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Impact of an Antimicrobial Stewardship Team on Reducing Antiretroviral Medication Errors

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Abstract

Background: Numerous interventions have been used to reduce medication errors related to antiretroviral (ARV) therapy for hospitalized patients with HIV. **Objective:** This study assessed the impact of an antimicrobial stewardship (ASP) team intervention on reducing the rate of ARV therapy errors in patients admitted to an academic medical center. **Methods:** This observational, retrospective study included patients who received ARV therapy from June 2016 to December 2017. The primary outcome was evaluation of ASP team performance in detecting ARV medication errors in the inpatient setting. Errors were further categorized by type (interaction, dosing, regimen). The Mann-Whitney *U* test and χ^2 tests were utilized to analyze continuous and categorical data, respectively. **Results:** Medication errors occurred in 51% of patients in the preintervention group (n = 152) and 48% of patients in the postintervention group (n = 203; $P = 0.43$). The most frequent medication error type was drug interactions in both groups, involving integrase strand transfer inhibitors and polyvalent cations (64% vs 67%). There was a significant difference between preintervention and postintervention groups regarding number of errors detected (13 vs 106, $P < 0.001$), corrected (12 vs 86, $P < 0.001$), and persisting at discharge (106 vs 18, $P < 0.001$). **Conclusion and Relevance:** Review of ARV regimens by an ASP team significantly decreased medication errors. Drug interactions are the most common medication error found in HIV-positive patients admitted to our academic center.

Keywords

antiretrovirals, clinical pharmacy, HIV/AIDS, medication errors, pharmaceutical care

Background

Antiretrovirals (ARVs) have significantly reduced morbidity and mortality among HIV-positive patients.[1,2] However, challenges for practitioners managing hospitalized HIV-positive patients remain. Errors related to ARVs have become a common occurrence in the hospital for several reasons: the complexity of ARV therapy, a lack of knowledge among and inexperience of practitioners, and inaccurate medication reconciliation.[3,4] Many of these errors originate during hospital stay, are resumed during the stay, and perpetuated at discharge.[5] Numerous studies on this topic report an ARV error rate of 5.8% to 86%, depending on the year the study was conducted.[4,6-10] These studies have found errors in almost every aspect of medication management, ranging from incomplete ARV regimens to incorrect administration.[11-15] These errors have the potential to lead to patient harm in the form of treatment failure, increased health care costs, and the development of drug resistance.[11-15] Recently, the Infectious Diseases Society of America, HIV Medicine Association, and American Academy of HIV Medicine have called to action the utility of ARV stewardship programs to reduce the risk of medication-related errors and enhance patient safety.[16]

Published studies evaluating ARV medication errors have assessed regimens comprising of nucleoside reverse transcriptase inhibitors (NRTIs) with a protease inhibitor (PI) or a nonnucleoside nucleoside reverse transcriptase inhibitor (NNRTI).[17] Errors related to the inclusion of an integrase strand transfer inhibitor (INSTI) in the HIV regimen have been understudied. INSTIs have emerged as first-line treatments in many clinical guidelines based on their efficacy, safety, and higher barrier to resistance.[17] As more patients

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are initiated or transitioned to INSTI-based regimens, medication errors related to their use will continue to emerge, and there may be a shift in the type of errors detected in the inpatient setting.

ARV therapy errors during hospitalization must be minimized to improve the quality of care provided to HIV-positive patients. Several strategies have been implemented in an attempt to achieve this objective: clinical pharmacist intervention, addition of combination ARV products to hospital formulary, revisions to computerized order-entry systems, and distribution of pocket-sized educational cards to staff.[10] The highest rate of error reduction is associated with monitoring HIV regimens by trained clinical pharmacists.[18-22] However, in these studies, the impact of a single pharmacist was measured.

To that end, the primary objective of this study was to evaluate the performance of an antimicrobial stewardship (ASP) team intervention in detecting ARV inaccuracies. The secondary objective was to evaluate the incidence and types of ARV errors in the preintervention and postintervention groups.

