Pharmaceutical Care for HIV Patients on Directly Observed Therapy

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BACKGROUND: Inner-city patients infected with HIV can be a challenging group to treat. Homelessness, mental illness, substance abuse, and hepatitis C infection may serve as barriers to effective treatment. A multidisciplinary team including the pharmacist can impact upon the delivery of care to the inner-city HIV patient population.

OBJECTIVE: To describe the implementation and provision of pharmaceutical care to inner-city patients taking directly observed therapy (DOT), as well as drug-related problems (DRPs) and their respective outcomes.

METHODS: Pharmaceutical care, including the prospective identification and management of DRPs, was provided by a clinical pharmacist.

RESULTS: Fifty-seven patients were followed over a 14-month period. Overall, 149 DRPs were identified and >95% were resolved. Those included (1) adverse effects (n = 56; gastrointestinal, central nervous system effects, allergies, laboratory abnormalities), (2) drug interactions (n = 32), (3) drugs indicated for comorbidities (n = 24; safety in pregnancy, tuberculosis, *Pneumocystis carinii* pneumonia prophylaxis, oral candidiasis, herpes zoster, nutritional supplements), (4) adherence issues (n = 20; altering timing of medication, changing formulation, decreasing pill burden), (5) drugs no longer indicated (n = 10; opportunistic infection prophylaxis, treatment of primary infection), and (6) dosage adjustment (n = 7) for weight and renal insufficiency.

CONCLUSIONS: In the provision of pharmaceutical care to HIV-infected patients on DOT, an HIV pharmacist significantly contributed to antiretroviral selection, monitoring of drug therapy, and managing DRPs. An HIV pharmacist can assist in promoting patient adherence and improved outcomes in this setting.

KEY WORDS: directly observed therapy, HIV.

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Historically, inner-city patients infected with HIV have been a challenging group to treat. They frequently have underlying comorbidities and psychosocial issues such as mental illness, addictions, and homelessness, which often impair their ability to access health care and adhere to long-term antiretroviral therapy.[1]

New treatment delivery methods are being explored to ameliorate services to inner-city patients. Directly observed therapy (DOT) for highly active antiretroviral therapy (HAART) programs modeled on tuberculosis programs have been recently reviewed.[2] The framework and structure of such programs differ considerably depending on the population and location, local healthcare infrastructure, and patient incentives offered.

The DOT for HAART project in Edmonton, Alberta, is in the final year of a 3-year pilot project to assess the im-

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pact of the program on patient outcomes. This program has been successful in delivering effective HIV treatment and reducing risk behavior for inner-city individuals with histories of homelessness, injection drug use, and sex-trade involvement.[3] It presently operates out of 2 inner-city houses where a variety of services have been delivered daily to >60 patients in the past 28 months. These include medication administration; outreach support; addiction support; meals, housing, and transportation assistance; and facilitated healthcare access. At the beginning of the second project year, an HIV clinical pharmacist position was implemented in the program. The objective of this paper is to describe the provision of pharmaceutical care to DOT for HAART patients in the first 14 months of the position. This includes both describing the implementation of pharmaceutical services and the types of drug-related problems (DRPs) found in this patient population. The presentation of overall program outcome data (eg, patient outcome, virologic and immunologic endpoints, addiction severity scores) is beyond the scope of this paper.

Methods

Research was conducted in compliance with the requirements of the site's legal and ethical requirements. The pharmacist position consisted of 0.5 full-time equivalent with time divided at the 2 DOT programs (one-half day weekly) and the tertiary care HIV clinic at the Royal Alexandra Hospital (2 days weekly). The pharmacist was also consulted on HIV patients who were hospitalized at the same institution. Many of the patients attended both the DOT program and the hospital-based clinic, thus facilitating continuity of care in community, ambulatory, and inpatient settings.

The general design of the DOT program has been described elsewhere.[3] Pharmacist involvement with DOT patients consisted of obtaining pertinent baseline data (ie, medical history, drug history, use of recreational drugs, pertinent laboratory data) and selecting an appropriate HAART regimen in consultation with the treating physician. The HIV pharmacist functioned in a major advisory capacity to physicians in the selection of initial therapies and salvage regimens for patients failing on existing therapy. In-depth patient medication counseling was then provided. Initial sessions generally lasted for 30–60 minutes. Medication administration, follow-up, outreach, and support then occurred daily by the DOT outreach staff. The pharmacist provided intensive weekly follow-up visits at the DOT facility to identify and monitor for DRPs. Assessments were conducted via patient interview, consultation with the DOT outreach staff and other healthcare workers, and review of both laboratory data and patient adherence records. Patient progress, including monthly adherence rates, was communicated to the treating physician via telephone, faxed letters, and at tertiary care clinic visits.

