

# Evaluating a Collaborative Approach to Improve Prior Authorization Efficiency in the Treatment of Hepatitis C Virus

Emily E. Dunn, PharmD; Kathryn Vranek, PharmD; Lauren M. Hynicka, PharmD, BCPS;  
Janet Gripshover, CRNP; Darryn Potosky, MD; T. Joseph Mattingly II, PharmD, MBA

**Objective:** A team-based approach to obtaining prior authorization approval was implemented utilizing a specialty pharmacy, a clinic-based pharmacy technician specialist, and a registered nurse to work with providers to obtain approval for medications for hepatitis C virus (HCV) infection. The objective of this study was to evaluate the time to approval for prescribed treatment of HCV infection. **Methods:** A retrospective observational study was conducted including patients treated for HCV infection by clinic providers who received at least 1 oral direct-acting antiviral HCV medication. Patients were divided into 2 groups, based on whether they were treated before or after the implementation of the team-based approach. Student *t* tests were used to compare average wait times before and after the intervention. **Results:** The sample included 180 patients, 68 treated before the intervention and 112 patients who initiated therapy after. All patients sampled required prior authorization approval by a third-party payer to begin therapy. There was a statistically significant reduction ( $P = .02$ ) in average wait time in the postintervention group ( $15.6 \pm 12.1$  days) once adjusted using dates of approval. **Conclusions:** Pharmacy collaboration may provide increases in efficiency in provider prior authorization practices and reduced wait time for patients to begin treatment.

**Key words:** interprofessional care, prior authorization, service efficiency, system navigation

Chronic hepatitis C virus (HCV) infection represents a major health system challenge for the United States, with approximately 3 million prevalent cases that could increase spending on pharmaceuticals substantially to treat eligible patients.<sup>1,2</sup> Prior to the first direct acting antiviral (DAA) medications receiving approval, this disease had classically been treated with ribavirin and pegylated interferon. Newer DAA therapies have become the standard of care for patients with chronic HCV infection due to efficacy and tolerability.<sup>3</sup> Economic models demonstrate the cost-effectiveness of these therapies and that the decline in work productivity reported in patients with untreated HCV infection

leads to an estimated \$7.14 billion in lost work suggesting that treating HCV infection in these patients would lead to an annual productivity savings of \$2.7 billion over a 1-year horizon.<sup>4,6</sup> Despite potential advantages of treating patients with these new therapies, strategies to control spending have created additional restrictions that may create barriers to care for many patients.<sup>7</sup>

Prior authorization is the process by which insurance companies determine whether treatment is medically necessary for an individual based on his or her diagnosis and condition. DAA therapy usually requires prior authorization or preapproval from third-party payers due to high costs. Do et al<sup>8</sup> found in a real-world HCV-infected cohort that 1 in 5 patients were denied access to these medications upon initial request. The majority of these initially denied patients eventually did receive prior authorization through the appeals process, with only 10% of patients unable to receive approval, indicating a potential administrative barrier that delays treatment of those who should be eligible.<sup>8</sup>

The administrative time involved in processing authorization requests to providers and health systems may impact overall clinic operations and efficiency, as well as add complexity for patients navigating the system. Communication between patients and providers throughout the HCV infection treatment cycle has been identified as a critical component of uptake and perception of patients' treatment experiences.<sup>9</sup> Additional time spent by clinic staff on administrative burdens poses an operational challenge that could increase wait times for HCV-infected patients or reduce the amount of time spent on providing education, information, or support. Patients undergoing treatment for HCV have

**Author Affiliations:** University of Maryland School of Pharmacy, Baltimore (Dr Dunn); Ambulatory Pharmacy, University of Maryland Medical Center, Baltimore (Dr Vranek); Department of Pharmacy Practice, University of Maryland School of Pharmacy, Baltimore (Drs Hynicka and Mattingly II); and Division of Gastroenterology and Hepatology, University of Maryland School of Medicine, Baltimore (Ms Gripshover and Dr Potosky).

**Correspondence:** T. Joseph Mattingly II, PharmD, MBA, Department of Pharmacy Practice, University of Maryland School of Pharmacy, 20 North Pine St, N415, Baltimore, MD 21201 (jmattingly@rx.umaryland.edu).

The authors thank Kimberly Allen from the University of Maryland Medical Center for her assistance with implementation and evaluation.

This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal.

The authors declare no conflicts of interest.

