

Evaluation of Specialty Pharmacy Services and Treatment Outcomes for Hepatitis C at a Large Academic Medical Center

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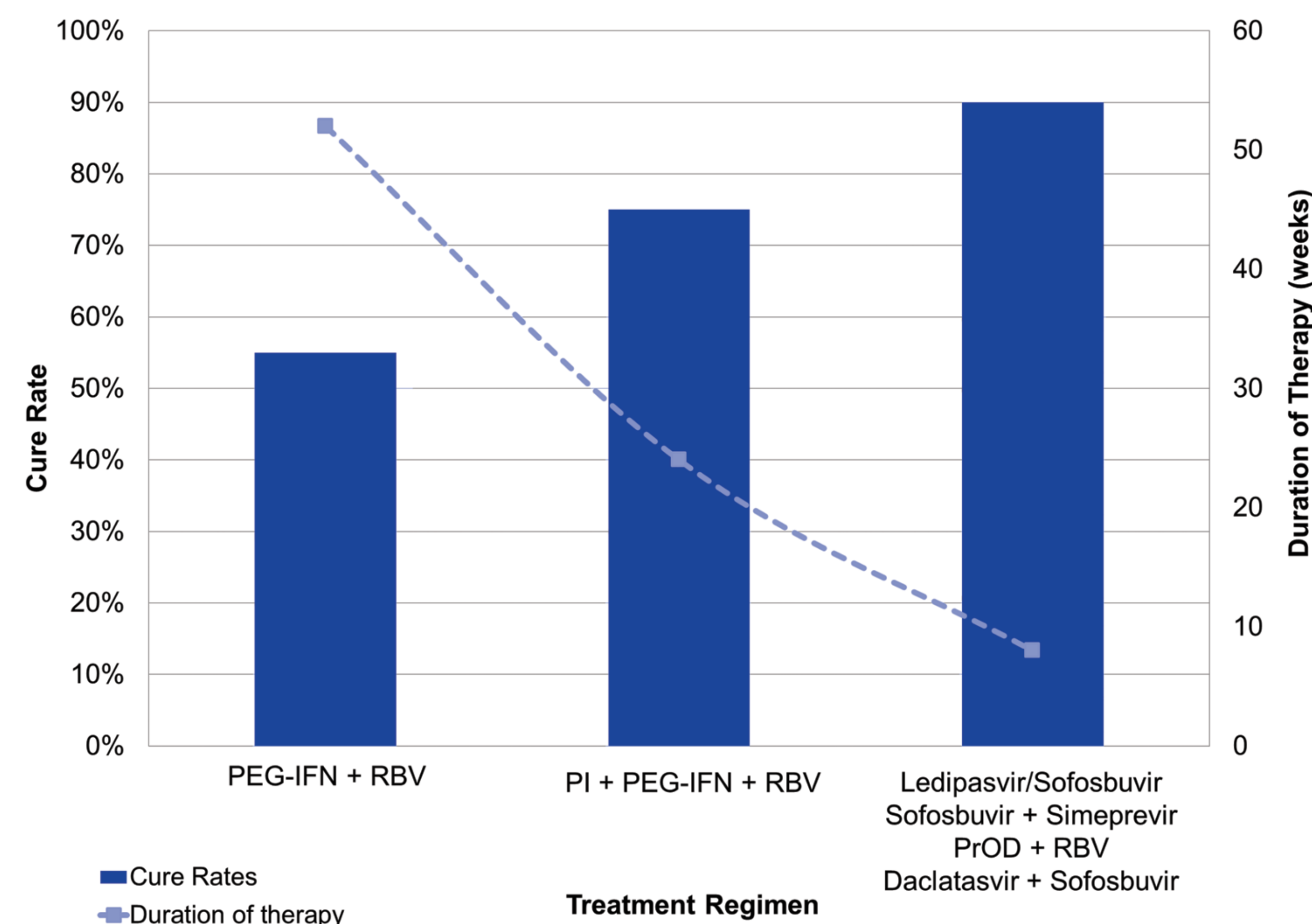
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Introduction

- Approximately 2.7 million people in the United States suffer from chronic hepatitis C virus (HCV) infection.¹
- Treatment is based on genotype and patient factors, and cure is achieved when patients have a sustained virologic response (SVR), which means HCV RNA levels are undetectable 12 weeks post-therapy completion.²
- The approval of new agents for chronic HCV infection over the past decade has revolutionized treatment as these medications are better tolerated and are associated with improved cure rates.²
- Hepatitis C medications were traditionally considered to be specialty products due to their complicated regimens, side effects, and administration. However, newer regimens are still often dispensed by specialty pharmacies because they require complicated insurance approvals, financial assistance, and ongoing follow-up.³
- Specialty pharmacies provide enhanced services such as insurance verification, financial assistance, patient education and monitoring, and refill reminders.^{4,5}
- Clinical trials conducted using these new therapies show cure rates of up to 100%, but a recent study indicates that cure rates in actual practice may be substantially lower. This may be attributed to patients not being adherent to their therapy, stopping therapy early, or experiencing difficulties with financial assistance.^{6,7}
- A retrospective study previously showed that specialty pharmacies were associated with increased adherence to a 3-drug regimen of pegylated interferon, ribavirin, and telaprevir.⁴
- Although specialty pharmacies have been shown to increase patient adherence to previously recommended regimens, little research has been done looking at newer agents.
- This study seeks to establish cure rates at the Beaumont Royal Oak hepatitis C clinic and to analyze services provided by Beaumont Specialty Pharmacy to its patients.

