

A psychiatric pharmacist in a liver clinic managing treated patients with chronic hepatitis C viral infection

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ABSTRACT

A board-certified psychiatric pharmacist is an ideal clinician to manage medication needs for patients being treated for chronic hepatitis C virus infection. Underlying psychiatric symptoms should be managed before initiating medications such as interferons- therapeutic biologicals associated with causing psychiatric adverse events, including suicide. The role of a psychiatric pharmacist in a hepatitis C liver clinic highlights the value of a psychiatric pharmacist providing direct patient care and improving the quality of healthcare services in a subspecialty practice model.

KEYWORDS

pharmacist, hepatitis c, ambulatory care

INTRODUCTION

Chronic hepatitis C (CHC) viral infection affects an estimated 5.2 million people or 1.3% of the United States population.^{1,2} Among comorbidities commonly existing with chronic hepatitis C virus (HCV) infection include depressive disorder, with a prevalence of 14%.³ Underlying psychiatric conditions may lead to ineligibility for antiviral treatment.⁴ Moreover, the standard treatments for all HCV genotypes include weekly subcutaneous injections of pegylated interferon (IFN)-alpha and twice-daily oral ribavirin (RBV), of which IFN is associated with causing depression and other psychiatric adverse drug reactions (ADRs) with an incidence of 33%.⁵ Other neuropsychiatric ADRs include anxiety, significant sleep disturbances, irritability, psychosis, and suicidality, all which may warrant immediate intervention.

The key to curing HCV infection is achieving a sustained virological response (SVR), defined as undetectable serum HCV-RNA at 24 weeks after the end of treatment.⁶ CHC treatment often requires long-term management by an interprofessional treatment team in order to achieve this treatment goal. The team can include multiple hepatologists, nurses, pharmacists, psychologists, administrative assistants, and psychiatrists (when needed).⁷

A barrier to achieving improved rates of SVR is the presence of co-morbid psychiatric illness and uncontrolled related symptoms. Early detection and treatment of depressive and anxiety disorders improves antiviral adherence in hepatitis C virally infected individuals.⁸ An interprofessional team approach to

clinical intervention may consist only of psychologists and psychiatrists to help reduce the risk of antiviral-induced psychiatric side effects.⁹ Another approach of integrating psychiatric and medical care in order to improve antiviral therapy adherence utilizes a psychiatric clinical nurse specialist in a hepatitis clinic.¹⁰ There is also evidence that a psychiatric pharmacist improves adherence to antiviral medications by concomitantly managing psychiatric symptoms with psychotropic agents and monitoring symptom response while the patient continues antivirals to achieve SVR.¹¹

Select clinical pharmacists are qualified to manage HCV-infected patients. In fact, pharmacist-managed HCV specialty clinics in Veteran's Administration healthcare systems are part of an interprofessional treatment model for providing critical support to HCV-infected patients.^{12,13} Pharmacists are ideal for providing patient education on HCV and medication administration since they monitor and manage numerous ADRs associated with antiviral treatment, adjust medication doses, and encourage medication adherence.^{12,14} A psychiatric pharmacist can perform these roles in addition to completing baseline psychiatric evaluations and managing IFN-induced psychiatric symptoms.¹⁵ There are investigators who believe that continuous psychiatric follow-up of treated patients is not currently being done.⁹ On the contrary, this essential practice is occurring in some settings that utilize a psychiatric pharmacist subspecializing in HCV management.¹⁵

This paper will describe the role of a psychiatric pharmacist subspecializing in an HCV clinic, working as

part of an interprofessional treatment team to manage HCV-infected individuals treated with antivirals (i.e., IFN, RBV and the protease inhibitors- PIs) and other medications used to manage related psychiatric ADRs. A description of the practice site is provided as well as practical information to guide the initiation of similar practice sites for psychiatric pharmacists interested in managing HCV-infected individuals.

