Evaluation of Medication Therapy Issues, Resolutions, and Adherence Among Persons With HIV in the Pharmacist-Led *Patient-Centered HIV Care Model*

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Objective: To identify medication therapy issues and resolutions and assess their relationship to antiretroviral therapy (ART) adherence among participants of the Patient-Centered HIV Care Model demonstration project.

Methods: Adult persons with HIV (PWH) in the United States were enrolled in the Patient-Centered HIV Care Model from August 2014 to September 2016. Pharmacists conducted regular medication therapy reviews and documented ART and non-ART issues and suggested resolutions. Adherence to ART was calculated using proportion of days covered (PDC), and the mean PDC by the number of ART issues was compared using a generalized linear model with linear trend estimation.

Results: The most common ART issue was adherence (57%). Adherence ART issues were resolved by adherence management (48%) or patient education (36%). Participants had a mean of 4.2 ART issues and 6.4 non-ART issues. PDC was 89% for those with 0 ART issues and 73% for those with ≥3 ART issues. Persons with 0 ART issues had an increase in adherence (+8%) in the postperiod, whereas those with ≥3 ART issues had a decrease in adherence (−6%) ($P = 0.02$) in the postperiod.

Conclusions: Identifying therapy issues could help pharmacists improve care for PWH. Because PWH are an aging population with an increased risk of comorbidities and polypharmacy, pharmacists and providers should collaborate to provide holistic, primary care solutions to address both the number and nature of therapy issues.

Key Words: medication therapy management, pharmacists, HIV, adherence, issues, barriers, resolutions

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INTRODUCTION

To achieve HIV viral suppression and remain virally suppressed, persons with HIV (PWH) must maintain adequate adherence to an appropriate HIV antiretroviral therapy (ART) and be retained in care. Although there is some debate about the adherence threshold needed to achieve viral suppression, it generally ranges from ≥85% for newer ART regimens to as high as ≥95% for older regimens, with the Pharmacy Quality Alliance citing a 90% adherence threshold for adherence reporting.[1–6] A person who remains adherent and in care can achieve viral suppression quickly and maintain viral suppression over long periods, if not indefinitely.[7–11] Viral suppression drastically reduces an individual's HIV-related morbidity and mortality and confers a near-zero chance of HIV transmission to an uninfected person.[12–15] However, recent data from the Centers for Disease Control suggest that only 65% of PWH who are diagnosed are virally suppressed, underscoring the need for enhanced emphasis on adherence and a better understanding of clinical care factors that may assist patients with adherence maintenance and viral suppression.[16]

Reasons for inadequate adherence to ART are related to a multitude of barriers to successful medication initiation and maintenance, including lack of access to treatment, ART complexity, side effects, stigma, treatment fatigue, depression, substance abuse, and the presence of other chronic conditions.[17,18] Consistent ART adherence necessitates that clinicians continuously monitor factors related to appropriateness and effectiveness of the regimen while addressing medication-related barriers or issues. Given the complexities of HIV treatment and the need for ongoing patient monitoring, the Department of Health and Human Services recommends that HIV providers work collaboratively as part of a multidisciplinary team to support HIV treatment, including education and adherence counseling for PWH.[19] As a result, pharmacists have been identified as key members of the HIV care team because they have regular contact with persons, are trained to help persons manage and adhere to complex medication regimens, and are able to assist clinical providers

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The data were collected and analyzed by Walgreen Co.

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with selecting or modifying ART. Furthermore, community-based, HIV-specialized pharmacists have additional training in the care and management of HIV, including managing ARV and non-ARV medication interactions, handling medication adverse events, and providing HIV specific patient education and adherence counseling to support adherence to and effectiveness of ARV treatment.[20]

As described elsewhere, the Patient-Centered HIV Care Model (PCHCM) used medication therapy management (MTM) as a means of sharing patient clinical information between partnered community-based HIV-specialized pharmacists and medical providers.[21] MTM consultations consisted of a medication therapy review, a personal medication record, a medication-related action plan, intervention and referral, and documentation and follow-up.[22] Through medication therapy review consultations, pharmacists collaborated with patients and providers to document and address therapy issues specific to each medication and propose suggested resolutions. Previously published results found that retention in care improved 13% and viral suppression improved by a relative 15%; the proportion of persons with a viral load >1500 copies/mL decreased by 46%.[21,23] Although there were no statistically significant improvements in ART adherence detected, there was a strong association between adherence to ART and viral suppression.