Figure 1. Hepatitis C Treatment Evolution: cure rates and treatment durations for HCV genotype 1



Objectives and Endpoints

	Outcomes	Endpoints
Primary	Adherence rates of BSP HCV patients	Medication possession ratio (MPR)
	Beaumont hepatitis C patients' clinical outcomes	Sustained virologic response (SVR) ≥ 12 weeks post-treatment
Secondary	Financial and operational assistance services offered to BSP HCV patients	<ul style="list-style-type: none"> • Prior authorization approval rate • Insurance appeal approval rate • Financial assistance received in dollars • Time to therapy
	Beaumont hepatitis C patients' treatment outcomes with respect to genotype, treatment regimen and other patient-specific factors	SVR12 with respect to: <ul style="list-style-type: none"> • Race, gender, BMI • Disease state progression • Prior treatment status • HIV, transplant and diabetes status • Baseline vitamin D levels

Methods

- This retrospective chart review study was approved by the Beaumont IRB Committee.
- Patients with original prescriptions sent to Beaumont Specialty Pharmacy (BSP) for HCV antiviral medications between April 2014 and September 2015 will be identified using a patient list developed by the specialty pharmacy and through reports from the outpatient pharmacy dispensing system.

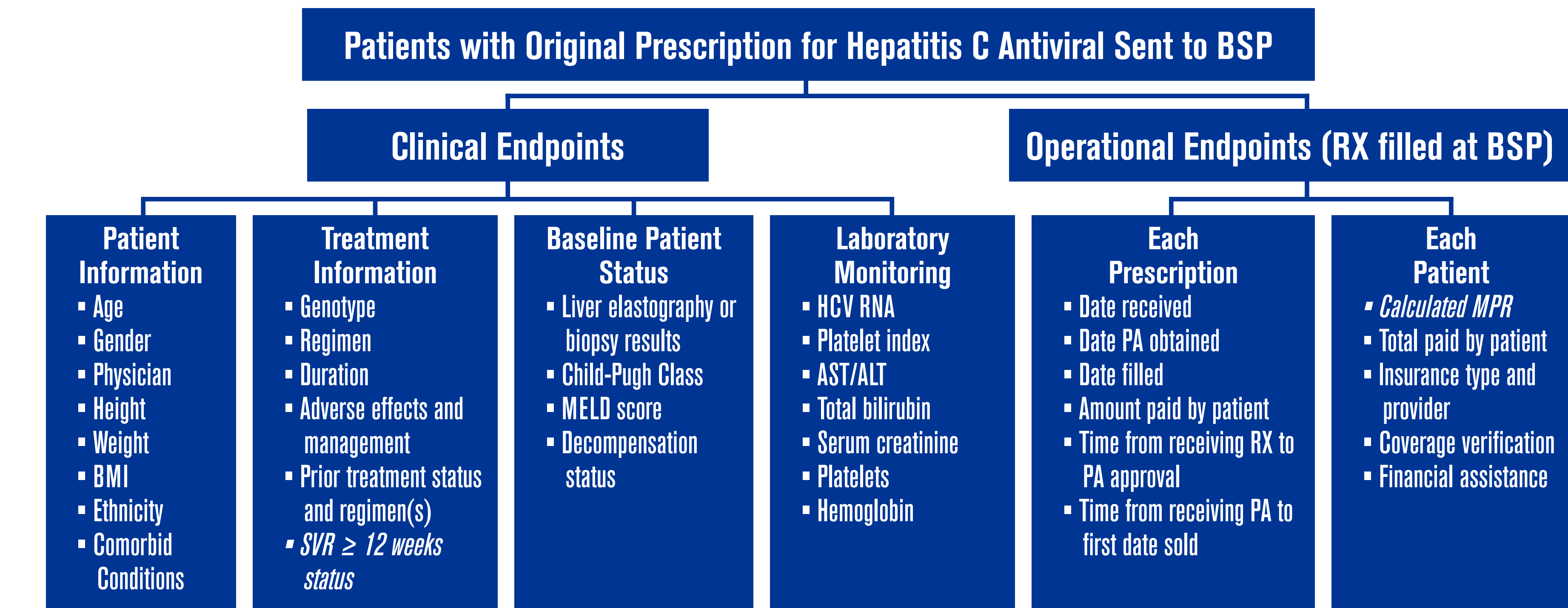
Figure 2. Study agents

Direct-Acting Antivirals	Combination Products	Other Anti-HCV Agents
Sofosbuvir	Ledipasvir/sofosbuvir	Pegylated interferon
Simeprevir	Ombitasavir/paritaprevir/ritonavir and dasabuvir	Ribavirin
Daclatasvir	Ombitasavir/paritaprevir/ritonavir	

- Clinical treatment information will be obtained utilizing electronic medical records.
- Patients who do not fill their medication at BSP will only be included in the clinical portion of this study.
- There are no exclusion criteria for this study.

Methods cont.

Figure 3. Data Collection Scheme



Data Analysis

- Descriptive statistics will be used for demographic and baseline data.
- All data including primary clinical outcome data will be reported as counts and percentages or mean +/- standard deviation as appropriate.
- Differences in SVR rate and MPR with respect to different analysis groups (treatment regimen, baseline liver disease status, etc.) will be calculated with a Chi-square test for categorical variables or an independent samples t-test for continuous variables.
- P-values < 0.05 will be considered statistically significant.
- MPR = total number of days medication was supplied within the refill interval divided by the number of days in the refill interval.

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Disclosure

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation: Julie Francisco, Nothing to disclose; Christine Yost, Nothing to disclose; Scott Sterrett, Nothing to disclose.