INNOVATIONS in pharmacy

Volume 8 | Number 2 Article 12

5-18-2017

Integration of Ambulatory Clinical Pharmacy Services in a Gastroenterology Clinic for Management of Hepatitis C Infection: A Pilot Study

Erika Bower
Health East Care System, erika.ridl.1@gmail.com

Haley Holtan
Hennepin County Medical Center, haley.holtan@hcmed.org

George Konstantinides
Hennepin County Medical Center, george.konstantinides@hcmed.org

Shannon Reidt
University of Minnesota College of Pharmacy, reid0113@umn.edu

Recommended Citation
Bower E, Holtan H, Konstantinides G, Reidt S. Integration of Ambulatory Clinical Pharmacy Services in a Gastroenterology Clinic for Management of Hepatitis C Infection: A Pilot Study. *Inov Pharm.* 2017;8(2): Article 12. http://pubs.lib.umn.edu/innovations/vol8/iss2/12

INNOVATIONS in pharmacy is published by the University of Minnesota Libraries Publishing.

Integration of Ambulatory Clinical Pharmacy Services in a Gastroenterology Clinic for Management of Hepatitis C Infection: A Pilot Study

Erika L Bower, PharmD[1]; Haley E Holtan, PharmD, BCACP[1]; George Konstantinides, PharmD, BCPS[1]; Shannon L. Reidt, PharmD, MPH, BCPS[2]

[1]Institutional Affiliation at Time of Research: Hennepin County Medical Center, Minneapolis, MN

[2]Institutional Affiliation at Time of Research: Hennepin County Medical Center, Minneapolis, MN and the University of Minnesota College of Pharmacy

Abstract

***Purpose**: The purpose of this study is to describe implementation of comprehensive medication management (CMM) services in a gastroenterology (GI) clinic for HCV patients on direct acting antivirals (DAAs), and to evaluate services in terms of identification of medication related problems (MRPs), patient satisfaction, and provider satisfaction. **Methods**: Six months of visit data was retrospectively collected to determine demographic data and to analyze pharmacist's identification of MRPs. Patient satisfaction surveys were collected using a thirteen question validated pharmacist-satisfaction survey. After pilot completion, a twelve-question survey was sent to all GI clinic staff members to evaluate overall staff satisfaction with services. **Results**: Ninety-four CMM visits were completed. A total of 246 MRPs were identified with an average of 2.6 MRPs per visit. Seventy-eight MRPs were related to appropriate indication, 27 to efficacy, 30 to safety, and 109 to adherence. Forty MRPs were related to drug-drug interactions. Patient satisfaction surveys revealed that 86% of respondents rated the quality of care and services from the clinical pharmacist as "Excellent". Patients better understood and felt confident with therapy. All staff satisfaction survey respondents strongly agreed or agreed that the pharmacist made valuable contributions to the clinic and patient care. All also strongly agreed that pharmacy's CMM services were an essential component to the management of HCV. **Conclusion**: Data supports continued involvement of clinical pharmacists within the clinic to promote safety and efficacy of DAAs. Patient and staff satisfaction survey results further illustrate the importance and value that CMM provided by clinical pharmacists can provide.*

Key words: ambulatory care, pharmacy, hepatitis C, medication therapy management

Introduction

Chronic hepatitis C viral (HCV) infection affects approximately 2.7-3.9 million persons in the United States, and 130-150 million worldwide.[1,2] Chronic infection substantially increases the risk of liver cirrhosis and hepatocellular carcinoma, resulting in significant morbidity and mortality. Until recently, HCV treatment options were limited and relied heavily on marginally effective and poorly tolerated agents. Since 2011, the treatment of HCV has changed dramatically with the approval of new direct antiviral agents (DAAs). DAA regimens, which include agents such as simeprevir, sofosbuvir, daclatasvir, and ledipasvir, have much higher success rates and are better tolerated than previous pharmacotherapy regimens. Many have been shown to cure approximately 90% of people with chronic infection dependent on the degree of hepatic disease and HCV viral load.[2] Although these agents demonstrate many favorable properties, they still present clinical challenges, including many difficult to manage drug-drug interactions and a need for strict medication adherence.