OBJECTIVE

The purpose of this analysis was 3-fold: (1) to enumerate ART and non-ART issues, (2) to identify how different ART and non-ART issues were resolved, and (3) to explore whether the number of ART issues was associated with adherence. Previous research has focused on identifying adherence issues among PWH[18,24] or focused on adherence and outcome improvement from ART simplification.[25,26] This analysis was one of the first of its kind to quantify the number of ART and non-ART issues separately and to explore the association of ART issue burden with adherence.

METHODS

Project Design and Participants

This analysis used data compiled from 8 of 10 sites that participated in the PCHCM demonstration project throughout the United States from August 2014 to September 2016. Most of these sites were Ryan White, Federally Qualified Health Center (FQHC), or FQHC look-alike clinics located in urban settings. Data from 2 sites were excluded from the analysis because of administrative changes during the duration of the demonstration project. The final analysis data set included information on pharmacists' assessment of therapy issues, suggested resolutions to documented issues, and follow-up of suggested resolutions. Data were collected for each patient and each medication during their quarterly medication therapy review conducted as part of the MTM consultations. Additional details about the model and medication therapy review are described in detail elsewhere.[21,23]

Measures: Therapy Issues

Pharmacists were asked to identify "general and/or HIV-specific therapy issue(s)" for each medication from a precoded list of 19 issues. Data from the precoded list were reviewed by pharmacists involved in clinical care for the demonstration project and grouped into 5 main themes before analysis: adherence, suboptimum, regimen, cost, and nontherapy. Therapy issues were grouped as ART issues and non-ART issues to preserve the distinction between issues specific to the treatment type. In addition, all other open-ended responses were reviewed by pharmacists and back coded into 1 of the 5 themes, when possible. The adherence theme included adherence over/underuse and unnecessary therapy. The suboptimum therapy theme included having a detectable HIV viral load and/or identified gaps in therapy. The regimen theme included adverse drug reactions, drug–drug interactions, problems with dose and duration, and simplification of ARV to a single tablet regimen, if possible. The cost theme included cost efficacy. The nontherapy theme included discrepancies between medication list(s), need for vaccination(s), absence of smoking cessation counseling, and problems with administration technique. For a complete list of 19 precoded issues and their subsequent themes refer to Table 1, Supplemental Digital Content, http://links.lww.com/QAI/B676.

TABLE 1. Characteristics of Persons From the Patient-Centered HIV Care Model Included in This Analysis*

Characteristic	Total in Analysis, n (%)
Total	561 (100)
Age, yr	
18–24	27 (5)
25–34	103 (18)
35–49	198 (35)
≥50	233 (42)
Race/ethnicity	
Black, non-Hispanic	305 (54)
Hispanic	95 (17)
Other/unknown	64 (11)
White, ethnicity unknown	15 (3)
White, non-Hispanic	82 (15)
Sex†	
Male	366 (65)
Female	178 (32)
Transgender	17 (3)
Medical insurance	
Private insurance	75 (13)
Medicaid	218 (39)
Medicare	110 (20)
Ryan White/ADAP	87 (16)
Uninsured/unknown/multiple	71 (13)

*The PCHCM demonstration project included 765 total participants from 10 sites; this analysis excluded 97 participants form site 7 and 107 participants from site 10 because of protocol deviations at both sites.

†Male and female sex refers to sex assigned at birth.

Measures: Suggested Resolutions

During each medication therapy review, pharmacists were also asked to identify "suggested resolution(s)" to the general and/or HIV-specific therapy issue(s) for each medication from a list of 23 precoded suggested resolutions. The precoded list of suggested resolutions was reviewed by pharmacists involved in clinical care for the demonstration project and grouped into 7 main themes before analysis: adherence management (ie, primarily adherence counseling), medical record update, medication assistance, medication modification, patient education, recommended testing, and nontherapy. Suggested resolutions were grouped as ART suggested resolutions and nonART suggested resolutions to preserve the distinction between resolutions specific to the treatment type. Before analysis, all other open-ended responses were reviewed by pharmacists and back coded into themes, when possible. For a complete list of 23 suggested resolutions and revised resolution groupings refer to Table 1, Supplemental Digital Content, http://links.lww.com/QAI/B676.

