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ORIGINAL RESEARCH

# Role of a clinical pharmacist as part of a multidisciplinary care team in the treatment of HCV in patients living with HIV/HCV coinfection

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**Background:** The objective of the study was to evaluate the role of a clinical pharmacist in hepatitis C virus (HCV) treatment of patients living with HIV/HCV coinfection.

**Methods:** We conducted a descriptive study to quantify the functions of a clinical pharmacist in HCV treatment of patients living with HIV/HCV coinfection who were initiating HCV treatment at a publicly funded clinic between March 18, 2015 and September 15, 2016. The clinical pharmacist's role was categorized into eight categories: 1) HCV prior authorization (PA) completion; 2) HCV medication adherence counseling; 3) HCV drug-drug interaction (DDI) counseling and screening; 4) HCV medication counseling regarding common adverse events (AEs); 5) HCV counseling regarding HCV treatment outcomes and risk of reinfection; 6) ordering laboratory tests and interpretation of HCV laboratory values; 7) HIV medication AE assessment; and 8) other (including refilling medications and management of other comorbidities).

**Results:** One hundred and thirty-five patients initiated treatment during this timeframe: 77.0% were males, 56.3% non-cirrhotic, 77.0% HCV treatment-naïve, 45.9% HCV genotype 1a, and 83.0% initiated on ledipasvir/sofosbuvir. The clinical pharmacist completed 150 PAs, counseled on HCV medication adherence in 79.2% of patients, conducted HCV DDI counseling and screening in 54.2%, and monitored HCV medication AEs in 54.2%. The clinical pharmacist counseled patients on HCV treatment outcomes and risk of reinfection in 53.1%, ordered laboratory tests in 44.8%, and reported and interpreted laboratory values in 44.8%. The clinical pharmacist assessed HIV medication AEs in 54.2% of patients and participated in other activities in 42.7%.

**Conclusion:** A clinical pharmacist's expertise as part of a multidisciplinary care team facilitates optimal treatment outcomes and provides critical support in the management of DAA therapy in individuals living with HIV/HCV coinfection.

**Keywords:** HIV/HCV, clinical pharmacist, multidisciplinary care team, direct acting-antivirals, coinfection

## Introduction

The Centers for Disease Control and Prevention approximates that 2.7–3.9 million people in the United States (US) are living with chronic hepatitis C virus (HCV). It is estimated that about one-quarter of people living with human immunodeficiency virus ([HIV] PLWH) in the US are also living with HCV.[1] Several studies show that PLWH who are living with HCV are at an increased risk for accelerated progression of hepatic fibrosis and decompensated liver disease.[2–6] Thus, it is a priority to treat PLWH and HCV with direct-acting antiviral (DAA) therapy. The American Association for the Study of Liver Diseases/ Infectious Disease Society of America (AASLD/

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IDSA)[5] and the Department of Health and Human Services (DHHS) guidelines on the use of antiretroviral agents in HIV-1-infected adults and adolescents[6] provide references and recommendations on initiating antiretroviral therapy (ART) for those living with HIV and HCV. There are many considerations when DAAs are initiated in individuals living with HIV/HCV coinfection that require expertise in pharmacology and medication management, including identification of drug-drug interactions (DDIs) and monitoring for adverse events (AEs). In addition, counseling on medication adherence and education on the prevention of HCV reinfection are key components of HCV treatment.[5,6]

Clinical pharmacists have played a critical role in the clinical management of individuals living with HIV and/or HCV.[7–24] Some of the roles of clinical pharmacists have included reviewing patients' medical records to identify appropriate ART and DAA medication regimens, acquisition of medications through prior authorizations (PAs), identifying potential DDIs, and monitoring laboratory tests to avoid AEs. Additional tasks have included simplifying medication regimens to reduce pill burden, medication adherence counseling, monitoring for AEs, and counseling and educating patients about HIV and/or HCV treatment.[7–24]

HCV therapies are costly and often require lengthy and time-consuming PAs from the patient's medical coverage, and a clinician is needed to provide close monitoring and follow-up to each patient.[5,6] However, there is a shortage of primary care providers for the management of chronic conditions, and to address this, institutions have implemented multidisciplinary care teams, often including clinical pharmacists.[7–25] It has been proposed that clinical pharmacists are capable of managing and intervening in HCV treatment in mono-infected patients given their intimate knowledge of medications, expertise in identifying DDIs, and ability to manage medication AEs.[10–24] Patients have supported the inclusion of a clinical pharmacist in healthcare teams for distinct disease states and have reported high levels of satisfaction with clinical pharmacists when they were involved with HCV treatment.[14] In a satisfaction survey, patients reported 100% satisfaction with the clinical services provided by the pharmacist, including time spent during visits, medication adherence counseling, and education on HCV disease state, medication storage, and administration.[14]

Few studies have evaluated the roles of clinical pharmacists treating HCV in individuals living with HIV/HCV coinfection. The objective of this study was to describe and quantify the details of a clinical pharmacist's role as part of a multidisciplinary care team in treating HCV in patients living with HIV/HCV coinfection.