Ambulatory clinical pharmacists are well suited to serve the HCV population by providing preventative care, comprehensive medication management (CMM), disease state evaluations, patient education, adherence support, adverse event management, dosing and treatment recommendations, and assessment of treatment efficacy.[3] Clinical pharmacists can also help reduce costs related to adverse events and drug interactions associated with therapy. Adherence support during treatment may offset costs associated with therapy failure and advancing liver disease.[3] Additionally, the Infectious Diseases Society of America (IDSA) HCV Guidelines recommend an assessment for potential drug-drug interactions and patient education prior to starting therapy, which further supports the inclusion of clinical pharmacy services.[4] Despite these benefits, few HCV clinics include clinical pharmacists in their workflow. Pharmacy services may be difficult to justify financially because there is little evidence demonstrating their impact on the management of HCV patients.

The purpose of this pilot study is to describe the implementation of CMM services in a gastroenterology (GI) clinic for HCV patients and to evaluate these services in terms of the identification of medication related problems, patient satisfaction, and provider satisfaction.

Corresponding Author: Erika L Bower, PharmD
Email: erika.ridl.1@gmail.com

Methods

Setting

Hennepin Healthcare System, Inc. is a large, urban, safety net health-system in Minneapolis, Minnesota, and includes Hennepin County Medical Center (HCMC) and primary care clinics across the metropolitan area. Pharmacists are well integrated within the health-system and have established CMM practices in primary and specialty care clinics throughout the institution. Clinical pharmacists provide CMM services as outlined by the Patient-Centered Medical Home Model[5] to ensure that all drug therapy is indicated, effective, safe, and convenient. Patients with HCV are managed by specialized advanced practice providers and physicians at the GI clinic. Providers in this clinic requested a clinical pharmacist to provide CMM to HCV patients because they had concerns that patients were having MRPs related to drug-drug interactions and adherence concerns.

Service Design and Implementation

Pharmacist services were incorporated into the workflow of the clinic (Figure 1) to provide services 8 hours per week. Providers used the EMR to place a referral for a CMM visit, and a scheduler contacted the patient to schedule the CMM visit. During the CMM visit, the pharmacist conducted a comprehensive medication review, reviewing each medication for indication, efficacy, safety, and assessing medication adherence. Social history was reviewed to assess readiness and ability to adhere to therapy and to identify any potential adherence barriers. Tools to aid with adherence, such as pillboxes, were often given to patients. The pharmacist screened the proposed HCV regimen for drug-drug interactions and ensured it was appropriate based on guideline recommendations and patient-specific factors. The pharmacist educated the patient on the proposed HCV therapy focusing on pertinent side effects, dosing, what to do if a dose is missed, and what to do in the event of a hospitalization. Follow up visits were provided to patients who had adherence issues or patients whose DAA regimen changed. The pharmacist documented the CMM visit in the EMR, and included a classification of MRPs identified related to indication, efficacy, safety, and/or adherence.[6] The pharmacist electronically sent the note and recommendations to the referring provider. Recommendations were also discussed with providers in person and during monthly care coordination meetings. Pharmacists billed for services utilizing medication therapy management CPT codes including: 99605 (new patient), 99606 (established patient), and 99607 (additional units of time). The level of service was determined utilizing the Minnesota Department of Human Services billing algorithm.[7]

Clinical pharmacy services in this pilot study were evaluated three ways. Clinical activity was evaluated by a retrospective chart review, while patient and clinic staff satisfaction was evaluated with surveys. All data was analyzed using descriptive statistics. This study was exempt from review by the Minneapolis Medical Research Foundation Institutional Review Board.

Evaluation of Clinical Activity

To evaluate clinical services provided by pharmacists, data was collected retrospectively over a six month time period from August 2015 to February 2016. Variables collected from the EMR included age, gender, HCV genotype, HCV polymerase chain reaction (PCR), DAA regimen, community pharmacy utilized, number and type of medication-related problems (MRPs), and the duration of each CMM encounter. The community pharmacy the patient used to obtain HCV therapy was collected to measure how frequently patients used non-HCMC pharmacies.

Patient Satisfaction Surveys

Patient satisfaction surveys were mailed to all patients seen by pharmacists from August 2015 through September 2015 and from November 2015 through December 2015. Surveys were sent during those time frames based on a schedule set forth by the pharmacy department. The pharmacy department typically surveys patients receiving pharmacy services twice per year. The ten question validated survey includes three domains: medication related needs, pharmacist-patient engagement, and overall satisfaction.[8] Questions were asked using four point categorical and Likert scales.