Measures: Adherence to ART

Adherence to ART was calculated using the proportion of days covered (PDC) measure. PDC is a claims-based metric that determines the proportion of days for which a person has at least 3 ARV components available, excluding ARV boosters.[6,27] PDC was calculated for all persons with at least 90 days of follow-up in the 12 months after enrollment in the project. Adherence change over baseline was calculated on a subset of persons with a minimum of 90 days of fill history in both the 12-month preenrollment and 12-month postenrollment periods. ART PDC is calculated by dividing the number of days a person has ART coverage during the measurement period by the length of the measurement period. Adjustments are made to account for medications with overlapping fill days' supply. Calculation of PDC is described in previously published analyses.[23]

Statistical Analysis

The number of persons with therapy issues and suggested resolutions were reported overall and separately for ART and non-ART because of therapy issues. In addition, the proportion of therapy issues by suggested resolution was reported separately for ART and non-ART medications. Finally, the mean number of ART and non-ART issues, along with the 95% confidence interval, was reported. Significant differences in the mean number of ART and non-ART issues overall were identified at the $P < 0.05$ level one-way analysis of variance (ANOVA) F-test followed by a Tukey–Kramer test for multiple comparisons within demographic characteristics.

The association of ARV adherence with an ART issue count was assessed by modeling PDC and issue count as an independent variable while adjusting for length of measurement period and clinical site. Covariates included were length of therapy, project site, and patient comorbidities. Age, gender, race/ethnicity, and insurance were not significant in bivariate analyses and were excluded from modeling. The difference in mean postperiod adherence and the mean adherence change (preperiod minus postperiod adherence) was tested using a generalized linear model with linear trend estimation. All data were analyzed using SAS version 9.4.

TABLE 2. Number of Persons With ART and Non-ART Issues and Resolutions Within the PCHCM Included in This Analysis (N = 561)

Characteristic	Persons With ART/Non-ART Issues/ Resolutions, n (%)	Persons With ART Issues/ Resolutions, n (%)	Persons With Non-ART Issues/ Resolutions, n (%)
Issues			
Any issue	548 (98)	450 (82)	507 (93)
Adherence	344 (63)	256 (57)	203 (40)
Suboptimum	313 (57)	102 (23)	280 (55)
Regimen	223 (41)	131 (29)	143 (28)
Cost	120 (22)	22 (5)	103 (20)
Nontherapy issues	455 (83)	242 (54)	429 (85)
Suggested resolutions			
Any suggested resolution	545 (97)	446 (82)	504 (92)
Medication modification	421 (77)	168 (38)	372 (74)
Patient education	340 (62)	216 (48)	255 (51)
Medical record update	219 (40)	43 (10)	211 (42)
Adherence management	217 (40)	161 (36)	113 (22)
Recommend testing	190 (35)	118 (26)	127 (25)
Medication assistance	65 (12)	38 (9)	29 (6)
Nontherapy resolutions	306 (56)	72 (16)	283 (56)

RESULTS

Demographics

Among the 561 persons included in this analysis, the largest proportion of persons were 50 years or older (42%), Black, non-Hispanic (54%), and men (65%). Participants were most likely to be insured by Medicaid (39%) or Medicare (20%) as their primary payer. Demographics of participants included in this analysis are shown in Table 1.

Therapy Issues and Suggested Resolutions

As shown in Table 2, most participants included in this analysis reported having at least 1 ART issue (82%) and almost all had at least 1 non-ART issue (93%). Among the 5 types of ART issues, the most common was adherence (57%), followed by nontherapy issues (54%) and regimen (29%); cost was the least reported ART issue among only 5% of participants. However, for non-ART issues, the most common was nontherapy issues (85%), followed by suboptimum (55%) and adherence (40%); cost was the least commonly reported non-ART issue, for 20% of persons.

Regarding suggested resolutions, most participants included in this analysis reported having at least 1 ART-suggested resolution (82%) and almost all had at least 1 non–ART-suggested resolution (92%). The most frequently reported ART-suggested resolutions were patient education (48%), followed by medication modification (38%) and adherence management (36%). By contrast, the most frequently reported non-ART resolutions were medication modification (74%), patient education (51%), and nontherapy resolutions (56%). Medication assistance was the least commonly reported resolution for ART and non-ART issues (9% and 6%, respectively).

Among ART and non-ART medication adherence issues, the most commonly identified suggested resolutions were adherence management (48% and 48%, respectively) and patient education (36% and 29%, respectively). For ART and non-ART suboptimum medication issues, the most commonly reported suggested resolutions were medication modification (54% and 81%, respectively). ART and non-ART regimen issues were most commonly addressed through medication modification (60% and 62%, respectively) or patient education (24% and 22%, respectively). ART medication cost issues were more commonly resolved by medication assistance than non-ART medication cost issues (88% and 24%, respectively). The suggested resolutions for other issues varied. Refer to Figure 1 for a graph of therapy issues by suggested resolutions.

