Background

• Patients with chronic hepatitis C virus (HCV) infection have diminished health related quality of life (HRQoL), particularly because of the presence of fatigue and other extrahepatic manifestations.1,2

• To inform HCV treatment decision making, it is important to understand health care resource and/or local clinical practice implications.

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Methods

This pooled analysis aims to report on real-world HCRU and HRQoL patients who experienced a Pangenotypic SVR12 rate of 98% in more than 2200 patients in registral clinical trials, but not currently well defined in real-world settings.

Results

• The overall SVR12 rate was 98.9% (95% CI 97.9 to 99.8%).

• SVR12 rates were consistently high across all countries and subgroups, regardless of the number of visits patients ended their clinical treatment.

• The early post-treatment visit was the visit most likely to be skipped.

• The percentage of patients attending each visit is shown in Figure 1.

Figure 1. Percentage of Patients Attending Each Visit by Subgroup of Interest

Conclusions

• The presence of patients with chronic HCV infection is real-world clinical settings such as those PDIS resulted in high SVR12 rates and clinically meaningful improvement in HRQoL, irrespective of the number of visits patients ended their clinical treatment.

• SVR12 based on the mean number of visits observed for patients, was less than that recommended in the protocol, with some variability between countries.

• The early post-treatment visit was the visit most likely to be skipped.

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Acknowledgments

This study was generously supported by an unrestricted educational grant from the American Association for the Study of Liver Diseases (AASLD), the European Association for the Study of the Liver (EASL), and the European Association for the Study of the Liver (EASL). The study was also partially supported by PDIS provided by Merck & Co., Inc., Kenilworth, New Jersey, USA.

Presented at the European Association for the Study of the Liver’s 54th Annual International Liver Congress, 10–14 April 2019, Vienna, Austria

Methods

• To inform HCV treatment decision making, it is important to understand health care resource and/or local clinical practice implications.

• Pangenotypic SVR12 rate of 98% in more than 2200 patients in registral clinical trials, but not currently well defined in real-world settings.

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Achieving accelerated elimination of hepatitis C virus infection by 2025: a case study in France

Victor de Ledinghen¹, Christophe Bureau², Yuri Sanchez Gonzalez³, Fabrice Ruggeri⁴, Homie Razavi⁵

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INTRODUCTION

With the introduction of curative therapies for hepatitis C virus (HCV) infection and removal of restrictions on antiviral treatment by fibrosis score, France is on track to achieve the World Health Organization’s (WHO) targets for elimination of HCV as a public health threat by 2030.¹

OBJECTIVES

To inform the path towards accelerated elimination, this analysis evaluates the clinical and economic impact of HCV elimination in France by 2025.

METHODS

A Markov disease progression model was developed to assess the impact over 2019-2030 from expanding HCV diagnosis and treatment, populated with demographic and epidemiological inputs and price data²–³ from France.

Clinical outcomes of cases of decompensated cirrhosis, hepatocellular carcinoma, liver transplantations, and liver-related deaths were analyzed.

Economic outcomes of costs of screening, antiviral treatment, liver-related complications, and extra-hepatic manifestations were analyzed.

LIMITATIONS

Number of HCV antibody screens and treatments, and unit costs of screening and treatment were assumed to stay constant annually, which may differ from future trends.

Model forecasts may differ from results observed in the real world.

RESULTS

Compared to the status quo, accelerated elimination in France would require screening of two times more people annually, or 28 million additional HCV antibody (AB) screens, over 2019–2025.

By 2030, accelerated elimination would avert:

- 7,244 new HCV infections,
- 74 cases of decompensated cirrhosis,
- 144 cases of hepatocellular carcinoma,
- 16 liver transplantations,
- 107 liver-related deaths

By 2030, accelerated elimination would yield cost savings of €162 million, with an ICER of €9,635/QALY.

COMPLICATIONS

To inform the path towards accelerated elimination, this analysis evaluates the clinical and economic impact of HCV elimination in France by 2025.

By 2023, 144 cases of hepatocellular carcinoma

2027

16 liver transplantations

2029

This accelerated elimination path would further reduce the clinical and economic burden of HCV and be cost-saving by 2030.

DISCUSSIONS

The design, study conduct, and financial support for the study were provided by AbbVie. AbbVie participated in the interpretation of data, review, and approval of this publication.

Victor de Ledinghen is an employee of CHU de Bordeaux. He has received consulting fees from AbbVie, Gilead, MSD, Pfizer, Intercept Pharma, EchoSens and SuperSonic Imagine.