DRPs were prospectively recorded and categorized as (1) adverse effects, (2) drug interactions, (3) dosage modification, (4) adherence issues, (5) drug indicated, and (6) drug not indicated. Management of DRPs depended on the nature of the problem. Simple problems such as drug–food interactions may have required more patient and staff counseling. Adherence rates <90% were deemed significant and often required more intensive teaching along with physician notification. More complex problems, such as antiretroviral failure, would have required direct communication with the treating physician to discuss remaining options.

Results

Over a 14-month period (May 2002–July 2003), 57 patients were enrolled into the program. There were 38 males (66.6%), 17 females (29.8%), and 2 transgender (3.5%) patients. Seventy-nine percent were First Nations aboriginal (n = 45) and 21% were white (n = 12); 95% (n = 54) were coinfected with hepatitis C. All patients had a history of substance abuse. Although several patients had previously used methadone, none was receiving methadone at the time of data analysis. There were 15 dropouts over the 14-month period. Reasons for dropouts were significant nonadherence despite numerous interventions (n = 9), drug holiday (n = 2), death (n = 2), left program (n = 1), and moved (n = 1).

Figure 1 summarizes HAART regimens utilized by patients in the program at the time of data analysis. Since the selection of HAART is complex and multifactorial, regimens were tailored to individual patients. When possible, once-daily therapy (n = 20) with a low pill burden was employed. However, the remainder of patients received twice-daily therapies (DOT for only one dose and a carry given for the second dose). In total, 149 DRPs were identified with both antivirals and ancillary medications (Figure 2). These are further described in Tables 1 and 2.

ADVERSE EFFECTS

As shown in Table 1, the most common category of DRP observed was adverse effects. Gastrointestinal adverse effects ranked first and, in most cases, were readily managed with antiemetics, antidiarrheals, and laxatives. There was one case of alcohol- and didanosine-induced pancreatitis that required hospitalization. Didanosine was replaced by zidovudine with no recurrences after 7 months.

Central nervous system (CNS) and peripheral nervous system adverse effects ranked second. These were mainly attributed to efavirenz (n = 10), which is known to cause temporary CNS adverse effects in >50% of patients.[4] To decrease efavirenz-induced daytime CNS effects, it has been recommended to take it at bedtime. However, the philosophy of DOT is to minimize unsupervised dosing, and the limited program operating hours required that medications be given under direct observation only during the daytime. Thus, most patients who continued on efavirenz were able to tolerate daytime dosing. Three patients experienced excess daytime sedation despite a protracted trial and required a change to bedtime self-administered dosing (non-DOT).

One patient suffered from severe dreams and suicidal ideation after taking efavirenz for 6 months. Although the patient had other contributors for these problems (ie, recently released from prison, inadequate housing, substance abuse), they may have resulted from delayed or lingering CNS reactions that have been described with efavirenz.[5] The patient was referred for further assessment and, through ongoing monitoring and support, has continued taking efavirenz for over one year with no major relapses.

Laboratory abnormalities ranked third (n = 10). Two patients developed transfusion-dependent anemia on zidovudine, thus necessitating a switch in HAART. Thrombocytopenia was seen in one patient with a history of heavy alcohol use. The regimen was modified to include zidovudine, which has demonstrated benefit in HIV-related thrombocytopenia.[6] The patient failed to respond and was

subsequently hospitalized with zidovudine-induced, transfusion-dependent pancytopenia, thus necessitating reverting to didanosine.

Elevated liver function test values (>5 times the upper limit of normal for either transaminase) were found in 5 patients. It is difficult to attribute these changes solely to HAART, as other confounders were hepatitis C coinfection and alcoholism. Two patients required discontinuation of HAART to be restarted at a later date, and 3 patients are being closely monitored for further elevations in transaminase values.