Mean Number of Therapy Issues and Resolutions

As noted in Table 3, among the 561 participants enrolled in the project and included in this analysis, the mean number of ART medication issues was 4.2 and the mean number of non-ART medication issues was 6.4. The

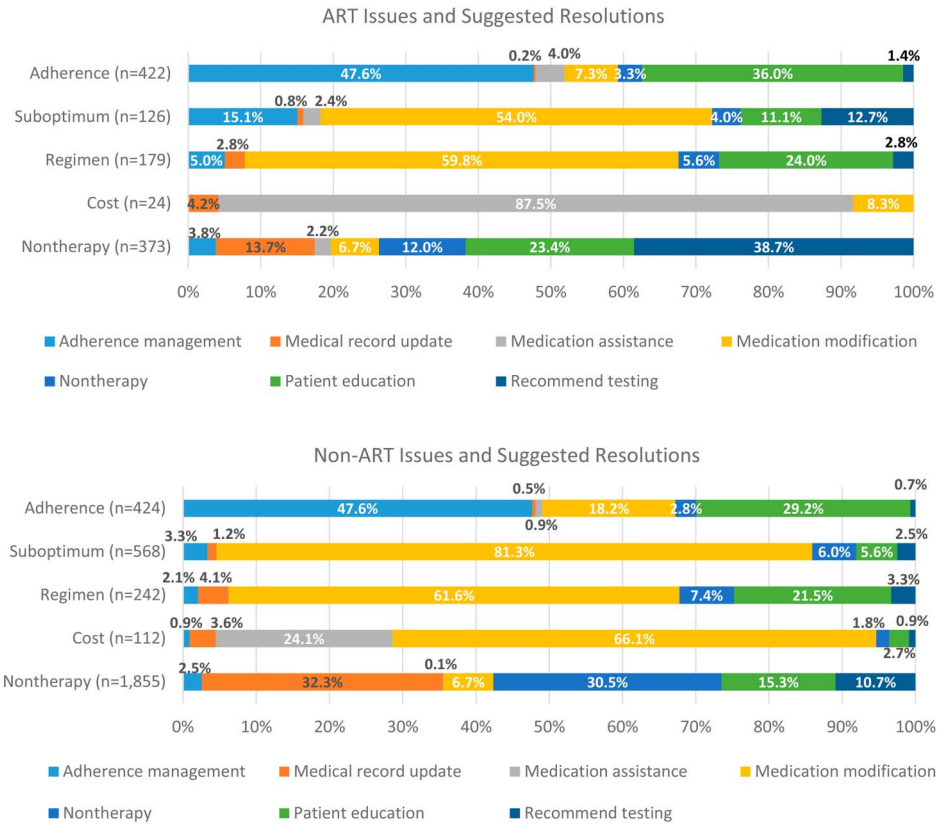

FIGURE 1. Proportion of ART and Non-ART issues by suggested resolutions (N = 4152). *Data are presented at the issue/resolution level; multiple issues/resolutions were reported per person. full color online

TABLE 3. Mean Number of ART-related and Non–ART-Related Issues per Person by Demographic Characteristics

Characteristic	ART Issues Per Person, Mean (95% CI)	Non-ART Issues Per Person, Mean (95% CI)
Overall	4.2 (3.8–4.5)	6.4 (5.9–7.0)
Age, yr*		
18–24	4.8 (2.9–6.7)	4.5 (2.4–6.5)[ab]
25–34	4.8 (3.9–5.6)	4.8 (3.8–5.9)[a]
35–49	4.2 (3.5–4.8)	6.2 (5.4–6.9)[ab]
≥50	3.8 (3.3–4.4)	7.6 (6.7–8.5)[b]
Race/ethnicity†		
Black, non-Hispanic	4.6 (4.1–5.1)[a]	6.4 (5.7–7.0)
Hispanic	2.9 (2.2–3.6)[b]	6.0 (5.0–6.9)
Other/unknown	3.8 (2.8–4.8)[ab]	7.1 (4.7–9.5)
White, ethnicity unknown	3.5 (1.6–5.4)[ab]	9.6 (6.0–13.2)
White, non-Hispanic	4.5 (3.4–5.5)[ab]	6.2 (4.9–7.4)
Sex*		
Male	4.1 (3.7–4.6)	6.5 (5.8–7.1)[a]
Female	4.3 (3.6–4.9)	6.0 (5.2–6.9)[a]
Transgender	4.7 (2.9–6.5)	10.9 (6.2–15.6)[b]
Medical insurance*		
Private insurance	4.1 (3.2–4.9)	5.9 (4.8–7.0)[ab]
Medicaid	4.0 (3.4–4.6)	6.3 (5.5–7.1)[b]
Medicare	4.5 (3.6–5.4)	8.5 (7.0–9.9)[a]
Ryan White/ADAP	4.6 (3.6–5.6)	5.6 (4.3–6.8)[b]
Uninsured/unknown/multiple	3.8 (2.8–4.7)	5.5 (4.2–6.7)[b]