Methods

A retrospective, observational study was conducted to examine the impact of an ASP team in identifying and intervening on ARV errors among patients admitted to a 496-bed academic institution in Philadelphia, over 2 years. The study was approved by the local institutional review board.

Patients were included in this study if they were 18 years or older, were HIV positive, and had received at least one ARV medication during hospitalization. Patients were excluded if they were receiving pre-exposure prophylaxis, were discharged from the emergency department, or were readmitted. Patients were separated into preintervention and postintervention cohorts based on their date of admission in relation to the initiation of the ASP team monitoring service, which began on July 1st, 2017. The ASP team consisted of an infectious diseases pharmacy specialist and a PGY2 infectious diseases pharmacy resident (authors TEB and AB).

The preintervention group consisted of patients hospitalized between July 2016 and December 2016; they were eligible for review of ARV medication orders by the staff pharmacists without specialized training in HIV pharmacotherapy, primary medical service physicians, and infectious diseases physicians. Patients in the preintervention group were identified using ICD-10 diagnosis code B20 (human immunodeficiency virus disease) or our electronic clinical surveillance software, TheraDoc.

The postintervention group were patients hospitalized between July 2017 and December 2017. This group received reviews of their ARV medications by the ASP team. Each morning, the ASP team obtained a report generated via the automated medication dispensing system of all patients receiving ARV medications in the hospital. The ASP team then calculated creatinine clearance to ensure appropriate dosing; contacted outpatient physicians and reviewed prescription claims history, as necessary; documented recommendations in the electronic health record; and contacted the primary medical service teams regarding any changes required to ensure accuracy of the regimen. Renal function was calculated per the Cockcroft-Gault formula at the time of start of ARV.[23] Documentation from or discussion with the primary provider on accuracy of calculated creatinine clearance was taken into consideration when evaluating for ARV renal dose adjustments. ARV regimens deviating from the recommendations of the Department of Health and Human Services (DHHS) treatment guidelines were further investigated, as described above.[24]

An independent review of all patients in the preintervention and postintervention period (by authors KN and SM) was conducted to assess the impact of the ASP team. If discrepant results were collected, a third pharmacist knowledgeable in HIV pharmacotherapy would adjudicate results.

Data retrieved from inpatient and outpatient electronic health records included age, sex, ethnicity, weight, serum creatinine, length of stay, comorbidities, ARV regimen, CD4 count and viral load within one year of index admission, primary medical service, and presence of an active infectious diseases consult on index admission. ARV errors were apportioned into three categories: drug interactions, incorrect regimen, and incorrect dosing. Drug interactions stated within the University of Liverpool HIV Drug Interactions tool (https://www.hiv-druginteractions.org/) or the DHHS guidelines and those that required a change in therapy were deemed significant.[24] Incorrect regimen referred to any inconsistencies in ARV from outpatient records and/or patient history compared with inpatient prescription (wrong regimen), formulations (tenofovir alafenamide [TAF] vs tenofovir disoproxil fumarate [TDF]), addition of drug, or omission of drug. Incorrect dosing was defined as dosing errors per renal dysfunction, dosing of pharmacokinetic boosters, or frequency errors.

The primary outcome was evaluation of ASP team performance in identifying errors of ARV regimen, after thorough review of patient characteristics and outpatient prescription history. The secondary outcome was the incidence and type of ARV error (interaction, regimen, or dosing) identified in each cohort.

Descriptive statistics were used to report baseline characteristics of the study participants. Categorical variables were described in percentages and aggregates, and quantitative variables were expressed as a median with interquartile range. The Mann-Whitney *U* test was used to compare continuous variables, and the χ^2 test was utilized to analyze categorical variables. An α level of 0.05 established statistical significance.