Christophe Bureau is an employee of CHU de Toulouse. He has received consulting fees from AbbVie, Gilead, Intercept, Norgine and Gore.

Yuri Sanchez Gonzalez is an employee of AbbVie Inc. and may own AbbVie stock or stock options.

Fabrice Ruggeri is an employee of AbbVie France Ltd. and may own AbbVie stock or stock options.

Homie Razavi is an employee of Center for Disease Analysis. The Center for Disease Analysis has received funding from AbbVie Inc. for this project.

Medical writing support was provided by Ioane Gamkrelidze, employee of Center for Disease Analysis, who contributed to the data analysis and/or the drafting of the abstract. AbbVie Inc. provided funding for this medical writing support.

REFERENCES


Patients with hepatitis C virus (HCV) face increased healthcare costs due to hepatic complications and extrahepatic manifestations affecting cardiovascular, central nervous system, immune, rheumatologic, and endocrine systems.\(^1\) Treatment of HCV infection has shown to reduce the risks of associated costs of hepatic and extrahepatic complications.\(^2\) In spite of these benefits, treatment is often delayed for patients with early stages of liver disease.\(^3,4\)

**METHODS (Continued)**

- A Markov state transition model of the natural history of HCV was developed to forecast liver-related and extrahepatic outcomes over a lifetime from the UK National Health Service (NHS) perspective.
- The model was based on health state frameworks in the published literature.\(^4,5,6\)
- Treatment attributes were based on clinical trials of glecaprevir (identiﬁed by AbbVie and Enanta) and pibrentasvir.\(^7\)

**RESULTS**

- Delaying treatment with glecaprevir/pibrentasvir increased long-term risks of compensated cirrhosis (CC), DCC, HCC, LT, and LrD; LTU further aggravated these risks.

- Assuming no LTU (vs. LTFU=0%), long-term liver-related outcomes increased with length of treatment delay. For instance, at year 5, there was an increased risk of CC of 2.7%, DCC (0.03%), HCC (1.0%), LT (0.05%), and LrD (1.0%). (Figure 2A)

- Assuming LTU (vs. LTFU) at year 5 increased to 41.4% (CC), 18.6% (DCC), 8.9% (HCC), 2.2% (LT), and 20.8% (LrD). (Figure 2B)

**DISCUSSIONS AND DISCLOSURES OF INTEREST**

The design, analysis, and ﬁnancial support of this study were provided by AbbVie Inc. AbbVie, Inc. had no involvement in the interpretation of data, review, and approval of the study. John Dillon is an employee of AbbVie, Inc. in addition, Dr. Dillon has received funding from AbbVie Ltd for a collaborative research study, grants and personal fees from Gilead, Merck, Astra Zeneca, Roche, and Alnylam reporting on the Spanish Hepatitis C trial to the Spanish National Institute of Health, and consultancy and honoraria from AbbVie Ltd, etc. The other authors report being employees of AbbVie Inc. or related companies.

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The authors gratefully acknowledge the contributions of Monika Hermansson and Svetlana Kalabina, who were employees of AbbVie Ltd and may own AbbVie stock. The authors also wish to acknowledge the research support from AbbVie Ltd. The authors also acknowledge the contribution in the interpretation of data, review, and approval of the study by John Dillon an employee of AbbVie, Inc. in addition, Dr. Dillon has received funding from AbbVie Ltd for a collaborative research study, grants and personal fees from Gilead, Merck, Astra Zeneca, Roche, and Alnylam reporting on the Spanish Hepatitis C trial to the Spanish National Institute of Health, and consultancy and honoraria from AbbVie Ltd, etc.

**REFERENCES**

4. Immediate versus delayed hepatitis C treatment in the United Kingdom: A pan-genotypic cost-effectiveness analysis. John Dillon\(^{6}\), Dominic Mitchell\(^{6}\), Suchin Virabhak\(^{6}\), Monika Hermansson\(^{7}\), Svetlana Kalabina\(^{7}\), Yuri Sanchez González\(^{8}\)

**BACKGROUND**

- Patients with hepatitis C virus (HCV) face increased healthcare costs due to hepatic complications and extrahepatic manifestations affecting cardiovascular, central nervous system, immune, rheumatologic, and endocrine systems.\(^1\)
- Treatment of HCV infection has shown to reduce the risks of associated costs of hepatic and extrahepatic complications.\(^2\) In spite of these benefits, treatment is often delayed for patients with early stages of liver disease.\(^3,4\)

**OBJECTIVES**

- This study explored the clinical and economic burden of delaying pan-genotypic hepatitis C treatment and the cost-effectiveness of immediate versus delayed treatment in the United Kingdom.\(^5\)