## Methods

This was a descriptive study of PLWH who were ≥18 years old, with chronic HCV infection, who initiated HCV treatment at a publicly funded safety-net clinic in San Francisco, CA, USA, between March 18, 2015 and September 15, 2016. The study start date was selected based on the hire date of the clinical pharmacist and the end date was chosen based on the initiation of data analysis for this study.

The clinical pharmacist had a doctorate of pharmacy with 14 years of experience in an HIV specialty outpatient pharmacy, and was certified as a Board Certified Pharmacotherapy Specialist and an American Academy of HIV Pharmacist. The role of the clinical pharmacist was categorized into eight main categories: 1) HCV PA completion; 2) HCV medication adherence counseling; 3) HCV DDI counseling and screening; 4) HCV medication counseling regarding common AEs; 5) HCV counseling regarding HCV treatment outcomes and risk of reinfection; 6) ordering laboratory tests and interpretation of HCV laboratory values; 7) HIV medication AE assessment; and 8) other (including refilling medications and management of other comorbidities). The goal of the study was to quantify the number of times these functions were completed by the clinical pharmacist. Other outcomes included sustained viral response at 12 weeks (SVR12) among patients completing HCV treatment during the study who had and did not have interactions with the clinical pharmacist, and the AEs that were managed by the clinical pharmacist.

In the study clinic, patients were evaluated by a full-time multidisciplinary care team consisting of a physician, a registered nurse, rotating infectious diseases fellows, and a clinical pharmacist. The multidisciplinary care team decided on HCV therapy based on current AASLD/IDSA guidelines, concomitant medications and comorbidities, and medical insurance formularies. Furthermore, the multidisciplinary care team met weekly to discuss patient updates and recommendations. In addition to the clinical pharmacist's scope of practice in California, a collaborative drug therapy agreement allowed the clinical pharmacist to prescribe medications to counteract AEs, refill ART and other chronic medications, and order laboratory tests.

The clinical pharmacist first performed a comprehensive medical record review of each patient prior to meeting with the multidisciplinary care team to discuss the treatment course and potential concerns. Once the multidisciplinary

care team agreed that DAA therapy was appropriate, the clinical pharmacist completed a PA and requested delivery of HCV medications to the clinic. Then, the clinical pharmacist scheduled an appointment with the patient to start therapy and provide information about the course of therapy. During this initial appointment with the patient, the clinical pharmacist discussed the need for medication adherence, what to do in the case of a missed dose, medication storage, management of potential AE, possible DDIs with prescription and over-the-counter medications (OTCs), necessary laboratory monitoring, plans for obtaining refills, likelihood of HCV cure, and counseling to reduce risk of HCV reinfection.

After treatment initiation, a follow-up telephone call or office visit was scheduled to assess medication adherence, AE, and patient concerns. Patients were seen every 2–4 weeks to pick up HCV medications. During these office visits, the clinical pharmacist provided ongoing verbal counseling on medication adherence, DDIs, DAA AE, risk of HCV reinfection, interpretation of HCV laboratory tests, management of other comorbidities as needed, and barriers to care. Patient-pharmacist interactions were formally documented in the patient's electronic medical records.

For this study, we collected data including patient demographics (age, sex, and race), history of substance use, underlying liver disease (ie, cirrhosis), liver serological markers (aspartate amino transferase, amino alanine transferase, total bilirubin, platelets, hemoglobin), HCV genotype, plasma HCV ribonucleic acid (RNA), comorbid conditions (eg, hypertension, diabetes, hyperlipidemia, and other chronic conditions), agents used for ART therapy, CD4+ cell count, plasma HIV RNA, and AEs reported during HCV treatment encounters with the clinical pharmacist.

We reviewed electronic medical records to evaluate pharmacist's roles as well as clinical and laboratory data. All data were collected by one author (AO), checked for quality assurance by another author (JG), and analysis was conducted by two authors (AO and PS). We collected all data in a password-protected Microsoft Excel spreadsheet that was kept on the university server and de-identified for analysis.

The clinic had approval from the University of California, San Francisco Institutional Review Board for retrospective studies and chart reviews with waiver of informed consent.