Results

A total of 355 patient admissions over the two-year period were examined. A total of 152 patient admissions occurred during the preintervention period, and 203 admissions occurred during the postintervention time frame. Patients in the postintervention group were significantly older than patients in the intervention group (50 vs 53, $P = 0.02$). Additionally, patients in the postintervention group remained in the hospital for a day longer than the preintervention patients (4 vs 5, $P = 0.03$). A lower median estimated creatinine clearance (78 vs 72 mL/min, $P = 0.01$) and higher likelihood of cardiac comorbidities (12% vs 21%, $P = 0.02$) were observed in the postintervention group. Furthermore, there was a significant increase in patients who had a CD4 count $\geq$200 cells/mm^3 (41% vs 62%, $P < 0.001$) and who were on INSTI-based regimens (37% vs 54%, $P = 0.002$) from preintervention to postintervention time periods. Finally, the number of patients on other regimens such as PI + INSTI + NRTI or PI + CCR5 (chemokine coreceptor antagonist) + NRTI, just to name a few (38% vs 26%, $P = 0.011$), decreased significantly as well. Table 1 provides a detailed description of the baseline characteristics of the two groups.

The overall incidence of errors was 119 in the preintervention and 124 in the postintervention group. Figure 1 illustrates the performance of the ASP team in detecting and correcting ARV medication errors. Approximately 11% of total errors were detected in the preintervention period, in contrast to 85% of errors in the postintervention time frame ($P < 0.001$). There was a significant difference in the number of errors being corrected by the primary medical team (12 vs 86, $P < 0.001$) and errors persisting at discharge (106 vs 18, $P < 0.001$) postintervention. After intervention was complete, 68 of 124 (88%) errors were corrected by the primary medical teams. The errors that persisted in the postintervention period were missed (six) during the review by the ASP team or occurred after ASP team review (12). Of the six errors missed by the ASP team, two were regimen based Elvitegravir/ cobicistat/ tenofovir disoproxil fumarate/ emtricitabine vs elvitegravir/ cobicistat/ tenofovir alafenamide/ emtricitabine and rilpivirine/ tenofovir disoproxil/ emtricitabine vs rilpivirine / tenofovir alafenamide/ emtricitabine (EVG/c/TDF/FTC vs EVG/c/TAF/FTC and RPV/TDF/FTC vs RPV/TAF/FTC) and four were interactions between INSTIs and polyvalent cations. A total of 20 recommendations relayed to the primary medical teams were not accepted. These recommendations were related to the regimen (one), dosing (four), and drug interactions (15). In the regimen category, missing NRTI therapy (FTC/TDF) was the only error left unchanged by the primary team. In reference to dosing, renal dose adjustment of lamivudine (n = 1) and emtricitabine (n = 2) and dolutegravir dosing for known resistance (n = 1) were not accepted. A total of 75% of unaccepted errors (15/20) were drug interactions. These consisted of INSTI-cation (n = 7), PI-atorvastatin (n = 4), cobicistat-atorvastatin (n = 2), and PI-quetiapine (n = 2).

Table 2 presents information on the secondary outcomes—ARV errors based on category. A considerable number of admissions in the preintervention and postintervention groups had at least one medication error (51% vs 48%, $P = 0.43$). Patient profiles with at least 3 medication errors were detected more in the preintervention group than in the postintervention group (13 vs 4, $P = 0.04$). Drug interactions accounted for two-thirds of the errors detected in both groups. The most common drug interaction identified in the two groups involved the concomitant administration of an integrase inhibitor with a polyvalent cation (eg, iron, magnesium, calcium). This interaction accounted for 67% and 64% of total interactions in the preintervention and postintervention groups, respectively. The second recurring interaction detected was a PI-atorvastatin 40 or 80 mg combination, accounting for about 10% of total errors in each group. Other commonly encountered interactions were the coadministration of a PI with quetiapine and rilpivirine with an acid suppressant. Regimen errors detected were mostly related to a switch in tenofovir formulation: TDF/FTC vs TAF/FTC, EVG/c/TDF/FTC vs EVG/c/TAF/FTC, and RPV/TDF/FTC vs RPV/TAF/FTC. This accounted for 3% of total errors in the preintervention group and 9% in the postintervention group. About 10% of errors in the preintervention and 7% in the postintervention group were a result of omitted medications. In addition, there was a numerical difference in the incidence of dosing errors between the 2 groups (21% vs 14%). The lack of renal adjustment errors occurred more frequently in the preintervention than the postintervention group (13% vs 4%), whereas incorrect dosing of ritonavir (not coadministered with a PI, wrong dose, wrong frequency) was a more frequent observation in the postintervention than the preintervention group (4% vs 6%).