**METHODS**

- A Markov state transition model of the natural history of HCV was developed to forecast liver-related and extrahepatic outcomes over a lifetime from the UK National Health Service (NHS) perspective.
- The model was based on health state frameworks in the academic literature.\(^4,5,6\) The natural history of HCV infection is shown in Figure 1A. The analysis focused on the immediate treatment of patients with HCV genotypes 1-6 and fibrosis stages F0-F2 vs delayed treatment in later years. In the base case, there was no patient loss to follow-up (LTFU) due to treatment delay. In scenario analysis, annual LTFU rates of 1%, 5%, 10%, and 20% were considered.
- Health outcomes included lifetime risks of decompensated cirrhosis (DCC), hepatic cirrhosis (HCC), liver transplantation (LT), and liver-related death (LrD).

**MODEL INPUTS**

- Patient demographics as well as hepatic and extrahepatic costs were drawn from UK sources.\(^4,5,6\) Transition probabilities and health state utilities were based on published literature.\(^4,5,6\)
- Treatment attributes were based on clinical trials of glecaprevir (identiﬁed by AbbVie and Enanta) and pibrentasvir.\(^7\)

**RESULTS**

- Delaying treatment with glecaprevir/pibrentasvir increased long-term risks of compensated cirrhosis (CC), DCC, HCC, LT, and LrD; LTU further aggravated these risks.

- Assuming no LTU (vs. LTFU=0%), long-term liver-related outcomes increased with length of treatment delay. For instance, at year 5, there was an increased risk of CC of 2.7%, DCC (0.03%), HCC (1.0%), LT (0.05%), and LrD (1.0%). (Figure 2A)

- Assuming LTU (vs. LTFU) at year 5 increased to 41.4% (CC), 18.6% (DCC), 8.9% (HCC), 2.2% (LT), and 20.8% (LrD). (Figure 2B)

**LIMITATIONS**

- There was limited information on the demographics of patients with chronic HCV in the UK; baseline data for patient distribution across genotypes, treatment history and fibrosis distribution were extracted from the Adelphi Patient Chart Tracking Study.\(^5\)

**CONCLUSIONS**

- Immediate versus delayed hepatitis C treatment decreased hepatic and extrahepatic costs as a dominant strategy in the UK as it delivered more QALYs at lower cost.

**FUTURE QUERIES**

- Immediate treatment mitigated the hepatic and extrahepatic burden of HCV as well as the risk of LTFU, thus maximizing the value of treatment to patients and payers.

**IMMEDIATE TREATMENT VS DELAYED TREATMENT**

- Delaying treatment substantially increased lifetime healthcare costs, especially due to the risk of LTFU.
- Assuming no LTU, the share of total cost attributable to hepatic cost fell from 81% to 61% as treatment was delayed from one to ten years (Figure 3A).
- When LTU=20%, the lifetime cost from delayed treatment increased at least 5-fold (vs. LTFU=0%), with similar shares attributable to hepatic vs extrahepatic costs (Figure 3B).
- In regression analysis, total costs were predicted to increase by £1,318 (£2.197) per every 1% increase in LTFU.
- Further research is needed to inform these parameters.

**IMMEDIATE TREATMENT VS DELAYED TREATMENT**

- Immediate treatment was a dominant strategy regardless of time of delay as it delivered more QALYs at lower costs (NMB=0). Moreover, the NMB associated with delayed treatment increased with higher risk of LTFU.

- In regression analysis, the NMB of immediate treatment was estimated to increase by £4,556 (£4,876) for every year treatment was delayed and by £1,981 (£1,421) for every year of treatment delay and by £4,556 (95% confidence interval: £1,214–£8,893) for every year treatment was delayed and by £1,981 (£1,421–£2,542) for every year of treatment delay.

**LIMITATIONS**

- We assumed a willingness-to-pay threshold of £20,000 per QALY vs NICE guidelines, increasing the threshold to less conservative levels would further strengthen the rationale for immediate treatment.

**DISCLOSURES AND DISCLOSURES OF INTEREST**

- The design, analysis, and ﬁnancial support of this study were provided by AbbVie Inc. AbbVie, Inc. had no involvement in the interpretation of data, review, and approval of the study. John Dillon is an employee of AbbVie, Inc. in addition, Dr. Dillon has received funding from AbbVie Ltd for a collaborative research study, grants and personal fees from Gilead, Merck, Astra Zeneca, Roche, and Alnylam reporting on the Spanish Hepatitis C trial to the Spanish National Institute of Health, and consultancy and honoraria from AbbVie Ltd, etc.