*Significantly different mean ARV issues at the $P < 0.05$ level using a one-way ANOVA F-test.
†Significantly different mean non-ARV issues at the $P < 0.05$ level using a one-way ANOVA F-test.
[ab]Values with different letters are significantly different at the $P < 0.05$ level using a Tukey–Kramer test for multiple comparisons.

mean number of ART medication issues was highest among persons of ages 18–24 years (mean 4.8) and lowest among persons of ages 50 or older (mean 3.8). Conversely, the mean number of non-ART issues was lowest among persons of ages 18–24 years (mean 4.5) and highest among persons of ages 50 or older (mean 7.6). By race and ethnicity, Black, non-Hispanic persons had the highest mean number of ART issues (mean 4.6), whereas white persons of unknown

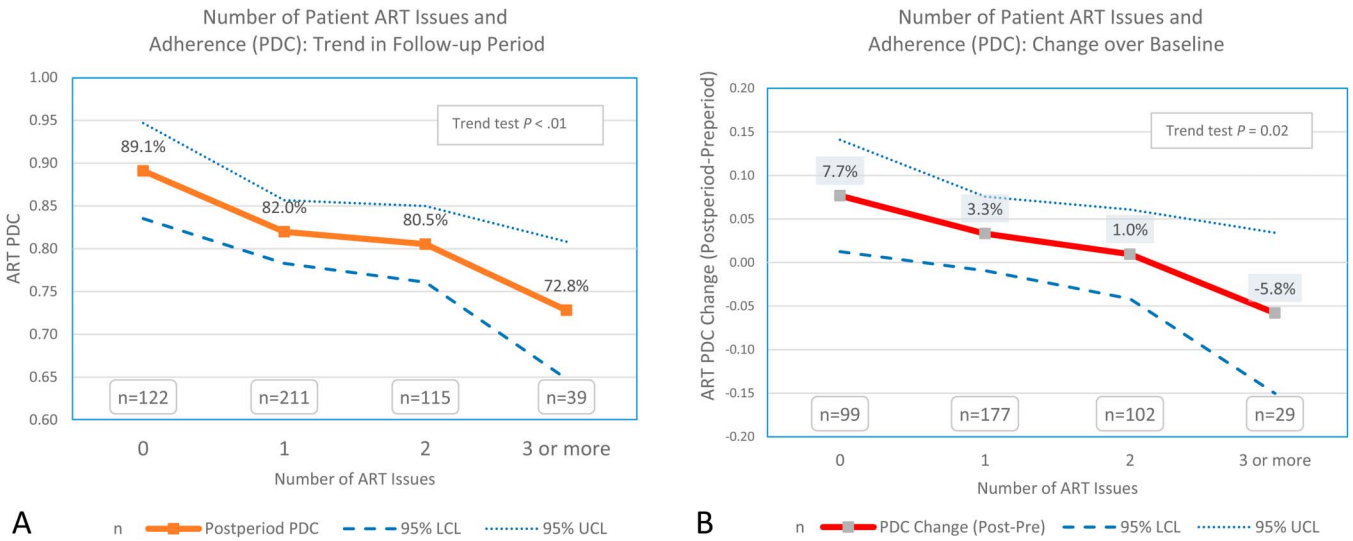

FIGURE 2. ART adherence (PDC) trends by the number of ART issues. *ART adherence calculations were conducted on a subset of persons with at least 90 days of medication coverage and up to 365 days of follow-up. **ART adherence change was calculated on a subset of persons with adequate pre-enrollment and post-enrollment follow-up. full color online

ethnicity had the highest mean number of non-ART issues (mean 9.6).