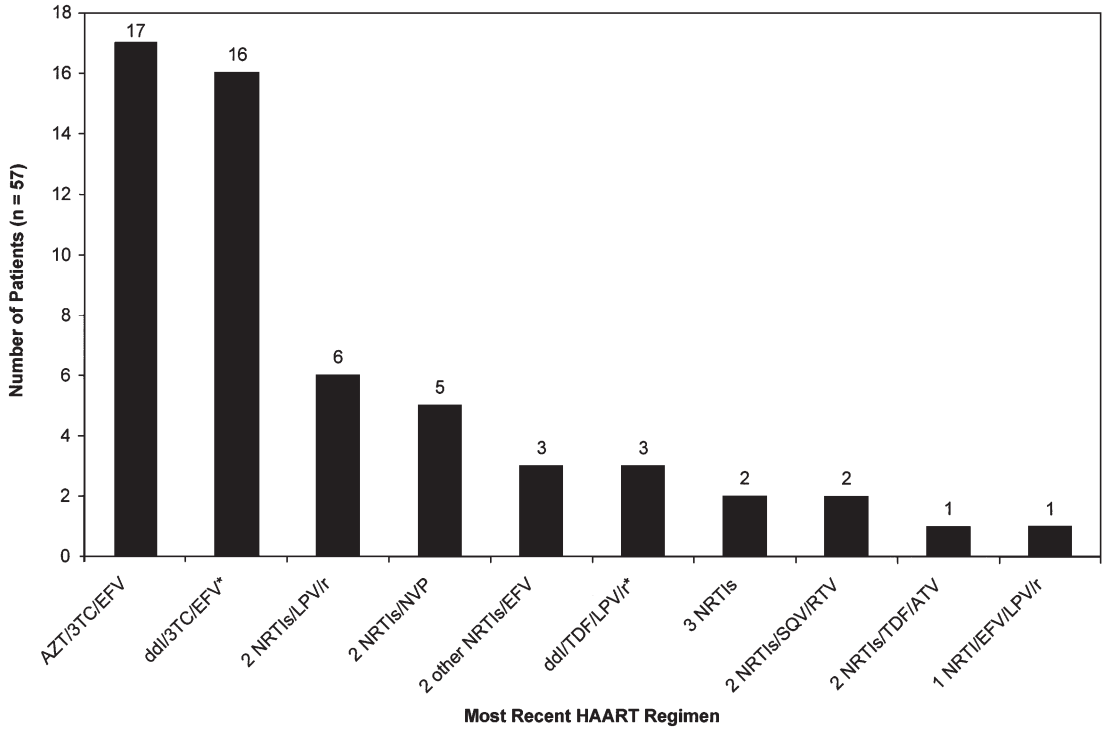

Figure 1. Once- and twice-daily HAART regimens. 3TC = lamivudine; ATV = atazanavir; AZT = zidovudine; ddI = didanosine; EFV = efavirenz; HAART = highly active antiretroviral therapy; LPV/r = lopinavir/ritonavir; NRTIs = nucleoside reverse transcriptase inhibitors (ie, abacavir, didanosine, lamivudine, stavudine, zidovudine); NVP = nevirapine; RTV = ritonavir; SQV = saquinavir; TDF = tenofovir; * = once daily.