*Q Manage Health Care*  
Vol. 26, No. 3, pp. 136–139

Copyright © 2017 The Authors. Published by Wolters Kluwer Health, Inc.  
DOI: 10.1097/QMH.000000000000137

also expressed a desire for multidisciplinary services, so incorporating collaborative processes that include physicians, nurses, and pharmacists could help enhance the patient experience.<sup>10,11</sup>

The high cost of DAA therapy over the course of 3 to 6 months creates a situation where any factors reducing the overall effectiveness of the treatment could eliminate the downstream cost-savings as fewer patients reach clinical cure. Patient-centered research in HCV infection has identified limitations of the medical system as a potential barrier to treatment adherence and completion.<sup>9</sup> Long wait times to receive care may diminish the real-world effectiveness of these therapies, as patients frustrated with the system may become less engaged.<sup>9</sup> The objective of this study was to evaluate the effectiveness of one collaborative approach implemented at a large urban academic medical center (MC) to obtain prior authorization approval for HCV therapy.

## METHODS

In 2014, the MC implemented an interdisciplinary team-based approach to obtain prior authorization approval for HCV therapy. The authors observed the clinic's prior authorization office practice. Following an internal review of process time and workflow, the authors developed a new workflow and proposed a team-based approach by training and creating a new role for an advanced pharmacy technician as a billing specialist for the clinic. A trained pharmacy technician was designated to work within an outpatient hepatology clinic alongside a new registered nurse coordinator to obtain prior authorization approval for medications for HCV infection. Before implementation of this process, the specialty pharmacy had no direct access to patients' clinical information. Pharmacy staff relied on clinical information necessary for prior authorization approval being faxed to the pharmacy by a nurse within the clinic.

Clinic providers electronically prescribe medications for HCV infection to the MC pharmacy for patients who wished to fill their prescriptions at this pharmacy. The clinic-based pharmacy technician gathers any necessary clinical information from the providers, nursing staff, or electronic medical record (EMR) directly and coordinates the prior authorization process to obtain necessary documentation required by the patients' pharmacy benefits manager (PBM). The registered nurse assisted in ordering laboratory tests and scheduling patient visits for the clinic. The pharmacy technician also submitted information to PBMs, requiring laboratory results after 4 weeks of treatment. Examples of required clinical information include HCV genotype, HCV RNA viral load, previous treatments, biopsy results, medical history, and fibrosis score. Upon approval, the pharmacy technician communicates with the specialty pharmacy and the patient to coordinate pick up or delivery of the medication.

A retrospective, observational study design was used to describe wait times before and after process implementation. This pilot included a convenience sample of any patients treated with at least one DAA

therapy from the clinic during the observation period. The interdisciplinary team-based process was implemented in November 2014. Patients treated between January 2014 and October 2014 were included in the preintervention sample to capture patients on newer DAA regimens that were approved in November and December 2013.<sup>12</sup> Patients treated between January 2015 and April 2015 were included in the postintervention sample. Patients treated in November 2014 and December 2014 were excluded from the sample to allow for a washout period as the technician transitioned into the clinic. Patients were excluded from the study if their prescriptions for DAA therapy were not processed as of June 5, 2015.

## Outcome variables

The primary outcome evaluated was the wait time between the date the prescription was written and when the prescription was approved and processed by the pharmacy. In the postintervention group, the clinic-based pharmacy technician maintained electronic records of the dates prior authorization approval was received from the PBM. For the preintervention group, the approval date was unknown but the pharmacy processing date was available. For comparison, an unadjusted average wait time was calculated using prescription written date and process date and an adjusted average wait time was determined in the postintervention group using the time from the written date to date of approval.

## Data collection and analysis

Demographic information was collected from the EMR. The dates the patients' prescriptions were written and processed were obtained from pharmacy claims. Prior authorization approval dates were collected from records maintained by the clinic-based pharmacy technician. For patients on regimens that included multiple medications for HCV infection, the latest date that a DAA was approved/processed was used. The mean wait times preintervention and postintervention were compared using a *t* test, and categorical data were compared using the  $\chi^2$  test for independence using SAS version 9.4 (Cary, North Carolina). This study received approval from the university institutional review board on April 7, 2015.

## RESULTS

### Sample demographics

A total of 180 patients were included in the sample; 68 patients (38%) were included in the preintervention sample, and 112 patients (62%) were included in the postintervention sample (Table 1). There were no differences in sex ( $P = .66$ ), race ( $P = .26$ ), and age ( $P = .48$ ) between the 2 groups. The postintervention group was more likely to be infected with genotype 1 ( $P = .006$ ), be prescribed a single prescription ( $P < .0001$ ), and be prescribed ledipasvir/sofosbuvir ( $P < .0001$ ). The differences in regimens were likely due to the fact that ledipasvir/sofosbuvir was approved in October 2014.