Univariate analyses (counts, means, and standard deviations) were performed using Microsoft Excel 2011.

# Results

## Baseline characteristics and treatment outcomes

Of the 135 patients who initiated HCV treatment with DAAs during the course of this study, 96 (71.1%) had in-person interactions with the clinical pharmacist. The population consisted of 77.0% male, 45.9% genotype 1a, 56.3% non-cirrhotic, and 77.0% HCV treatment-naïve patients (Table 1). Most patients were started on the combination drug of ledipasvir/sofosbuvir (83.0%) for 12 weeks (84.4%). Among the 59 patients who had SVR12 results available at end of study period, 94.9% achieved SVR.

One hundred and thirty-four PLWH were on ART (99.3%) prior to starting DAA therapy. The most common ART was the fixed-dose combination of abacavir/lamivudine/dolutegravir (20.1%). ART regimens were changed by the physician and clinical pharmacist in 31 patients (23.0%) to avoid drug interactions with DAAs. ART changes mainly occurred to avoid the use of boosted protease inhibitor and tenofovir disoproxil fumarate with ledipasvir/sofosbuvir. due to concern for potentially elevated plasma tenofovir concentrations.[5,6]

## Pharmacist role and interactions

The clinical pharmacist completed a total of 150 PAs, encompassing 124 of the total 135 patients. The PAs for the remaining 11 patients were completed by other members of the HCV multidisciplinary care team. Of the 96 patients with whom the clinical pharmacist interacted with in person, there was a mean of 3.5 face-to-face encounters per patient and 0.7 telephone-encounters per patient.

Virologic data for SVR12 at study endpoint was available in 59 patients who completed HCV treatment during the study timeframe. Forty-five of these individuals had a clinical pharmacist interaction and 14 did not (Table 2). Out of the patients who had clinical pharmacist interactions and in whom virologic data were available (n=45), 95.6% achieved SVR12. Two patients had HCV recurrence after completing treatment. One patient was pegylated interferon/ribavirin treatment-experienced and did not achieve SVR12. This patient was found to have baseline NS5a-resistant virus and was later successfully treated in a clinical trial using triple DAA therapy. The second patient had a relapse with intravenous drug use, sharing of needles, and condomless sex that led to the high clinical suspicion of HCV reinfection.

The clinical pharmacist verbally counseled 79.2% of patients on HCV medication adherence (Table 3) and partici-

**Table 1** Baseline characteristics

| Characteristics | n=135 |
|---|---|
| Age (years), mean (SD) | 53.8 (8.3) |
| Sex at birth, n (%) | |
| Male | 104 (77.0) |
| Female | 31 (23.0) |
| Race, n (%) | |
| White | 58 (43.0) |
| African American | 54 (40.0) |
| American Indian or Alaskan | 2 (1.5) |
| Asian | 5 (3.7) |
| Other | 16 (11.9) |
| History of substance use, n (%) | 81 (60.0) |
| HCV genotype, n (%) | |
| 1a | 62 (45.9) |
| 1b | 18 (13.3) |
| 1a/b | 40 (29.6) |
| Other | 15 (11.1) |
| HCV treatment status, n (%) | |
| Naïve, n (%) | 104 (77.0) |
| Experienced, n (%) | 16 (11.9) |
| Unknown, n (%) | 15 (11.1) |
| Cirrhosis status, n (%) | |
| Non-cirrhotic | 76 (56.3) |
| Cirrhotic | 42 (31.1) |
| Unknown | 17 (12.6) |
| Baseline HCV RNA ($log_{10}$IU/mL), mean (range, SD) | 6.46 (1.7–7.7, 6.7) |
| ALT (u/L), mean (SD) | 59.9 (57.2) |
| Platelet count (x$10^3$/uL), mean (SD) | 215.4 (81.5) |
| Hemoglobin (g/dL), mean (SD) | 13.9 (1.5) |
| Total bilirubin (mg/dL), mean (SD) | 0.7 (0.60) |
| CD4+ cell count (cells/$mm^3$), mean (SD) | 600 (322.7) |
| Undetectable plasma HIV RNA, n (%) | 119 (88.1) |
| On HIV antiretroviral therapy, n (%) | 134 (99.3) |
| ART regimens, n (%) | |
| Integrase inhibitor-based ART regimen | 81 (60.0) |
| Protease inhibitor-based ART regimen | 18 (13.3) |
| Non-nucleoside reverse transcriptase inhibitors-based ART regimen | 20 (14.8) |
| Other | 15 (11.1) |
| ART regimen modified to accommodate DAA, n (%) | 31 (23.0) |
| Direct-acting antivirals, n (%) | |
| Ledipasvir/sofosbuvir | 112 (83.0) |
| Other | 23 (17.0) |
| Duration of treatment, n (%) | |
| <12 weeks | 1 (0.7) |
| 12 weeks | 114 (84.4) |
| >12 weeks | 20 (14.8) |