DESCRIPTION OF THE PRACTICE SITE

The clinical practice site is an outpatient specialty clinic in a Los Angeles County-University of Southern California Healthcare Network-based teaching facility. This government-funded medical center provides access to health services for the medically underserved population and is the largest single provider of health care in L.A. County. There are over 1 million ambulatory care visits each year.

The practitioners in the hepatitis clinic include 1 board-certified psychiatric pharmacist attending, 3-4 gastroenterology physician attendings, and 10-11 medical interns and fellows with post-graduate experience and training in hepatology and gastroenterology. Administrative staff includes 5 nurses who assist with scheduling patients and assisting the pharmacist in ordering labs as well as multi-lingual interpreting services (usually Spanish-to-English).

The specialty clinic operates one day per week for 4 hours. The pharmacist, however, is typically on site for 5-6 hours each week, managing 2-6 patients during each clinic service day. The collaborative agreement makes provisions for 2 of the 14 clinic rooms to be reserved each week for pharmacy services. This allows sufficient space for the pharmacist to supervise pharmacy interns who may be providing patient counseling services as part of an Advanced Pharmacy Practice Experience (APPE).

PSYCHIATRIC PHARMACIST ACTIVITIES

Prior to the presence of an on-site psychiatric pharmacist, all patients suspected of having an underlying and unmanaged psychiatric condition were given a written referral to see a psychiatrist at a separate psychiatry clinic facility prior to the initiation of HCV medications. This required a wait time of 1-3 months per chronic HCV-infected patient. Many were "lost to follow up" after being sent to the department of psychiatry, never to be seen again by the department of gastroenterology.¹¹ In several of these instances, the patient was never re-evaluated to start on antiviral treatment. The psychiatric pharmacist, providing service at the liver clinic since 2004, is currently able to see patients at the liver clinic on the

same day once the patient is identified as an HCV-treatment candidate. In doing so, the patient avoids the wait time related to referral to an outside department, whereby improving efficiency and continuity of healthcare delivery.

Referral to the Psychiatric Pharmacist

Physicians complete initial hepatitis-related evaluations of all virally-infected patients. If the patient is a candidate for anti-HCV treatment, the patient is referred to the pharmacist to receive initial medication counseling. Each week, the attending physicians inform all new teaching residents, interns and fellows that there is a psychiatric pharmacist on service and any patients who may require additional psychiatric evaluation and screening should be referred to this pharmacist. If the physician is uncertain of whether or not a psychiatric condition should preclude the patient from initiating antiviral medications, the patient is also referred to the pharmacist for further extensive evaluation.

There may be instances where the patient has a pre-existing psychiatric diagnosis and is already being managed by an outside provider. Such a patient is not referred to the on-site pharmacist for the purposes of a psychiatric evaluation; however, the patient is still referred for the objective of initiating IFN and RBV (as well as a PI such as boceprevir or telaprevir if the patient is HCV genotype 1). In the majority of cases (89%), the pharmacist will be utilized for carrying out psychiatric-related evaluations.¹⁵ There are instances, though, where the patient must be evaluated thoroughly by a psychiatrist before the pharmacist makes contact with the patient. MDs may initially detect a patient as acutely symptomatic for a psychotic or mood disorder. The incidence of this accounts for 3% of patients who are originally supposed to start HCV medications but do not until he or she is "cleared" by a psychiatrist's evaluation by written documentation that the patient's psychiatric condition is being routinely supervised.¹⁵ After the patient is documented as being psychiatrically stable, the patient will be referred to the pharmacist.

Description of Pharmacist Activities

The pharmacist makes several, specific interventions:

Initial psychiatric evaluation and screening

The pharmacist evaluates all patients at baseline before pegylated IFN-alpha is started. Each patient is asked to complete the following assessment scales: Personal Health Questionnaire (PHQ-9) for depression, Beck Depression Inventory (BDI), The Pittsburgh Sleep Quality Index (PSQI), Insomnia Sleep Questionnaire (ISQ), and

the Chronic Liver Disease Questionnaire HCV (CLDQ-HCV) to evaluate quality of life.