Discussion

In the era of HIV-positive patients having life spans similar to those of non–HIV-positive patients, this investigation has shed light on the importance of ARV stewardship efforts. The most crucial conclusion of our analysis was that the ASP team intervention significantly reduced ARV medications errors from 89% to 15% ($P < 0.001$). In an era where ARV regimens are coformulated in multiple single-tablet regimens, this study emphasizes the continued vitality of clinical pharmacists in conducting ARV medication reviews. DePuy et al[25] conducted a study, similar to ours, and included a large cohort (77.1%) of patients with INSTI-based regimens, but did not include a comparator arm. To our knowledge, this is the first study comparing a clinical pharmacist intervention with control in an age where INSTI-based regimens are the most commonly prescribed cocktail. By minimizing the

Table 1. Baseline Characteristics and Demographics.

Characteristic	Preintervention (n = 152)	Postintervention (n = 203)	*P* Value
Age (years), median (IQR)	50 (44-57)	53 (45-59)	0.024[a]
Male	96 (63)	130 (64)	0.802[b]
Race, n (%)			
African American	131 (86)	162 (80)	0.154[b]
Caucasian	7 (5)	18 (9)	0.117[b]
Hispanic American	4 (2)	12 (6)	0.137[b]
Other	11 (7)	11 (5)	0.492[b]
Weight (kg)	75 (61-86)	75 (66-90)	0.093[a]
Comorbid conditions, n (%)			
Cardiac (MI, HF)	18 (12)	43 (21)	0.020[b]
Neurological (dementia, CVA)	14 (9)	16 (8)	0.670[b]
Respiratory (COPD)	40 (26)	36 (18)	0.055[b]
Malignancy (solid, leukemia, lymphoma)	16 (10)	12 (6)	0.115[b]
Hepatic (hepatitis, cirrhosis)	50 (33)	16 (8)	<0.001[b]
Diabetes (1 and 2)	19 (12)	41 (20)	0.053[b]
Renal disease (CKD, chronic dialysis)	29 (19)	56 (27)	0.059[b]
ARV regimen by class, n (%)			
INSTI + NRTI	49 (33)	76 (38)	0.310[b]
INSTI/booster + NRTI	7 (5)	33 (16)	<0.001[b]
PI/booster + NRTI	22 (14)	20 (10)	0.190[b]
NNRTI + NRTI	15 (10)	21 (10)	0.867[b]
Other regimens	59 (38)	53 (26)	0.011[b]
CD4 (cells/mm^3), n (%)			
<200	64 (42)	42 (20)	<0.001[b]
≥200	63 (41)	125 (62)	<0.001[b]
Unknown	26 (17)	36 (18)	0.856[b]
Viral load (copies/mL), n (%)			
Undetectable (<20)	43 (28)	71 (35)	0.169[b]
Detectable (>20)	67 (44)	56 (28)	0.235[b]
Unknown	43 (28)	76 (37)	0.065[b]
Admission SCr (mg/dL), median (IQR)	0.91 (0.76-1.2)	1.04 (0.85-2.13)	0.002[a]
CrCl (mL/min), median (IQR)	78 (58-108)	72 (36-96)	0.012[a]
Length of stay (days), median (IQR)	4 (3-7)	5 (3-9)	0.038[a]
Primary team on admission, n (%)			
General medicine	97 (63)	115 (57)	0.199[b]
Critical care units	12 (8)	20 (10)	0.512[b]
Other	44 (29)	69 (33)	0.294[b]
ID consultation, n (%)	59 (39)	81 (40)	0.797[b]