**Abbreviations:** HCV, hepatitis C virus; RNA, ribonucleic acid; ALT, alanine transferase; HIV, human immunodeficiency virus; ART, antiretroviral therapy; DAA, direct-acting antiviral.

pated in the management of other non-HCV comorbidities (42.7%) (ie, hypertension, diabetes, hyperlipidemia, and other chronic conditions) and refilling of non-HCV medications (33.3%).

The clinical pharmacist inquired and assessed for AEs attributed to DAA therapy. In total, 35 patients (36.5%) self-reported AEs to the clinical pharmacist. Common AEs included fatigue/low energy (15.6%), headaches (10.4%), nausea (10.4%), loose stools (7.3%), vomiting (2.1%), insomnia (1.0%), and/or other (6.3%). Under a collaborative drug therapy agreement with the clinic, the clinical pharmacist prescribed medications to ease AEs in seven patients (20.0%). The most commonly prescribed class of medications was antiemetic for nausea caused by DAA.

## Discussion

Our study quantified the clinical services of a clinical pharmacist for HCV treatment in patients living with HIV/HCV coinfection. When providing care to PLWH who are also living with HCV coinfection, there are several considerations that need to be taken into account. The detailed evaluation of the types and frequency of the interactions a clinical pharmacist has with patients is fundamental to understanding this role and impact on HCV treatment.

Data from our study show that patients living with HIV/HCV coinfection, who are managed by a clinical pharmacist as part of a multidisciplinary care team, achieved a high HCV cure rate during the study. This cure rate is similar to real-world settings and clinical trials focused on this population.[23,26–30] There was a low frequency of AEs and the clinical pharmacist interacted with patients in numerous ways as described in the following sections.

### Medication acquisition and PA completion

In general, the clinical pharmacist may be responsible for completing, submitting the PA, appealing denials, attaining extensions, and managing communication with the pharmacy and insurers.[19] This function reduces the administrative burden and workload on other providers and increases efficiency by creating a single point of contact for PAs while ensuring continuity of care.

### HCV medication adherence counseling

Adherence to DAAs is pivotal for the success of HCV treatment. Clinical pharmacists can positively impact HCV treatment by counseling and reinforcing the importance of medication adherence to DAAs during regular follow-up visits, another key function that reduces burden on providers and offers an essential service. In addition to encouraging and monitoring medication adherence to DAAs, clinical pharmacists can provide patient-specific strategies to help with medication adherence, such as providing pillboxes,

**Table 2** HCV treatment outcomes

| | SVR12 available at study endpoint | Pharmacist interaction | No pharmacist interaction |
|---|---|---|---|
| Total | 59 | 45 | 14 |
| SVR12, n (%) | 56 (94.9) | 43 (95.6) | 13 (92.9) |
| HCV recurrence, n (%) | 2 (3.4) | 2 (4.4) | 0 |
| Stopped treatment, n (%) | 1 (1.7) | 0 | 1 (7.1) |

**Abbreviations:** HCV, hepatitis C virus; SVR12, sustained viral response at 12 weeks.

**Table 3** Pharmacist in-person interactions by categories (n=96)

| Categories | n=96 |
|---|---|
| 1- HCV prior authorization completion, n (%) | 86 (89.6)[a] |
| 2- HCV medication adherence counseling, n (%) | 76 (79.2) |
| 3- HCV drug-drug interactions counseling and screening, n (%) | 52 (54.2) |
| 4- HCV medication counseling regarding common adverse events, n (%) | 52 (54.2) |
| 5- HCV counseling regarding HCV treatment outcomes and risk of reinfection, n (%) | 51(53.1) |
| 6- Ordering laboratory tests and interpretation of HCV laboratory values, n (%) | 43 (44.8) |
| 7- HIV medication adverse event assessment, n (%) | 52 (54.2) |
| 8- Other | |
| Management of non-HCV comorbidities, n (%) | 41 (42.7) |
| Refilling non-HCV medications, n (%) | 32 (33.3) |

**Note:** [a]In total, 150 PAs were completed for 124 patients; however, the clinical pharmacist had direct contact with 96 patients.
**Abbreviations:** HCV, hepatitis C virus; HIV, human immunodeficiency virus; PAs, prior authorizations.

engaging supportive family members, and encouraging use of medication reminders.[19]

## HCV DDI counseling and screening

Many DDIs need to be considered with DAAs, including ART and commonly used OTCs like proton pump inhibitors. Prior to starting DAA therapy in PLWH, the clinical pharmacist should conduct a thorough evaluation for DDIs and assess for new medications at each visit. The DHHS and AASLD/IDSA guidelines and medication search engines provide a list of common DDIs.[5,6] At each encounter, the clinical pharmacist should counsel the patient on common DDIs and instruct them on consulting a healthcare provider before starting any new medication and/or OTCs.