Therapy Issues and Adherence

As shown in Figure 2A, as the number of ART issues increased, there was a trend of lower ART adherence as measured by PDC ($P < 0.01$); PDC was 89% for those with no ART issues and 73% for those with 3 or more ART issues. As shown in Figure 2B, as the number of ART issues increased, the difference in preperiod to postperiod PDC declined ($P = 0.02$); persons with no ART issues had an 8% increase in adherence, whereas those with 3 or more ART issues had a 6% decrease in their adherence from the preperiod to postperiod.

DISCUSSION

Although PDC was more than 80% and PDC increased over baseline for those with less than 3 issues, the decline in PDC and the decline in PDC improvement among those with increasing ART issues highlights several potential explanations. First, that there may be a threshold of treatment complexity and/or patient engagement which pharmacist interventions could have the greatest impact. In particular, pharmacists may be able to help patients achieve an adherence threshold that approaches optimal by identifying and addressing ART issues in the context of MTM. However, the ability to improve adherence diminishes in the context of 3 or more ART issues. Second, the type and number of therapy issues may need to be taken into account to fully identify the potential impact of patient interventions. A similar study on adherence issues identified significant decreases in patient adherence for each unit increase in barrier score.[28] Two additional research studies demonstrated the ability of pharmacists to address patient issues and improve clinical outcomes. The first found that HIV clinical pharmacists were able to reduce pill burden and dosing frequency, increase medication adherence, and improve clinical outcomes.[26] The second identified improvements in CD4 counts, viral loads, and drug-related toxicities as a result of pharmacists' interventions.[29]

The high proportion of persons with identified ART and non-ART issues (98%) was not surprising given that this demonstration project addressed ART and non-ART issues among persons with more advanced disease, polypharmacy, and/or a higher proportion of comorbidities. Moreover, the mean number of ART issues we identified was similar to the results of a related qualitative study of adherence barriers, which found between 3 barriers among those not retained in care and 5 among those retained in care.[30] A higher number of ART issues and lower non-ART issues among younger adults were not surprising given that younger adults are more likely to be new to HIV treatment and face different issues related to ART adherence, including medical, psychological, and logistical factors that are specific to persons with a more recent HIV diagnosis.[31] By contrast, older persons who may have been living with HIV longer are more likely to face barriers such as fatigue or ART/non-ART polypharmacy.[32] The higher mean number of ART issues among Black, non-Hispanic persons is consistent with other findings regarding adherence challenges for Black, non-Hispanic PWH, including lower access to health services and health insurance, stigma, health literacy, and lack of trust in providers and the care system.[33,34]

Differences in the proportion of persons with ART and non-ART issues are likely the result of multiple factors unique to ART and non-ART. For example, excluding nontherapy issues, adherence was more commonly identified as an issue for ART compared with non-ART medications, which could be due to the regimen, side effects, timing, cost, pill burden, and other issues unique to ART.[28] Furthermore, excluding nontherapy issues, suboptimal was the most commonly identified non-ART issue, which was often related to the need for additional medications to treat a comorbid condition. Fewer persons had cost issues for ART vs. non-ART medications, which may be due to the pharmacists' assistance with and the availability of ART-related copay assistance programs that are often less available for non-ART medications.

LIMITATIONS

This analysis has several limitations. The PCHCM demonstration project was not a research study, and the pretest and posttest evaluation design is not as rigorous as a study with control groups. Because of administrative changes during the duration of the demonstration project, data collections were not consistent across all clinical sites; therefore, 2 sites were excluded. To facilitate this analysis, clinical notes on issues and resolutions were categorized into broader themes. Although these themes were reviewed for clinical relevance and accuracy, some subjective judgment was involved. We used primary payer to identify insurance coverage; thus, we did not account for those dually eligible for Medicare and Medicaid. The demographics of our sample may not be representative of all PWH because this study was conducted primarily at Ryan White and/or FQHC or FQHC look-alike clinics in urban settings. Finally, the adherence analysis was performed on a subset of persons who met the inclusion criteria for PDC calculations and not the entire sample of persons included in the analysis.

CONCLUSIONS

Based on the findings in this analysis, the number of ART issues may affect the ability to improve adherence, and there may be a threshold where pharmacists' and providers' ability to affect adherence is minimal (ie, 3 or more ART issues). Furthermore, the type and number of ART issues may need to be taken into account to fully identify the potential impact of patient interventions and such an assessment should be completed both at the therapeutic class and holistically. Because PWH are an aging population with an increased risk of comorbidities and polypharmacy, pharmacists and providers should collaborate to provide holistic, primary care solutions to address both the number and nature of ART issues.

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