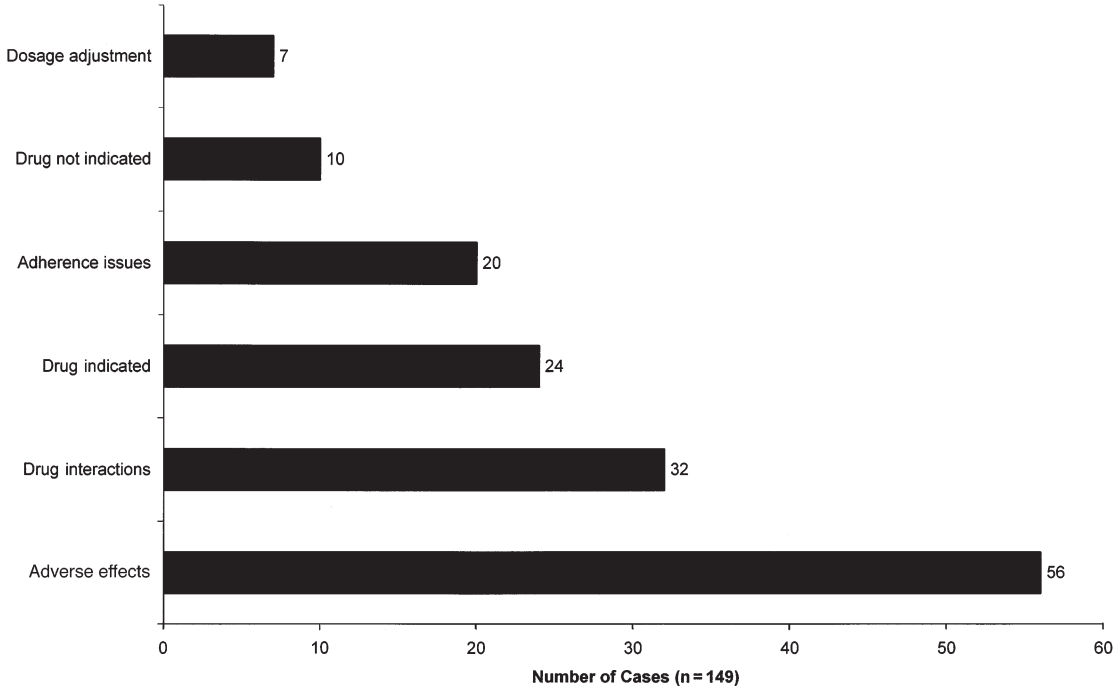

Figure 2. Drug-related problems indentified.

Four drug allergies were observed, 3 of which necessitated hospitalization in 2 patients. All reactions resolved upon discontinuation of the offending agent. Causative agents included cotrimoxazole, nevirapine, and dapsone.

DRUG INTERACTIONS

Thirty-two drug interactions were identified; 56% of these were drug–food interactions that required intervention and additional teaching/counseling. The drugs included didanosine (given without food),[7] lopinavir/ritonavir (with food),[8] and tenofovir (with food). At the time of prescribing, it was recommended to take tenofovir with food to enhance absorption; however, the product monograph now states that the drug can be taken regardless of meals.[9] Five interactions were found with efavirenz and either phenytoin or psychotropics. Potent inducers of the cytochrome P450 liver enzymes, including carbamazepine, phenytoin, and phenobarbital, have significant potential to reduce serum concentrations of CYP450 substrates (ie, protease inhibitors and nonnucleoside reverse transcriptase inhibitor classes of HAART).[10-12] Management includes using valproic acid[13] or, when appropriate, prescribing a recommended triple nucleoside regimen (ie, Trizivir) with phenytoin. Three interactions were noted with tenofovir and didanosine, a combination that requires a significant dosage reduction of didanosine.[9]

Lopinavir/ritonavir was suspected in 2 interactions. One patient experienced blackouts, dizziness, and excessive sedation while on concomitant clonazepam, zopiclone, and olanzapine, thus requiring up to a 50% dose reduction in some of the psychotropics.[14] Another patient who routinely injected pentazocine and methylphenidate experienced excess hot flushes, fever, insomnia, and hyperactivity while taking lopinavir/ritonavir. It is possible that ritonavir, a potent hepatic enzyme inhibitor, potentiated the effects of methylphenidate, a known hepatic substrate.[15]

The new protease inhibitor atazanavir is a CYP450 inhibitor that requires an acidic pH for absorption. One patient required a 50% dosage reduction in clarithromycin and discontinuation of omeprazole while taking atazanavir.[16]

Table 1. Adverse Effects and Management

Adverse Effect (n = 56; 37.6%)	Causative Agent (N)	Management (N)
Gastrointestinal (23)		
nausea, heartburn, abdominal pain (14)	HIV and MAC prophylactic agents	dimenhydrinate, metoclopramide, prochlorperazine, nabilone, omeprazole
diarrhea (5)	nelfinavir, azithromycin, lopinavir/ritonavir	loperamide, diphenoxylate
constipation (2)	iron supplements	Metamucil, sennosides
pancreatitis (1)	alcohol, didanosine	hospitalization, DC didanosine
black stool (1)	bismuth subsalicylate	DC
Nervous system (19)		
insomnia (4)	efavirenz (3), bupropion (1)	temazepam, split efavirenz dose
daytime sedation (4)	efavirenz (3), olanzapine (1)	change to nighttime dosing
severe dreams (2) with suicidal ideation (1)	efavirenz (3)	counseling, refer for assessment and support
headache (2)	zidovudine	acetaminophen
potential teratogenicity (1)	efavirenz	DC
dizziness (1)	gabapentin	DC
peripheral paresthesias (1)	lopinavir/ritonavir	counseling
extrapyramidal reaction (tremor) (1)	metoclopramide	DC
diaphoresis (1)	paroxetine	cyproheptadine
peripheral neuropathy (1)	didanosine	ongoing monitoring
Laboratory abnormalities (10)		
elevated AST and/or ALT >5 × ULN (5)	alcohol and/or HAART	DC HAART (2), monitor LFTs (3)
anemia (hemoglobin <80 g/L) (3)	zidovudine (2), iron/folate deficiency (1)	transfusion (2) and change to didanosine iron/folate supplements
thrombocytopenia platelets <50 × 10^9/L (1)	HIV disease, HAART, and/or cotrimoxazole	replace didanosine with zidovudine
elevated lipase >2 × ULN (1)	alcohol, didanosine	ongoing monitoring
Allergies (4)		
rash (4)	cotrimoxazole (2), nevirapine (1), dapsone (1)	hospitalization (3), DC (4), successful rechallenge with cotrimoxazole (1)