Abbreviations: ARV, antiretroviral; CHF, congestive heart failure; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; CrCl, creatinine clearance; CVA, cerebrovascular accident; HF, heart failure; ID, infectious diseases; INSTI, integrase strand transfer inhibitor; IQR, interquartile range; MI, myocardial infarction; NNRTI, nonnucleoside reverse transcriptase inhibitor; NRTI, nucleoside reverse transcriptase inhibitor; PI, protease inhibitor; SCr, serum creatinine.
[a]Mann-Whitney *U* test.
[b]χ^2 Test.

number of errors during hospitalization, the ASP team curtailed the propagation of errors to the outpatient realm. Although infectious diseases physicians were consulted on 39% of patients in the preintervention group, the number of errors persisting remained high (89%). This observation highlights the immense value of the infectious diseases pharmacy specialist(s) to a multidisciplinary team. The rate of errors persisting after ASP team review could have potentially been smaller if 20 additional recommendations were accepted. There was no record of the reasons for disregard of these recommendations. Because of the retrospective nature of this study, it is possible that renal dose recommendations (4/20) were not accepted either as a result of providers' judgment that renal function would recover or approach an acceptable baseline or to avoid separation of a single-tablet regimen. Recommendations related to drug interactions

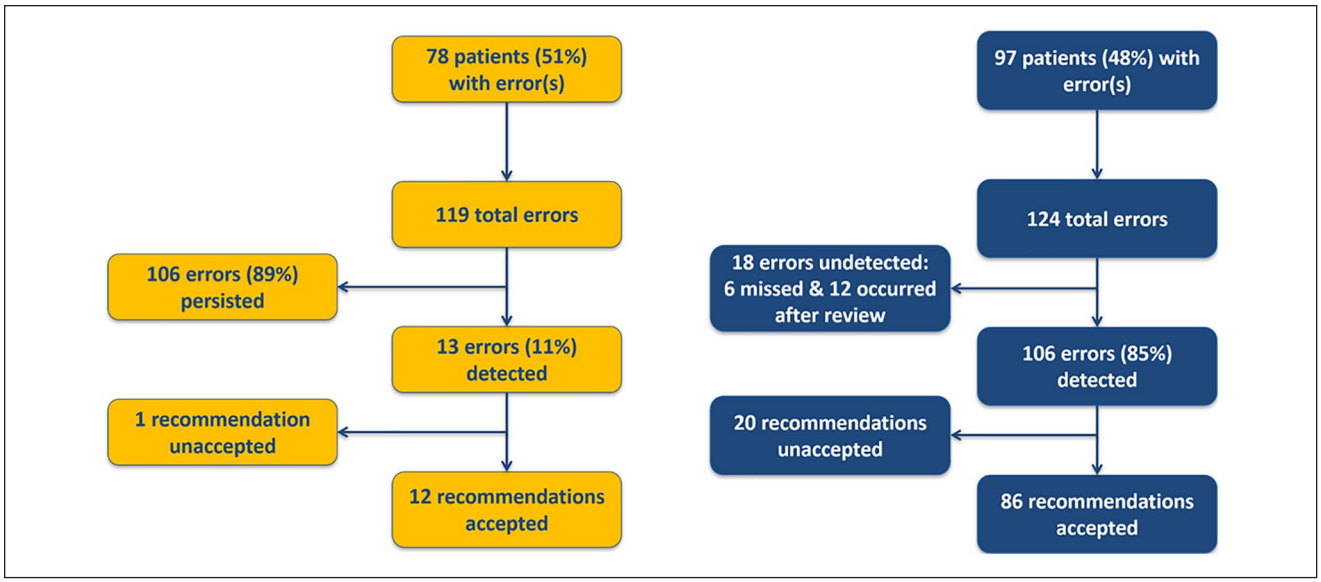

Figure 1. Preintervention (yellow) and postintervention (blue) antiretroviral medication error schematic.