## HCV and HIV medication counseling regarding common AEs

Concurrent treatment with ART and DAA therapy may be complicated by AEs, which can jeopardize adherence and treatment success. It is important for the clinical pharmacist to assess for any AE that may exacerbate or impede medication adherence.[16] During the initial visit, the clinical pharmacist should inform the patient of potential AEs associated with DAA. During follow-up visits, the clinical pharmacist should assess for any AEs and assist in addressing these. Patients should be encouraged to contact the clinical pharmacist to report any AEs during treatment.

## HCV counseling regarding HCV treatment outcomes and risk of reinfection

The clinical pharmacist should counsel the patient on the high probability of achieving sustained HCV virologic response and the importance of adherence in attaining SVR12. Patients should be informed that neither curative therapy nor persistent HCV antibody positivity prevents reinfection. A meta-analysis has found patients living with HIV/HCV coinfection to be at a high risk for reinfection, thus highlighting the need for education regarding reinfection.[31] Ongoing assessment for reinfection is recommended for patients at risk for reinfection (eg, those with injection drug use who shared needles/equipment and men who have sex with men) as well as counseling on how to reduce these risks.[5]

## Ordering laboratory tests and interpretation of HCV laboratory values

In many practice settings, clinical pharmacists can order laboratory tests and play an important role in reviewing baseline laboratory values prior to starting DAA therapy.[19]

Typically, these include assessment of hepatic and renal function as well as confirmation of HCV viremia, evaluation of HCV genotype, and HCV resistance testing. The AASLD/IDSA guidelines offer recommendations for monitoring HCV RNA levels, medication adherence, renal function, and other clinical parameters.[5] The clinical pharmacist plays an important role in laboratory monitoring during and after therapy by ordering and tracking laboratory tests and flagging abnormal values for review. These functions can result in reduced healthcare provider workload.

## Other

The clinical pharmacist is a healthcare provider who can address questions about other disease states and/or medications and can provide referrals to a primary care provider as needed. On follow-up visits, the clinical pharmacist can optimize therapy for other medical conditions, assess medication adherence and AEs, reduce pill burden, and refill non-DAA medications.

This study was limited by its retrospective design. We were restricted to data provided by electronic medical records to assess the clinical pharmacist's interactions and were unable to ascertain an accurate medication list including OTC medications. We examined a relatively short timeframe that may not reveal the complete involvement of the clinical pharmacist with patients pre-HCV or post-HCV treatment. Finally, this study had a small sample size and, due to the location and resources of the clinic, findings may not be generalizable.

# Conclusion

New DAA treatments have transformed the HCV treatment landscape by significantly increasing HCV cure rates in 12 weeks or fewer and using oral medications which are generally well-tolerated and have low pill burden. However, HCV programs need team members who are knowledgeable in medication selection, procurement medication adherence, laboratory monitoring, and follow-up. In an ambulatory care setting, a clinical pharmacist can provide these services for individuals living with HIV/HCV coinfection and thereby alleviate the providers' workload in the HCV team. It is estimated that workforce growth by 2019 will not accommodate the projected increases in the number of PLWH and individuals living with HIV/HCV coinfection; therefore, the roles of clinical pharmacists are particularly relevant to reduce the overall workload of other healthcare professionals.[32]

There are many considerations when treating patients living with HIV/HCV coinfection and results from this study suggest that clinical pharmacists' expertise plays a defined and critical role. Patients living with HIV/HCV coinfection whose treatment is managed by clinical pharmacists within the context of a multidisciplinary care team obtain favorable treatment outcomes that are comparable to clinical trials. Given this capacity, clinical pharmacists should receive ongoing clinical training and support to conduct and expand these roles in the treatment of HCV and be incorporated into multidisciplinary healthcare teams. Future studies should evaluate the cost-effectiveness of the role of clinical pharmacists in the medical care of patients living with HIV/HCV coinfection as well patient and multidisciplinary care team satisfaction.


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