ALT = alanine aminotransferase; AST = aspartate aminotransferase; DC = discontinue; HAART = highly active antiretroviral therapy; LFTs = liver function tests; MAC = *Mycobacterium avium* complex; ULN = upper limit of normal.

DRUG INDICATED

A new drug was indicated in 24 cases. The pharmacist was directly involved in making recommendations for drug therapy in these cases. Six patients failed their existing HAART regimen and required selection of a new regimen based on genotype resistance testing. Medications were indicated for the treatment or prophylaxis of several HIV-related infections, including *Pneumocystis carinii* pneumonia (PCP) prophylaxis (CD4+ lymphocyte count <0.20 × 10^9/L), oral candidiasis, herpes zoster, and tuberculosis prophylaxis. One woman required folate, prenatal vitamins, laxatives, and antihistamines during pregnancy.

ADHERENCE ISSUES

There were 20 adherence-related DRPs. Three involved discontinuation of HAART until the patients were in a better position to commit to therapy. Twelve patients required either a change in the medication administration time, simplification of their regimens (ie, from twice daily to once daily), or beepers to enhance adherence. Three patients required a

change in drug formulation (eg, liquid, smaller pills) or a decrease in pill burden. Two patients required DOT delivery while in the emergency department or in the hospital, as lapses in drug delivery often occur in these settings.

DRUG NOT INDICATED

Drugs were no longer indicated and were therefore discontinued in 10 patients for several reasons. Prophylaxis for HIV-related infections was initiated due to increased CD4+ cell count (PCP, *Mycobacterium avium* complex, candida; n = 6). Treatment of primary HIV infection treatment was likely adequate (ie, minimum 6 mo) in 2 patients who were becoming nonadherent. In further discussion with the treating physician, it was recommended to discontinue therapy to prevent drug resistance and preserve future drug options. Anticonvulsant therapy was discontinued in a patient who experienced head trauma several years ago, and antidepressants were stopped in another patient who no longer felt she required them. In discussion with the treating physician, it was deemed appropriate to discontinue these drugs with close monitoring.

Table 2. Other Drug-Related Problems

Drug-Related Problem	Description (number of problems)
Drug interaction (n = 32; 21.5%)	drug–food (didanosine, lopinavir/ritonavir, tenofovir) (18) didanosine–tenofovir (3) efavirenz–phenytoin (3) efavirenz–psychotropics (2) herbals–HIV/hepatitis C coinfection (2) atazanavir–clarithromycin (1) atazanavir–omeprazole (1) lopinavir/ritonavir–olanzapine, zopiclone, clonazepam (1) lopinavir/ritonavir–pentazocine/methylphenidate (1)
Drug indicated (n = 24; 16.1%)	failing HAART due to resistance (6) PCP prophylaxis (4) ancillary therapy in pregnancy (4) oral candidiasis (3) herpes zoster (2) anal infection (1); pruritus ani (1) nutritional supplements (2) tuberculosis prophylaxis (1)
Adherence issues (n = 20; 13.4%)	change timing (6) missing second unobserved dose frequently (6) discontinue therapy due to nonadherence (3) formulation change (2) home or hospital drug delivery and follow-up (2) decrease pill burden (1)
Drug no longer indicated (n = 10; 6.7%)	PCP prophylaxis (3) MAC prophylaxis (2) HAART in primary infection (2) fluconazole for candidiasis (1) paroxetine for depression (1) anticonvulsant (1)
Dosage adjustment (n = 7; 4.7%)	didanosine (1), lamivudine (1) in renal failure cotrimoxazole (2) didanosine for weight <60 kg (1) fluconazole dosage increase in nonresponsive candida (1) valproic acid dosage increase (1)

HAART = highly active antiretroviral therapy; MAC = *Mycobacterium avium* complex; PCP = *Pneumocystis carinii* pneumonia.