**Table 1. Characteristics of the Entire Sample**

	Preintervention	%	Postintervention	%	Total	%	<i>P</i> <sup>a</sup>
Sample	68	38	112	62	180	100	
Sex							
Male	39	57	68	61	107	60	.66
Female	29	43	44	39	73	40	
Race							
White	26	38	31	1	57	32	.26
Black	42	62	80	71	122	68	
Other	0	0	1	28	1	1	
Age (SD)	59 (9.7)		60 (8.2)				.48
Genotype							
1	59	87	109	97	168	93	.006
Other	9	13	3	3	12	7	
Hepatitis C regimen							
HARV	9	13	103	92	112	62	<.0001
HARV/RIB	0	0	2	2	2	1	
SIM/SOF	17	25	3	3	20	11	
SOF/RIB	21	31	1	1	22	12	
VIEK	0	0	3	3	3	2	
SOF/PEG/RIB	19	28	0	0	19	11	
SIM/SOF/RIB	2	3	0	0	2	1	
Prescription count							
1	9	13	106	95	115	64	<.0001
2	38	56	6	5	44	24	
≥3	21	31	0	0	21	12	

<sup>a</sup>Chi-square analysis used for demographic variables, *t* test for continuous.

### Wait times

In the unadjusted model, the change in average wait time ( $P = .13$ ) between the preintervention group ( $23.4 \pm 24.5$  days) and the postintervention group ( $18.3 \pm 15.7$  days) was not statistically significant. The reduction ( $P = .02$ ) in average wait time was statistically significant in the postintervention group ( $15.6 \pm 12.1$  days) once adjusted using dates of approval (Table 2).

**Table 2. Pre- and Postintervention Average Patient Wait**

Group	Average Wait (SD)	Wait Time Range	<i>P</i>
Unadjusted			
Preintervention	23.4 (24.5)	0-101	.13
Postintervention	18.3 (15.7)	0-63	
Adjusted			
Preintervention	23.4 (24.5)	0-101	.02
Postintervention	15.6 (12.1)	0-60	

### DISCUSSION

The average wait time observed in the preintervention group is similar to the wait times observed in other research regarding prior authorizations of HCV infection treatment.<sup>8</sup> Do et al<sup>8</sup> found that approximately 1 in 5 prescriptions for HCV therapy are initially denied by PBMs, which require provider appeal. Introducing a collaborative approach to processing prior authorizations between pharmacy and the clinic staff resulted in a reduction in the time between the provider ordering the medication and the pharmacy's awareness that the medication had been approved by the PBM. In addition to the reduction in mean wait time in the adjusted model, the spread in the distribution of times was reduced as seen by the reduced standard deviation in both unadjusted and adjusted models. From a customer service standpoint, more precision with wait times allows the clinic and pharmacy teams to manage patient expectations and improve satisfaction with service.<sup>13</sup> A multidisciplinary approach may also improve the customer experience, as previous studies have found high patient satisfaction associated with

collaborations between physicians, nurses, and pharmacists in the care of HCV-infected patients.<sup>9,11</sup>

This study adds a new approach using a trained clinic-based pharmacy technician resource within an outpatient clinic along with a registered nurse coordinator to facilitate prior authorization approvals. In addition to streamlining processes for prior authorization and improving communication between departments, this collaboration provided an advancement opportunity for a well-trained pharmacy technician. Pharmacy technicians have been previously utilized in billing specialist roles in health systems, but little research has been published demonstrating positive outcomes for patients or systems utilizing technicians in this role.<sup>14</sup> The initial success of the program has encouraged expansion of a second pharmacy technician trained to serve 2 other clinics within the MC system.

Limitations include the reliance on pharmacy claims data as a proxy for approval times in the preintervention sample and the unavailability of denial information. Other variables may influence the time between insurance approval and final pharmacy processing, such as patient out-of-pocket costs or other patient-level factors. The lack of information around insurance denials or prescriber appeals in the preintervention group also limited this study in analysis of intervention effectiveness. As a retrospective observational study, patients were not randomized to the intervention and control groups, limiting the internal validity of the results provided. However, this pilot provides reasonable estimates for prior authorization times to power a stronger prospective investigation and demonstrates a potential innovation for health system pharmacy practice to improve efficiencies in this process.