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**Global timing of hepatitis C virus elimination: estimating the year countries will achieve the World Health Organization elimination targets**

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**INTRODUCTION**
- The introduction of highly efficacious pan-genotypic therapies for hepatitis C virus (HCV) infection has made the elimination of HCV an attainable goal.

**OBJECTIVES**
- This study assessed the progress made in 45 high-income countries and territories towards meeting the 2030 HCV elimination targets set by the World Health Organization (WHO) for incidence, mortality, diagnosis, and treatment.

**METHODS**
- A previously published Markov disease progression model of HCV infection was populated with demographic and epidemiological inputs for 45 high-income countries and territories from the United Nations World Population Prospects and the Polaris Observations, respectively.
- Primary modification to the published model was the calculation of incidence:
  - Incident cases of HCV were separated into vertically and horizontally acquired infections.
  - Future incidence was assumed to change at the same annual rate as prevalence.
  - FO [on METAIRV scale] prevalence was used where treatment was restricted by fibrosis score, and overall prevalence was used where treatment was not restricted to simulate the impact of treatment as prevention.

**RESULTS**
- Maintaining the standard of care in 2017 (number of new diagnoses and antiviral treatments, the number of high-income countries and territories that failed to meet each WHO target in 2017: 34 (incidence), 30 (mortality), 20 (diagnosis), and 26 (treatment)
- Starting in 2020, was calculated the minimum number of annual treatments necessary to achieve the target treatment for HCV elimination, starting in 2020, was calculated.

**CONCLUSIONS**
- Despite the introduction of curative therapies, 85% of high-income countries and territories are not on track to meet the WHO’s aims that would eliminate HCV as a public health threat by 2030, and 67% are off-track by at least 20 years.
- Immediate action to improve HCV diagnosis and treatment is needed to reach the global elimination of HCV by 2030 an attainable goal.

**REFERENCES**
Patient Flow Across Physician Specialties Over the Course of the Hepatitis C Care Cascade: A Real-World Analysis From the United States
Sanika Rege1, Yuri Sanchez Gonzalez2, Steven Marx2, Shivaji Manthena3, Nancy Reau3
1College of Pharmacy, University of Houston, Houston, Texas, USA; 2Health Economics and Outcomes Research, AbbVie Inc., Chicago, Illinois, USA; 3Rush University Medical Center, Chicago, Illinois, USA

Presented at the European Association for the Study of the Liver’s 54th Annual International Liver Congress, April 10–14, 2019, Vienna, Austria

INTRODUCTION

- An estimated 2.4 million people in the United States are infected with hepatitis C virus (HCV), a major cause of liver disease and cirrhosis.
- With the advent of direct-acting antivirals, high cure rates for HCV are achievable but rely on closing key gaps in the HCV care cascade to meet the HCV elimination targets set by the World Health Organization (WHO).
- Guidelines outline the standard patient journey from screening to cure.
- A 2014 meta-analysis found large gaps at each step of the HCV care cascade, including only 50% of patients being diagnosed and aware of their HCV infection and only 16% of patients receiving treatment.

Gaps in HCV Care Cascade

METHODS

- Data from 2 de-identified national laboratory datasets (January 2013 – December 2016).
- Patients in this study represent the majority of US patients screened for HCV Ab and / or tested for HCV RNA between 2013 and 2016.
- Screening: Patients who received HCV Ab test.
- Awareness: Patients who received HCV RNA viral load test irrespective of HCV Ab test.
- Diagnosis: Patients who had a positive HCV RNA viral load test.
- Linkage to care: Patients with positive HCV RNA viral load test who visited a physician to receive liver function test and / or genotype assessments and received treatment.
  - Liver function was assessed per modified Fibrosis-4 (FIB-4) Index scoring based on alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels and platelet count.
  - Treatment was not directly observed but inferred via change in viral load.
- The number and proportion of patients at each step in the care cascade was calculated per physician specialty.
- Sankey diagrams were used to visualize the flow of patients across physician specialties at various steps in the care cascade, with the width of each arrow / arm proportional to the patient flow quantity.

