who do not benefit from discounts negotiated by public or private payers.

Conclusion

In this cross-sectional study of eleven high-income nations, we found that the US is an out-lier in the magnitude of overall cost-related non-adherence to prescription medications and in the difference in cost-related nonadherence between younger women and men. Medication nonadherence is associated with adverse clinical outcomes for chronic conditions such as diabetes and hypertension. Thus, sex differences in cost-related nonadherence in the US may produce important sex-related disparities in health outcomes that deserve further research and policy attention. \blacksquare

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Invited Commentary | Health Policy

Cost-Sharing Under Medicare Part D Paying Dearly to End the HIV Epidemic?

Julie E. Myers, MD, MPH

In 2019, the first-ever national plan to end HIV in the US was announced. Treatment and prevention with antiretroviral drugs (ie, preexposure prophylaxis [PrEP]), both highly effective strategies, are at the core of this plan. However, access to medications to prevent or treat HIV is not ensured currently, particularly because drug costs are high and insurance coverage can sometimes leave gaps that may limit uptake and detract from adherence.

The study by Tseng and colleagues¹ helps to answer a critical, practical question about such gaps: exactly how much do individuals with Medicare Part D health plan coverage pay in out-of-pocket costs for antiretroviral drugs for treatment or prevention? They analyzed 3326 Part D plans from around the US for the first quarter of 2019 to determine the annual treatment cost for 18 HIV treatment regimens and 2 HIV PrEP drugs and calculated how much each involved entity (ie, patient, plan, Medicare, or manufacturer) would pay monthly for patients with or without low-income subsidies. What they found is staggering: in the face of median annual antiretroviral prices exceeding \$35 000 for treatment and \$20 000 for prevention, individuals lacking low-income subsidies could have to pay as much as \$3000 to \$4000 out of pocket annually for HIV medications alone. Tseng et al¹ also reported that cost-sharing varied throughout the year, with the highest burden to patients early on. Once the catastrophic coverage threshold was breached between February and May, Medicare bore the brunt of costs, shouldering 53% to 67% of the costs for treatment and 50% of the costs for prevention.

Yet, as shocking as the estimated out-of-pocket costs are, they may actually underrepresent the severity of the situation. Medicare recipients living with HIV, especially the 21% who are recipients by virtue of their age² (and not disability), often use several prescription medications beyond their antiretroviral therapy. Yet the estimate provided by Tseng et al¹ included only antiretroviral therapy or PrEP and no other prescription drugs, therefore likely significantly underestimating actual out-of-pocket costs, especially for people with HIV, although the antiretroviral drug class is certainly among the most expensive, with among the fewest generic options.

Furthermore, at the same time that the US has experienced a 3-fold increase in the proportion of Medicare recipients who are living with HIV since the mid-1990s, the number of Medicare enrollees in need of antiretroviral drugs for treatment (or prevention) will continue to increase as more people with HIV (and people who are at increased risk of HIV) age into Medicare in the years ahead. In fact, Medicare is the single largest source of federal funding for HIV care and treatment, and the proportion of care that is funded by Medicare will likely only continue to increase.

Tseng et al¹ used 2019 data for their analysis, but we can expect out-of-pocket costs to increase, as 2020 brings change to Medicare Part D.³ As in the past, there are increases in the deductible and the initial coverage limit. However, the most substantial change, one that comes as a result of an expiration of a provision of the Patient Protection and Affordable Care Act that constrained increases of out-of-pocket costs for Medicare Part D enrollees during 2014 to 2019, is an increase of \$1250 in the out-of-pocket spending threshold. Although only approximately 1.0 million of 44.6 million enrollees (2.2%) without low-income subsidies reached the catastrophic phase in 2017, that proportion will likely increase in 2020, and presumably a greater proportion of enrollees than ever will be living with HIV, although the proportion will likely be fewer than 1%. However, for these individuals, the burden is likely significant: relatively few Medicare recipients are wealthy enough to

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afford thousands of dollars in drug costs. For reference, in 2016, the median annual income for Medicare recipients was \$26 200, and only 5% of Medicare recipients had incomes higher than \$103 450 per year.⁴

The concern with such a high cost burden on the individual is that adherence and, ultimately, health outcomes, are likely to deteriorate. It is now well documented that treatment for HIV blocks viral replication, which improves individual health and prevents onward transmission to sexual partners, a phenomenon popularized as *undetectable equals untransmittable*, or *U=U*. Belenky et al⁵ found that antiretroviral therapy adherence and viral load suppression remained stable despite increased out-of-pocket spending in the context of Medicare Part D plans, but this should not be particularly reassuring: that study was conducted among dual-eligible (ie, Medicaid and Medicare eligible) women who were followed in a longitudinal cohort study; thus, this cohort was perhaps less representative of Medicare Part D recipients in general and much more likely to have received low-income subsidies as dual Medicaid and Medicare recipients.⁵ In these and other studies, focusing solely on HIV outcomes may miss other important outcomes. What is the effect of greater individual expenditures on the families of these recipients? As out-of-pocket costs increased, were their health and other needs met? What about those of their dependent family members?