Staff Satisfaction Surveys

Ten months after ambulatory care pharmacy services were implemented in the GI clinic, a survey was sent to all GI clinic staff members via Survey Monkey (Palo Alto, CA). The objective of the survey was to evaluate provider satisfaction with clinical pharmacy services. The survey consisted of twelve questions and used Likert scale and open-ended questions. The last question was open-ended and asked for general comments and suggestions to improve the service.

Results

Clinical Activity

During the six-month pilot period, 135 CMM referrals were made for HCV patients in the GI clinic. Ninety-six CMM visits were completed and included 86 new patient visits and 10 follow up visits. The remainder of the referrals were either unable to be completed (29) or were performed in a different clinic (12). The average age for patients was 51 years and 70% were male (Table 1). The most common HCV genotype addressed was genotype 1a (58.1%), and the most commonly prescribed medication was ledipasvir/sofosbuvir for 12 weeks (48.8%) (Table 2). Over half (65%) of patients obtained their HCV medication from HCMC pharmacies.

A total of 246 MRPs were identified from the 96 CMM visits. Seventy-eight MRPs (31.7%) were related to appropriate indication, 27 (11.0%) to medication efficacy, 30 (12.2%) to safety, and 109 (44.3%) to medication adherence. Many of the

MRPs related to adherence resulted from patients not understanding medication instructions. Of all MRPs identified, 40 (16.2%) were related to drug-drug interactions with DAA treatment. The most common interaction identified included use of acid-suppression therapy, such as proton pump inhibitors, histamine-2 antagonists, or calcium carbonate. Drug interactions specifically related to acid-suppression therapy occurred in 26 of the 40 cases (65%). For a portion of patients on acid-suppressing medications, an antacid therapy change was required (medicine, dose, etc.). For other patients, education on appropriate timing (between the DAA and acid-suppressing medication) resolved this interaction. The average visit length was 40 minutes, and the pharmacist identified an average of 2.6 MRPs per visit.

Patient Satisfaction

Forty-five surveys were mailed to patients and fourteen (31%) were completed. A majority (57%) of respondents were male and between the ages of 41 and 60. Eighty-six percent of respondents rated the quality of care and services from the clinical pharmacist as "Excellent", 7% responded as "Very Good", and 7% responded as "Good". Ninety-three percent of respondents strongly agreed or agreed that the pharmacist helped them understand the indications of their medications and increased their confidence in managing their medications. Ninety-three percent of respondents strongly agreed or agreed that they would recommend their clinical pharmacist to a friend or family member. One patient was not satisfied with their clinical pharmacist experience.

Staff Satisfaction

Electronic surveys were administered to 15 GI clinic staff members including nurses, physicians, and support staff. Nine surveys were completed, and respondents included registered and licensed practical nurses (5), advanced practice provider (1), administrative and support staff (3). All respondents strongly agreed or agreed that the pharmacist made valuable contributions to the GI clinic and patient care. All respondents strongly agreed that pharmacy's CMM services were an essential component to the management of HCV. When asked what additional services pharmacists could provide in the GI clinic, respondents reported that the pharmacist should follow complicated patients, such as those with cirrhosis, more closely. Respondents reported that the pharmacist was valuable in managing drug-drug interactions and requested the pharmacist staff GI clinic more frequently than 8 hours per week.

Discussion

Over a six-month period of service design and implementation, clinical pharmacy services were successfully implemented. Clinical pharmacists were able to identify an average of 2.6 MRPs per visit. Many of the MRPs identified related to drug-drug interactions that had potential to impact safety and effectiveness of HCV treatment. The majority of MRPs identified related to adherence, which led to the pharmacist providing adherence coaching. Adherence to HCV therapies is especially important because incomplete treatment may result in treatment failure and could impact drug resistance.[3] This pilot study suggests that a pharmacist providing CMM can contribute to the safe and effective use of DAAs and support patients in adhering to treatment.

Clinical pharmacy services were viewed positively by patients and GI clinic staff. Survey results indicated nearly all patients felt more confident in managing their medications after receiving CMM. We believe this is due to the focused drug counseling and the length of time spent evaluating every medication. GI clinic staff reported that CMM services were an essential component of the care provided in the GI clinic. Data from the survey reflected clinic trends, as referrals remained steady throughout the pilot. Additionally, three write-in survey comments from a prescribing provider and two registered nurses, directly referred to the clinical pharmacist's expertise in the management of drug-drug interactions, which relates to the IDSA's recommendation for evaluation of drug-drug interactions.[4] Overall, survey data confirms the value of clinical pharmacy services to both patients and clinic staff members.