OBJECTIVES

AIMS

- To assess the flow of HCV patients across physician specialties in the United States over the course of care.
- To identify trends and gaps in the HCV care cascade in a real-world setting.
RESULTS

Frequency of Patients at Each Step in HCV Care Cascade

<table>
<thead>
<tr>
<th>Step in HCV Care Cascade</th>
<th>Frequency (N)</th>
<th>Proportion of Indicated Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening (first Ab test)</td>
<td>17,177,546</td>
<td>–</td>
</tr>
<tr>
<td>Detection (first positive Ab test)</td>
<td>974,277</td>
<td>5.7% of screened</td>
</tr>
<tr>
<td>Confirmatory test (first HCV RNA test [positive or negative] following positive Ab test)</td>
<td>527,340</td>
<td>54.1% of Ab+</td>
</tr>
<tr>
<td>HCV RNA+ (first positive HCV RNA test following positive Ab test)</td>
<td>337,846</td>
<td>64.1% of Ab+ RNA-tested</td>
</tr>
<tr>
<td>Awareness (first HCV RNA test irrespective of Ab test)</td>
<td>1,721,020</td>
<td>–</td>
</tr>
<tr>
<td>Diagnosis (first positive HCV RNA test irrespective of Ab test)</td>
<td>913,529</td>
<td>53.1% of RNA-tested</td>
</tr>
<tr>
<td>Genotype test (first genotype test following positive HCV RNA test)</td>
<td>487,263</td>
<td>53.3% of RNA+</td>
</tr>
<tr>
<td>Liver function test (first liver function test following positive HCV RNA test)</td>
<td>390,162</td>
<td>42.7% of RNA+</td>
</tr>
<tr>
<td>Diagnosis and linkage to care (positive HCV RNA test &amp; ≥2 HCV RNA lab tests)</td>
<td>172,835</td>
<td>10.5% of diagnosed linked to care</td>
</tr>
<tr>
<td>Treatment (after diagnosis)</td>
<td>18,220</td>
<td>–</td>
</tr>
</tbody>
</table>

HCV Care Cascade by Physician Specialty
- Over the course of the care cascade:
  - Decreased proportion of lab tests ordered by generalists and obstetrician / gynecologists (OB/GYN)
  - Increased proportion of lab tests ordered by HCV specialists

Patient Flow Across Physician Specialty: Gaps in Diagnosis to Genotype or Liver Function Testing
- 46.7% of patients diagnosed by HCV RNA test did not have an HCV genotype test
- 57.3% of patients diagnosed by HCV RNA test did not have a liver function test

Patient Flow Across Physician Specialty: Gaps in Detection to Confirmatory Test
- Among patients who tested HCV Ab+, 46% of patients did not receive confirmatory RNA testing
Patient Flow Across Physician Specialty: Gaps in Diagnosis\textsuperscript{a} to Treatment

- Out of patients who received at least 2 HCV RNA lab tests as part of HCV diagnosis, 90% did not receive treatment

Patient Flow Across Physician Specialty From Diagnosis to Treatment In Cirrhotic vs. Non-Cirrhotic Patients

- Among treated patients (n=18,220), there were no meaningful differences in patient flow trends between patients whose disease was classified as cirrhotic\textsuperscript{a} (n=2,296) vs. those whose HCV was non-cirrhotic (n=9,159)

\*Cirrhosis defined as FIB-4 score >5.2

LIMITATIONS

- The analysis cannot distinguish treatment from spontaneous clearance, as it relies on changes in viral load laboratory tests rather than prescription of treatment
- The analysis did not include patients without an HCV RNA test during or after therapy
- Liver fibrosis was assessed by ALT, AST, and platelet lab values and not diagnosis codes
- Although the study is based on a large dataset of laboratory data, results may not be generalizable beyond the study sample
CONCLUSIONS

- Significant gaps were identified in all stages of the HCV care cascade, particularly from screening to diagnosis and from diagnosis to treatment.
- Data indicate that although generalists initiate HCV screening in greater than one third of patients, a growing proportion of patients receive further assessments and treatment by HCV specialists.
- Timely screening, monitoring, and linkage to care by generalists and immediate treatment upon HCV diagnosis by specialists could help to reduce the gaps in the care cascade to accelerate HCV elimination.

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AbbVie participated in interpretation of data, review, and approval of the data presented. All authors contributed to development of this presentation and maintained control over final content.

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REFERENCES


DISCLOSURES

Sanika Rege: PhD student at the College of Pharmacy, University of Houston, and financially supported for graduate research work by AbbVie Inc. as a part of a summer internship.

Yuri Sanchez Gonzalez, Steven Marx, and Shivaji Manthena: Employees of AbbVie Inc. and may own stocks and / or options of the company.

Nancy Reau: Employee of Rush University Medical Center and consultant for AbbVie Inc., Gilead Sciences, Inc., Merck and Co., Inc., and Bristol-Myers Squibb Company; her institution has received research support from AbbVie Inc. and Gilead Sciences, Inc.