Based on the scores and evaluation of the patient results, interventions may include starting appropriate psychotropic agents prior to starting HCV treatment and/or referring the patient to a psychiatrist, if indicated. Extensive baseline past psychiatric and medication history is recorded by the pharmacist and then discussed with the physicians as needed. Anticipated family support is assessed and discussed with the prescribing physician.

Initial treatment counseling

The initial session by the pharmacist is a one-hour clinic encounter to complete an exhaustive IFN, RBV and PI counseling session and to establish a therapeutic alliance between the pharmacist and patient. Interventions include: identifying uncontrolled disease states that may prevent patients from starting HCV treatment; obtaining a complete medication use history; demonstrating how to administer a subcutaneous injection; describing appropriate needle disposal; filling out a treatment calendar for the patient that includes follow up laboratory visit appointments, return-to-clinic visits, stop and start dates of medications; counseling on the importance of medication adherence; describing the process of refilling medications in a timely manner; managing hematopoietic adverse drug reactions such as anemia, leukopenia, and thrombocytopenia; interpretation of baseline laboratory values and the expectation of blood count changes throughout therapy; managing dermatological ADRs; providing diet and nutrition counseling; counseling on the abstinence of alcohol; offering smoking cessation therapies; discussing psychiatric ADRs while offering reassurances that the psychiatric pharmacist will offer treatment options at the patient's follow up clinic visits if ever needed. In addition, the patient's motivating factors for adhering to antivirals are assessed, documented in the

patient record, and discussed with the treatment team.

Monitoring and managing antiviral-induced psychiatric ADRs

If an underlying psychiatric condition requires management with medications, psychotropic medications are prescribed accordingly. Currently, physicians are accepting 100% of the recommendations made by the psychiatric pharmacist regarding the use and management of psychotropic medications. Physicians sign all prescriptions for medications recommended by the pharmacist after discussing the patient case. The pharmacist will continue to follow-up with the patient after initiating a psychotropic medication and adjust doses accordingly. Patients being seen by an outside psychiatrist are asked for permission by the pharmacist to correspond directly about psychiatric care. At each return pharmacist visit, the patient is asked to complete the rating scales that were completed during the baseline visit. Simultaneously, the patient is able to sustain antiviral treatment with a greater chance of achieving SVR. Table 1 lists the medications commonly prescribed and managed by the psychiatric pharmacist.

Monitoring and managing of other adverse drug reactions

The pharmacist assesses patients at treatment intervals determined by the HCV treatment protocols and based on the patient's treatment progress. The patient is monitored for SVR status, complete blood cell count, adherence to medications and monitoring requirements, vaccination schedules, and other treatment-related ADRs. These visits to the pharmacist are used to manage any treatment-emergent ADRs. When indicated, the pharmacist assists with initiating weight-based hematopoietic agents and provides additional counseling on the use and monitoring of these products. Commonly used ADR management medications are listed in Table 1.

Table 1. Common medications used by HCV-infected individuals managed by a psychiatric pharmacist

Antivirals	Hematopoietic Agents	Antidepressants	Hypnotics	Other
Pegylated interferon-alfas	Aranesp® darbepoetin alfa	Amitriptyline	Diphenhydramine	Acetaminophen
Ribavirin	Epogen® epoetin alfa	Citalopram	Temazepam	Triamcinolone
Victrelis® Boceprevir	Neupogen® filgrastim	Escitalopram	Zolpidem	Hydrocortisone
Incivek® Telaprevir	Promacta® eltrombopag	Mirtazapine		Prednisone
Olysio™ Simeprevir	Nplate® romiplostim	Sertraline		Levothyroxine
Sovaldi™ Sofosbuvir		Trazodone		

Other activities at the liver clinic

In addition to patient care-related activities, clinical research is carried out by the pharmacist.^{16,17} The pharmacist also collaborates with hepatologists on research activities to propagate a collaborative work environment.¹⁸ The pharmacist also provides updated scientific literature to clinicians on psychiatry and HCV-related topics as well as drug information on various medications used to manage side effects associated with antiviral medications. There are many opportunities to review psychotropic medication classes with hepatologists during staffing. For example, a review of antidepressant medication classes beyond selective serotonin reuptake inhibitors is welcomed.