A challenge of implementing CMM services is financial justification. In this pilot study, pharmacists billed insurance companies for CMM using MTM CPT codes. Although many insurance companies did reimburse CMM services, the lack of provider status with Medicare programs limited our overall billing power and actual reimbursement did not cover the cost of pharmacist services. Future financial justification could include revenue generated from patients using health-system pharmacies to obtain HCV medications. Financial justification could also include considering those costs avoided from inappropriate use of DAAs. For example, if a drug-drug interaction were not managed appropriately, a treatment failure could result.

This study has limitations. It is uncertain how CMM impacted sustained virologic response (SVR) because of the short duration of this study. In this pilot, most patients were seen only once by a pharmacist so it is unknown how closer follow-up might affect outcomes. Future research should evaluate the impact of CMM on SVR and consider the intensity of pharmacist follow up provided. Lastly, response rates of patient and provider surveys were low so it is uncertain how representative data is of the populations surveyed.

Conclusion

CMM services provided to HCV patients in a GI clinic strongly align with recommendations set forth by the IDSA HCV guidelines[6], and contribute to safe and effective medication use. Our pilot study data supports continued involvement of clinical pharmacists within the clinic. Patient and staff

satisfaction survey results further illustrate the importance and value that CMM provided by clinical pharmacists can provide.

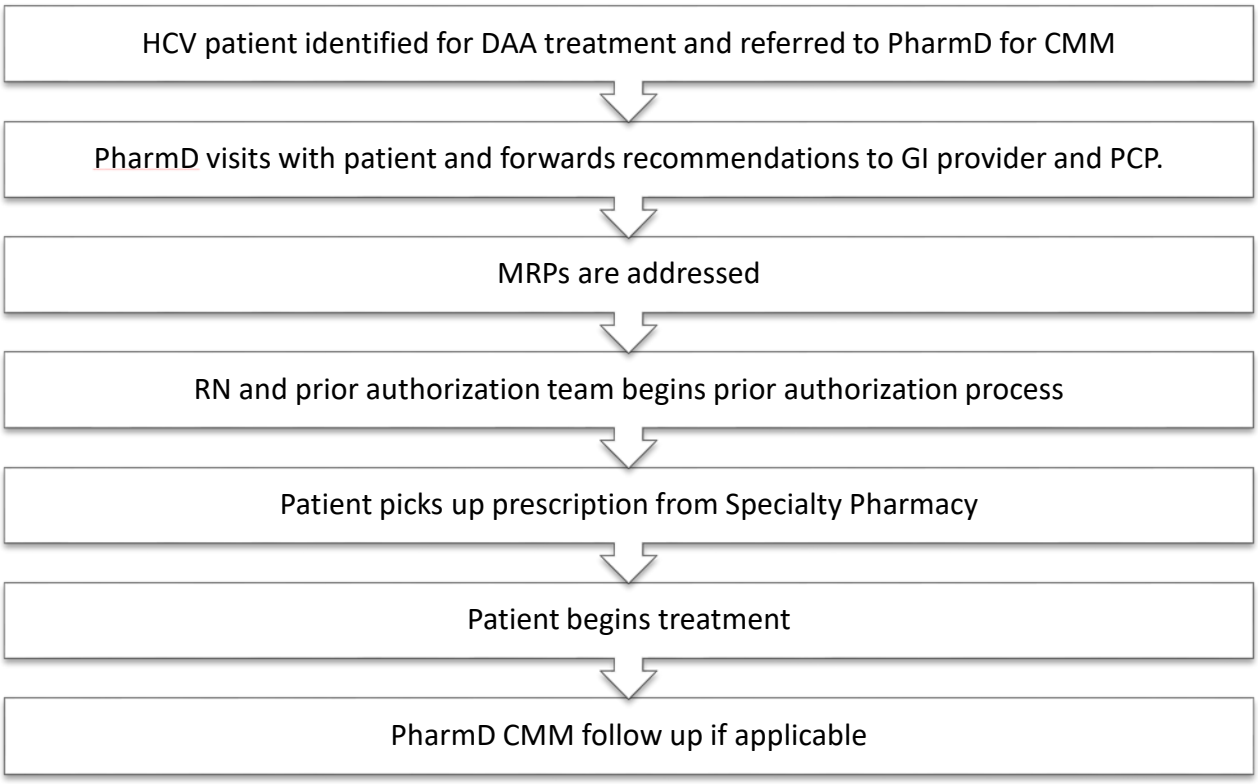
Acknowledgements: No grant funding was received throughout the duration of this project. "We declare no conflicts of interest or financial interests that the authors or members of their immediate families have in any product or service discussed in the manuscript, including grants (pending or received), employment, gifts, stock holdings or options, honoraria, consultancies, expert testimony, patents and royalties".