Third-party payers often have different requirements for patients to be approved for therapy that may vary from medical guidelines. This study did not evaluate the appropriateness of DAA therapy selected or whether adding a trained pharmacy technician would impact compliance to payer HCV infection treatment guidelines. Future research may warrant evaluating payer guideline compliance for initial submission for approval, as both submission and review require administrative labor and effort from providers, pharmacies, payers, and patients.

## CONCLUSIONS

Designating a pharmacy technician and a registered nurse to work directly within specialty clinics may lead to system efficiencies for patients prescribed medi-

cations that require complex prior authorization processes. Pharmacy departments working directly with providers and nurses to navigate the third-party payer system may enable more prompt initiation of therapy.

## REFERENCES

1. Denniston MM, Jiles RB, Drobeniuc J, et al. Chronic hepatitis C virus infection in the United States, National Health and Nutrition Examination Survey 2003 to 2010. *Ann Intern Med.* 2014;160(5):293-300. doi:10.7326/M13-1133.
2. Chhatwal J, Kanwal F, Roberts MS, Dunn MA. Cost-effectiveness and budget impact of hepatitis C virus treatment with sofosbuvir and ledipasvir in the United States. *Ann Intern Med.* 2015;162(6):397-406. doi:10.7326/M14-1336.
3. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for testing, managing, and treating hepatitis C. AASLD/ISDA: HCV guidance: recommendations for testing, managing, and treating hepatitis C. <http://www.hcvguidelines.org/full-report-view>. Published 2016. Accessed January 30, 2017.
4. Younossi Z, Brown A, Buti M, et al. Impact of eradicating hepatitis C virus on the work productivity of chronic hepatitis C (CH-C) patients: An economic model from five European countries. *J Viral Hepat.* 2016;23(3):217-226. doi:10.1111/jvh.12483.
5. Najafzadeh M, Andersson K, Shrank WH, et al. Cost-effectiveness of novel regimens for the treatment of hepatitis C virus. *Ann Intern Med.* 2015;162(6):407-419. doi:10.7326/M14-1152.
6. Zhao YJ, Khoo AL, Lin L, et al. Cost-effectiveness of strategy-based approach to treatment of genotype 1 chronic hepatitis C. *J Gastroenterol Hepatol.* 2016;31(9):1628-1637. doi:10.1111/jgh.13341.
7. Barua S, Greenwald R, Grebely J, Dore GJ, Swan T, Taylor LE. Restrictions for Medicaid reimbursement of sofosbuvir for the treatment of hepatitis C virus infection in the United States. *Ann Intern Med.* 2015;163(3):215-223. doi:10.7326/M15-0406.
8. Do A, Mittal Y, Liapakis A, et al. Drug authorization for sofosbuvir/ledipasvir (Harvoni) for chronic HCV infection in a real-world cohort: a new barrier in the HCV care cascade. *PLoS One.* 2015;10(8):e0135645. doi:10.1371/journal.pone.0135645.
9. Sublette VA, Smith SK, George J, McCaffery K, Douglas MW. The hepatitis C treatment experience: patients' perceptions of the facilitators of and barriers to uptake, adherence and completion. *Psychol Health.* 2015;30(8):987-1004. doi:10.1080/08870446.2015.1012195.
10. Manos MM, Ho CK, Murphy RC, Shvachko VA. Physical, social, and psychological consequences of treatment for hepatitis C: a community-based evaluation of patient-reported outcomes. *Patient.* 2013;6(1):23-34. doi:10.1007/s40271-013-0005-4.
11. Martin MT, Faber DM. Patient satisfaction with the clinical pharmacist and prescribers during hepatitis C virus management. *J Clin Pharm Ther.* 2016;41(6):645-649. doi:10.1111/jcpt.12436.
12. US Food and Drug Administration. Approval of Sovaldi (sofosbuvir) tablets for the treatment of hepatitis C. For Patients. <https://www.fda.gov/forpatients/illness/hepatitisbc/ucm377920.htm>. Published September 25, 2014. Accessed June 6, 2017.
13. Parasuraman A, Berry LL, Zeithaml VA. Understanding customer expectations of service. *Sloan Manage Rev.* 1991;32(3):39-49.
14. Myers CE. Opportunities and challenges related to pharmacy technicians in supporting optimal pharmacy practice models in health systems. *Am J Heal Pharm.* 2011;68(12):1128-1136. doi:10.2146/ajhp110056.