Pharmacist's Contribution to Continuity of Patient Care

The pharmacist is in constant contact with the HCV-infected patient started on antivirals, whether it is a 6- or 12-month treatment course. If patients develop psychiatric complications anytime during the course of treatment from IFN and RBV, the physician will refer the patient to the psychiatric pharmacist on site. The pharmacist manages mood disorders, anxiety disorders, sleep complaints, psychotic symptoms, and hypomania. The patient is seen at scheduled follow-up visits, but also returns to clinic more frequently if needed for management of psychiatric symptoms with medications. Patients also have access to the pharmacist's pager for immediate assistance. By staffing an "in-house" psychiatric pharmacist in the liver clinic, patients receive clinical evaluations for both antiviral management and psychiatric monitoring in a single visit.

ESTABLISHING A HEPATITIS C VIRUS TREATMENT PRACTICE SITE

Starting a clinical practice site in a specialty, ambulatory care unit means developing a "win-win" relationship with practicing clinicians who can find reasons to collaborate with pharmacists. Pharmacists are trained and qualified to provide medication management care in the primary care setting.¹⁹ Pharmacists should subspecialize in ambulatory disease states for which there is high comorbidity of psychiatric diagnoses where physicians may find it useful to have an on-site psychiatric pharmacist to help manage usual disease-related medications but also psychotropics. In the case of HCV, it happens that one of the primary medications used to manage HCV infection (i.e., IFN) causes psychiatric ADRs.

Practical Recommendations

i. Establish staff support- secretaries and nurses will assist the pharmacist with necessary laboratory order

processing and establishing return-to-clinic patient visits for the MD with or without the PharmD.

ii. Identify a contact person from pertinent pharmaceutical companies- each of these companies can provide patient education support products, medication demonstration guides, and patient medication dosing timers that will help with patient medication management:

1. Hoffmann-La Roche Inc./Genentech, Inc.: Pegasys®- pegylated interferon-alpha-2a
 2. Merck & Co., Inc.: PegIntron®- pegylated-interferon-alpha-2b and Victrelis®- boceprevir
 3. Vertex Pharmaceuticals: Incivek®- telaprevir
 4. Janssen Therapeutics: Olysio™-simeprevir
 5. Gilead Sciences, Inc: Sovaldi™- sofosbuvir
- Interferon manufacturers provide sharps containers used by patients to dispose IFN needles.

iii. Know the hematopoietic agents- you will be asked to help manage patients if they develop anemia (counsel on erythrocyte-stimulating agents, ESA), leukopenia (granulocyte colony-stimulating agents, G-CSF), and/or thrombocytopenia (thrombopoietic agents).

iv. Create patient tools in different languages- these include calendars that cover the duration of HCV treatment (i.e., 6-12 months), easy-to-follow dosing guides to improve heavy pill-burden-associated non-adherence, and educational materials about acetaminophen use as well as dietary modifications in HCV patients.

v. Be familiar with the HCV treatment guidelines in addition to knowing appropriate psychotropics to use, the psychiatric pharmacist in a liver clinic should keep up-to-date about managing hepatitis C with complete knowledge of related medications used to manage ADRs.^{6,20-23}

CONCLUSION

The process of developing a specialty practice site where a psychiatric pharmacist is an essential member of the interprofessional treatment team has changed and improved the way the liver clinic conducts its patient care. The placement of a pharmacist who assists with the management of HCV-infected patients and concomitantly tends to their psychiatric needs improves the continuity of care. The objective is not to replace a psychiatrist; rather, a trained clinician such as a board-certified psychiatric pharmacist can complete the functions of a clinical liver pharmacist as well as influence psychiatric care for the HCV-infected patient who

requires anti-viral treatment but also develops related psychiatric ADRs. Currently, pharmacist-initiated interventions have become an important component of antiviral adherence and improved HCV treatment and management.

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