Disclosure Statement: The authors have nothing to disclose

References

1. Centers for Disease Control. Viral Hepatitis – Hepatitis C Information. 2016. Available at: http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm. (accessed 2016 Nov 30)
2. World Health Organization. Hepatitis C Fact Sheet. http://www.who.int/mediacentre/factsheets/fs164/en/ (accessed 2016 Nov 30)
3. Mohammad RA, Bulloch MN, Chan J, et al. Provision of Clinical Pharmacist Services for Individuals with Chronic Hepatitis C Viral Infection: Joint Opinion of the GI/Liver/Nutrition and Infectious Diseases Practice and Research Networks of the American College of Clinical Pharmacy. *Pharmacotherapy.*2014; 34(12):1341-1354.
4. American Association for the Study of Liver Diseases and Infectious Disease Society of America. HCV Guidance: Recommendations for testing, managing, and treating hepatitis C. (July 2016). http://www.hcvguidelines.org/full-report/monitoring-patients-who-are-starting-hepatitis-c-treatment-are-treatment-or-have. (accessed 2016 Nov 30)
5. The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes Resource Guide. 2012. https://www.accp.com/docs/positions/misc/CMM%20Resource%20Guide.pdf. (accessed 2016 Jan 4)
6. Cipolle, RJ. Strand, L., Morley, P. Pharmaceutical Care Practice: The Patient-Centered Approach to Medication Management, Third Edition. New York, NY: McGraw-Hill; 2012
7. Minnesota Department of Human Services. Medication Therapy Management Services. http://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=dhs16_136889
8. Moon J, Kolar C, Brummel A, et al. Development and Validation of a Patient Satisfaction Survey for Comprehensive Medication Management. *J Manag Care Spec Pharm*, 2016 Jan;22(1):81-86

Figure 1: Pharmacist workflow process in GI clinic



CMM: comprehensive medication management
DAA: direct-acting antiviral
MRP: medication-related problem

Table 1. Demographics of HCV Patients

Age (yrs) (average)	51+/- 7.6
Gender Male (n, %)	60 (70)
Genotype (n, %)	
1a	50 (58.1)
1b	15 (17.4)
2	6 (6.9)
3	8 (9.3)
4	6 (6.9)
5	0 (0)
6	1 (1.1)
Presence of Cirrhosis (n, %)	18 (20.9)

HCV= hepatitis C virus

Table 2. HCV treatment regimens among patients receiving medication therapy management (n, %)

Ledipasvir/Sofosbuvir (Harvoni) x 12 weeks	42 (48.8)
Ledipasvir/Sofosbuvir (Harvoni) x 8 weeks	18 (20.9)
Ledipasvir/Sofosbuvir (Harvoni) + Ribavirin x 12 weeks	2 (2.3)
Simeprevir + Sofosbuvir + Ribavirin x 24 weeks	1 (1.2)
Sofosbuvir + Daclatasvir x 12 weeks	6 (7.0)
Sofosbuvir + Daclatasvir + Ribavirin x 16 weeks	1 (1.2)
Sofosbuvir + Daclatasvir + Ribavirin x 24 weeks	1 (1.2)
Sofosbuvir + Ribavirin x 12 weeks	5 (5.8)
Sofosbuvir + Ribavirin x 16 weeks	1 (1.2)
Dasabuvir/Ombitasvir/Paritaprevir/Ritonavir (Viekira Pak) x 12 weeks	3 (3.5)
Dasabuvir/Ombitasvir/Paritaprevir/Ritonavir (Viekira Pak) + Ribavirin x 12 weeks	6 (7.0)

HCV=hepatitis C virus