DOSAGE ADJUSTMENT

Dosage adjustments were required in 7 patients for 3 main indications: renal failure, patient weight, or subtherapeutic concentrations.

Discussion

Over a 14-month period, 149 DRPs were prospectively identified by an HIV pharmacist in 57 patients (mean 2.6 DRPs/pt.). The pharmacist was able to make appropriate recommendations for management of all DRPs, and resolution of DRPs occurred in the majority of cases (>95%). These figures underestimate the true number of DRPs in this population since only those identified and/or managed directly by the pharmacist (who attended the DOT program once weekly) are included in the analysis.

In the past 15 years, the role of the pharmacist in HIV care has evolved considerably. Numerous reports have described the provision of pharmacy services to HIV patients in the ambulatory and hospital settings.[17-21] While some of these programs have focused mainly on adherence interventions,[21] others have described the provision of pharmaceutical services[17-19] and the pharmacist's role in the continuity of care in this population.[20] Another article described hospital admissions with adverse drug reactions (21.4%) and interactions (2.1%) in HIV patients in the post-HAART era. The authors recommended that, through enhanced awareness of the types of serious adverse reactions and interactions observed, clinicians may be able to improve monitoring and manage these reactions in an ambulatory setting.[22]

The Canadian Collaborative HIV/AIDS Pharmacy Network has published a comprehensive consensus paper on the multifaceted role that the pharmacist now has in HIV care.[23] There is major emphasis in dealing with adherence issues, patient counseling, and managing drug interactions and adverse effects. All of these factors are closely interrelated and can ultimately result in better patient outcomes if dealt with accordingly. In support of this, Haddad et al.[24] completed a Cochrane review and found that pharmacist-led intervention (educational and supportive counseling, follow-up) was the only available intervention in a controlled study that was shown to increase adherence to HAART and subsequently improve virologic outcomes. A recent review on reasons for HAART discontinuation found that drug toxicity and intolerance ranked first and were responsible for 20–78% of all discontinuations.[25] In general, these toxicities occurred within the first 3 months of therapy. As such, efforts should focus on intensive support, counseling, and management of adverse reactions in the first few months of therapy.

This is the first article to describe the contributions of the pharmacist in a DOT for HAART setting. Continuous and frequent follow-up enabled the pharmacist to establish ongoing trusting relationships with many individuals. This

resulted in enhanced awareness of the special needs and social situations of these inner-city patients, which subsequently impacted on the selection of therapy and the identification of DRPs. The model of continuity of care that has been adopted has made this position unique and highly successful. In addition to the community outreach component via the DOT program, the pharmacist served as a full team member in a tertiary care HIV clinic, provided consultation on hospital inpatients, and developed liaisons with other tertiary HIV clinics, general practitioners, and community pharmacies that dispense antiretrovirals. With enhanced access to the patient and other healthcare workers in multiple healthcare settings, DRPs were identified and managed more readily and efficiently.

Summary

An HIV pharmacist provided pharmaceutical care and continuity of care for HIV-infected patients through contributions in tertiary care clinics and during inpatient hospital admissions. Given that the DOT for HAART project is currently in the final year, it is unknown whether ongoing funding will be granted to formalize and continue the program. We hope that future pharmacy funding will be justified through demonstrating the significant and positive impact that the pharmacist has had in the program to date.

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EXTRACTO

INTRODUCCIÓN: Los pacientes infectados por el virus de la inmunodeficiencia humana (VIH) que habitan las ciudades pueden resultar un grupo diana a tratar. Las condiciones de las personas sin techo, las enfermedades mentales, la utilización de sustancias de abuso, y la presencia de hepatitis C pueden resultar una barrera para un tratamiento efectivo. Un equipo multidisciplinario, que incluya un farmacéutico, puede impactar sobre la atención sanitaria ofrecida a esta población infectada por VIH.