All of this leads to another critical question: what would be the effect of eliminating these high copayments for antiretroviral drugs? For now, this is a theoretical query. But a decade ago, a commercial health plan undertook just such a study among a different set of patients who were chronically ill: those discharged from the hospital after myocardial infarction. The plan randomly assigned these men and women to either full prescription coverage (ie, absence of copayment) or usual prescription coverage for all statin, β -blocker, angiotensin converting enzyme inhibitor, or angiotensin-receptor blocker medications. These were not people living with HIV, but they were living with an illness for which highly effective medications could avert adverse outcomes. Although there was no reduction in first major vascular event or revascularization (the primary end point), patients in the full-coverage group had a 4% to 6% increase in adherence and a decrease in the incidence of total major vascular events or revascularization; patient cost was also decreased, all without increasing total spending, offering compelling support for taking a similar approach with antiretroviral drugs.

As the study by Tseng et al¹ indicates, individuals who are eligible for low-income subsidies—77% of Medicare beneficiaries with HIV in 2014—would be spared the burden of such high out-of-pocket costs through the Part D Extra Help Program and AIDS Drug Assistance Program (ADAP). While the combination of the 2 effectively reduces what any person with HIV has to pay out of pocket for medications, this outcome is achieved through an administratively complex program, and in the case of ADAP, income eligibility thresholds that vary more than 2-fold among states. Additionally, individuals without an HIV diagnosis do not benefit from ADAP. Although some states maintain ADAP-like programs for those in need of PrEP, and the manufacturer also runs co-pay assistance programs, these are for individuals without insurance.

Tseng et al¹ highlight recent efforts to reduce patients' cost-sharing through proposed legislation to redesign Part D; possible interventions might involve capping out-of-pocket costs annually, passing discounts and rebates to patients directly, or at least making the out-of-pocket costs more predictable from month to month. Ideally, whatever Part D restructuring is ultimately undertaken will further incorporate principles of value-based insurance design, in which financial incentives are better aligned with what is determined to be high-value care, helping to signal to patients in the most concrete terms—through their wallets—that antiretroviral drug uptake and adherence are worth it, the opposite of the message conveyed by thousands of dollars in costs they have to shoulder now. But how to lighten the load for patients without passing on these costs to the public?

One answer is both simple and incredibly complicated: address the high prices of drugs themselves. Drug prices are high for myriad reasons, including certain aspects of US patent law that effectively allow manufacturers to set prices and then constrain competition. ⁷ Short of more

narrowly interpreting and enforcing existing antitrust laws and policies, allowing Medicare to negotiate drug prices paid for by Medicare Part D plans would likely help us move toward more affordable antiretroviral drug prices. For although success in ending HIV/AIDS in the US will obviously come at a price, we need to find a way to avoid burdening the people who are underserved and draining public coffers—a way to pay these costs fully without paying dearly.

ARTICLE INFORMATION

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Non-adherence to HIV treatment for cost-saving reasons reported by 8% in American study

Roger Pebody

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Much of the excessive cost of prescription drugs in the United States falls on patients, and national surveillance data has now found that this has a real impact on HIV treatment outcomes. A study presented at the <u>Conference on Retroviruses and Opportunistic Infections (CROI 2019)</u> earlier this month found that 13% of people with diagnosed HIV reported at least one cost-saving strategy, including 8% who did not always adhere to their treatment to cut costs. Rates of viral suppression and engagement in care were lower in those reporting non-adherence for economic reasons.

Dr Linda Beer of the Centers of Disease Control and Prevention (CDC) presented the study. Data came from the Medical Monitoring Project, which collects clinical and behavioural information from individuals carefully sampled to be representative of the range of people diagnosed with HIV in the United States. Interview data and medical records were available for 3650 people taking prescription drugs in 2015-2016.

Based on self-report:

- 8% had asked their doctor for a lower-cost medication to save money
- 1% had bought prescription drugs from another country to save money
- 2% had used alternative therapies to save money
- 4% had skipped medication doses to save money
- 4% had taken less medicine to save money
- 6% had delayed filling a prescription to save money

Looking specifically at the last three of those strategies, they were more common in individuals with private insurance (prevalence ratio 1.76, p <0.01), reflecting the problem of incomplete coverage and co-payments associated with private insurance. As might be expected, they were more common in individuals who had sought, but not received, help from the Ryan White AIDS Drug Assistance Program (prevalence ratio 3.88, p <0.01). They were also more common in individuals who had a disability (prevalence ratio 1.91, p <0.01).

Individuals reporting these cost-saving non-adherence strategies were significantly less likely to be virally suppressed (prevalence ratio 0.83, p < 0.01) or engaged in care (prevalence ratio 0.88, p < 0.01).

They were also more likely to have visited an emergency room or been hospitalised more than once.

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Beer L et al. Nonadherence due to prescription drug costs among U.S. adults with HIV, 2015-2016. Conference on Retroviruses and Opportunistic Infections, Seattle, abstract 1078, 2019.

View the abstract and poster on the conference website.





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