Table 2. ARV-Related Medication Errors.

Variable	Preintervention (n = 152)	Postintervention (n = 203)	*P* Value
Overall incidence of error	119	124	NA
Number of patient profiles with error, n (%)	78 (51)	97 (48)	0.434[a]
1 Error	51/78 (65)	74/97 (76)	0.179[a]
2 Errors	17/78 (22)	19/97 (20)	0.906[a]
≥3 Errors	10/78 (13)	4/97 (4)	0.039[a]
Drug interaction errors, n (%)	77/119 (65)	82/124 (66)	0.816[a]
PI-atorvastatin	11/119 (9)	13/124 (10)	
Integrase-cation	49/119 (4)	55/124 (44)	
Rilpivirine-acid suppressants	2/119 (2)	6/124 (5)	
PI-quetiapine	9/119 (8)	2/124 (2)	
Other[b]	6/119 (5)	6/124 (5)	
Regimen errors, n (%)	17/119 (14)	25/124 (20)	0.226[a]
TDF/TAF switch	4/119 (3)	11/124 (9)	
Omission of any drug	12/119 (10)	9/124 (7)	
Wrong regimen	0/119 (0)	4/124 (3)	
Addition of any drug	1/119 (1)	1/124 (1)	
Dosing errors, n (%)	25/119 (21)	17/124 (14)	0.133[a]
Lack of renal adjustment	15/119 (13)	5/124 (4)	
Ritonavir dosing[c]	5/119 (4)	8/124 (6)	
Incorrect frequency	3/119 (3)	2/124 (2)	
Other[d]	3/119 (3)	2/124 (2)	

Abbreviations: ARV, antiretroviral; DTG, dolutegravir; INSTI, integrase strand transferase inhibitor; PI, protease inhibitor; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate.
[a]χ^2 Test.
[b]Others include PI-phenytoin, PI-DOAC (direct oral anticoagulant), cobicistat-atorvastatin, cobicistat-quetiapine, INSTI-phenytoin, PI-maraviroc.
[c]Not coadministered with PI, wrong dose, wrong frequency.
[d]Incorrect dosing of DTG or dosing error because of switch to liquid formulation.

may not have been accepted because patients had been on certain interacting medications as outpatients, with no noted virological failure. Education and harnessing support of information technology may have alleviated errors being missed by the ASP team and even by providers on order entry.

Second, drug interactions remained the most frequent medication error. The rate of drug interaction was highest

for recipients of INSTI-based regimens and polyvalent cations. These cations bind to the INSTI and may lead to reduction of INSTI concentrations by 40% to 70%.[26] This interaction was found more frequently in the postintervention group (49/119 vs 55/124, $P = 0.616$), perhaps due to more patients with cardiac comorbidities and increase in use of INSTI-based regimens. Prior studies describe PIs as the class involved in most drug interactions. The coadministration of atazanavir with an acid suppressant was the most frequently detected interaction in prior published studies.[10,19,20] In our study, this interaction occurred twice in both groups. The low incidence of this interaction can be ascribed to atazanavir-based regimens being graded as a nonpreferred regimen in the DHHS guidelines.[24] Another frequent interaction observed in our study was between PI and substrates of CYP3A4—atorvastatin, quetiapine, and phenytoin. As expected, these errors occurred with a similar frequency in both groups, because PI-based regimens continued to be utilized, albeit there was a slight decrease, over this time period. Many of the dosing and regimen errors can be attributed to insufficient oversight by health care practitioners and may suggest lack of expertise in HIV pharmacotherapy. The lack of switch errors between TDF/FTC vs TAF/FTC in the preintervention group may be related to the FDA's approval date of the latter medication in April 2016.[24] During the preintervention period, TAF/FTC had not yet been embraced by many prescribers and, thus, was not utilized as often as TDF/FTC (4/119 vs 11/124).