OBJETIVO: (1) Describir la implementación y provisión de la atención farmacéutica a los pacientes de la ciudad incluídos en tratamiento directamente observado (TDO); (2) describir los problemas relacionados con el tratamiento (PRT) y sus resultados.

MÉTODOS: La atención farmacéutica, incluyendo la identificación prospectiva y la gestión de los problemas relacionados con la medicación, fue suministrada por un farmacéutico clínico.

RESULTADOS: Se realizó el seguimiento de 57 pacientes durante más de 14 meses. La identificación y gestión de los PRT incluían (1) efectos adversos (n = 56): gastrointestinales, sobre el sistema nervioso central, alergias, y desviaciones en los resultados de laboratorio; (2)

interacciones de medicamentos (n = 32); (3) medicamentos indicados para comorbilidad asociada (n = 24): seguridad en el embarazo, tuberculosis, y profilaxis de neumonía por *Pneumocystis carinii*, candidiasis oral, herpes zoster, y suplementos nutricionales; (4) acontecimientos relacionados con la adherencia al tratamiento (n = 20): modificar la pauta de administración de la medicación, cambios en la formulación, y disminuir la carga de la medicación; (5) medicamentos no indicados (n = 10): profilaxis de infecciones oportunistas, tratamiento de infecciones primarias; y (6) ajuste de dosis (n = 7) en función del peso y por insuficiencia renal.

CONCLUSIONES: En la provisión de la atención farmacéutica a los pacientes infectados por VIH en TDO, un farmacéutico encargado de dichos pacientes contribuye significativamente a la selección del antiretroviral, monitorización de la medicación, y manejo de los PRT. Globalmente, se identificaron 149 PRT y se resolvieron más del 95% de los casos. Un farmacéutico encargado de los pacientes infectados por VIH puede contribuir a la promoción de la adherencia a los tratamientos y mejorar los resultados en este terreno.

Corinne Zara

RÉSUMÉ

OBJECTIF: Décrire l'implantation et la distribution de soins pharmaceutiques à des citadins intégrés dans un programme de suivi étroit de la thérapie chez des personnes recevant un traitement antirétroviral hautement actif (HAART). Certains citadins infectés par le VIH forment un groupe de patients difficiles à traiter. Les sans-abri, les personnes présentant un problème de santé mentale, les narcomanes et les personnes infectées par le virus de l'hépatite C présentent des défis additionnels quant à l'obtention d'un traitement optimal efficace. Une équipe multidisciplinaire, incluant un pharmacien, peut avoir un impact positif sur la distribution des soins à cette clientèle particulière. Décrire les problèmes liés à la médication et leur impact respectif.

MÉTHODOLOGIE: Des soins pharmaceutiques, incluant le monitoring et le suivi des problèmes liés à la médication, ont été donné par un pharmacien.

RÉSULTATS: Cinquante-sept patients ont été suivi pendant 14 mois. Voici la liste des problèmes liés à la médication qui ont été identifiés: Effets indésirables du tractus gastro-intestinal, du système nerveux central, des allergies, et des tests de laboratoire anormaux (n = 56); interactions médicamenteuses (n = 32); sélection de médicaments à cause de conditions médicales co-existantes: innocuité lors de grossesse, prévention de la tuberculose et de la pneumonie à *Pneumocystis carinii*, traitement de la candidose orale, de l'infection par *l'Herpès zoster,* et prévention de la cachexie par les suppléments nutritionnels; problèmes d'observance à la thérapie médicamenteuse (n = 20): modification du moment de la prise des médicaments, changements de formulation, diminution du nombre de comprimés à prendre; arrêt des médicaments non indiqués (n = 10): prophylaxie d'infections opportunistes qui n'est plus requise, traitement de l'infection primaire; ajustement de la posologie (n = 7) selon le poids ou la présence d'insuffisance rénale.

CONCLUSIONS: Dans la distribution de soins pharmaceutiques aux personnes infectées par le VIH bénéficiant d'un suivi étroit de la thérapie, le pharmacien peut contribuer de façon significative à la sélection des antirétroviraux, au monitoring de la thérapie médicamenteuse, et à la résolution des problèmes liés aux médicaments. En tout, cent 49 problèmes liés à la thérapie ont été identifiés et plus de 95% d'entre eux ont été résolus. Un pharmacien spécialisé dans le traitement des personnes infectées par le VIH peut aider à augmenter l'observance au traitement médicamenteux et améliorer les résultats chez ce type de clientèle.

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