Furthermore, INSTI-based regimens have superseded other ARV therapies as the most commonly prescribed regimen. Within the year separating the 2 cohorts, INSTI-based regimens increased from constituting a third of all regimens to more than half. In our cohort, the INSTI-based regimen increase seems to be driven by elvitegravir specifically, which may be a result of the ease of using elvitegravir combination tablets. Biktarvy (BIC/TAF/FTC), the newest single-tablet INSTI-based agent, was not approved at the time of study analysis. PI-based regimens were the first line choice in past studies.[10,12,22] In our study, the proportion of patients on a PI-based regimen decreased by a small margin (4%). However, we witnessed a continued role of PIs in combination with INSTI-based regimens in order to treat a drug-resistant virus and maintain a high barrier to resistance.[26] Patel et al[18] conducted a study with a patient population similar to ours in regard to type of regimen, although raltegravir was the prevailing INSTI rather than dolutegravir. In our institution, increased use of dolutegravir can be attributed to the medication having a higher barrier to resistance, favorable efficacy and safety data, dosing convenience, and limited induction or inhibition of the CYP3A4 enzyme.[27]

The results of this study align with other studies with a similar design that evaluated the impact of pharmacist interventions on ARV stewardship. Carcelero et al[22] conducted an observational, prospective study that involved a PGY2 pharmacy resident trained in HIV pharmacotherapy and the staff infectious diseases pharmacist. Their study was of a smaller sample (189 admissions, no control group), and the ARV error rate was lower (22% of admissions). Similar to our findings, drug interactions (33%) were the top category for medication errors. Liedtke et al[28] performed a retrospective observational study of a pharmacist monitoring 330 patients. Similar to our study, a control group was utilized by Liedtke et al, and they demonstrated that an infectious diseases pharmacy specialist can reduce ARV errors by a substantial amount (74.9%). Our study diverges from that of Liedtke and colleagues because we collected errors related to dosage timing (eg, ritonavir coadministered with PI), so the error rates may have been higher because of this difference.[28] The results from our study and the aforementioned studies converge in suggesting that medication error rates improve when pharmacists with expertise in HIV pharmacotherapy review ARV regimens.

This study had several limitations. As a retrospective study, there were details related to the detection and correction of errors that were unavailable. Underdocumentation of errors may have resulted in an error recorded as undetected, but truly recognized by a practitioner. We did not include drug interactions that, per DHHS guidelines, required only monitoring. This may have reduced the rate of drug interactions and the overall ARV error rate. It is likely that errors of omission were not captured as a consequence of the inclusion criteria requiring patients to receive at least one ARV medication during hospitalization. In addition, we calculated creatinine clearance specific to one point in time, which did not allow for evaluation of acute kidney injury. However, renal dose adjustment errors comprised a small proportion of total errors; and thus, the likelihood that total errors rates would be skewed is low. We did not evaluate the significance of multiple-tablet versus single-tablet regimens in regard to error rates, which may have provided yet another perspective to mechanisms driving ARV errors. Finally, our study was a single-centered endeavor utilizing a dedicated infectious diseases pharmacy specialist; therefore, results may not be generalizable to other hospitals that lack such personnel.

Conclusion and Relevance

Our study adds to the body of evidence demonstrating that pharmacists can decrease the frequency of ARV errors and the need to incorporate such reviews in well-established stewardship programs. It also reveals the shift in the use of PI-based regimens to INSTI-based regimens. With this shift, there remains a risk of harmful ARV errors during hospitalizations, with the most common being drug interactions.

Authors' Note

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Declaration of Conflicting Interests

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