in 247 (2.8%) patients, including 3 (13%) HBsAg+, 12 (3%) HBsAg/-anti-HBc+, 112 (3%) HBsAg/-anti-HBc, and 30 (1%) never tested group. HT ≥3 was attributed to HBV reactivation in 3 patients including 2 with baseline HBsAg+, 50 with other causes of liver injury, and in the remaining patients the cause was unclear. Antiviral prophylaxis was started in 5 HBsAg+ patients prior to anti-TNF. Conclusions: In this large cohort of patients receiving anti-TNF, roughly half were tested for HBV prior to initiation of therapy. Reactivation of HBV occurred in 17% of HBsAg+ pts. A few cases of HT-3 were attributed to HBV reactivation but the cause of HT-3 was unclear in most cases.

Disclosures:
Mary Patricia Pauly - Grant/Research Support: Merck, Gilead, Roche
Anna S. Lok - Advisory Committees or Review Panels: Gilead, Immune Targeting System, MedImmune, Arrowhead, Bayer, GSK, Janssen, Novartis, ISIS, Tekmira; Grant/Research Support: Abbott, BMS, Gilead, Merck, Roche, Boehringer
The following people have nothing to disclose: Lue-Yen Tucker, Jean-Luc Szpakowski, David Baer, Joanna B. Ready, Jessica P. Hwang

**73 Projected Health and Economic Impact of Hepatitis C on the United States Medicare System From 2010 to 2024**

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Over a million Americans with hepatitis C virus (HCV) will age into Medicare by 2024. Information on the clinical and economic burden of HCV in Medicare is limited. We used primary data to estimate the clinical burden of HCV in Medicare in 2009 and forecast this burden until 2024 assuming 3 treatment strategies. Our Medicare administrative claims data contained 122,417 patient years of diagnosed HCV across the years 2002-2009. Using ICD-9-CM codes, we divided HCV patients into 6 stages; chronic HCV, cirrhosis, decompensated cirrhosis (DCC), hepatocellular carcinoma, transplant/post-transplant, and death occurring in a year with diagnosed HCV. We estimated incremental annual costs of each stage using a two-part health expenditure. We weighted the data to estimate the Medicare population in each HCV stage as of 2009 and estimated new cases of HCV entering Medicare from 2010-2024 using NHANES. We used a simulation to forecast future HCV health outcomes in Medicare, assuming no treatment (NT), treatment with pegylated interferon, ribavirin, and a protease inhibitor (PRPI), and an all-oral high efficacy regimen (AO). We estimated 796,232 patients with HCV in Medicare in 2009, of whom 63.1% had chronic infection only, 9.9% had cirrhosis, 14.7% had DCC, 2.5% had HCC, 2.6% transplant or post-transplant maintenance, and 7.2% died during 2009. We estimated that between 2010 and 2024, an additional 1,027,066 individuals with chronic HCV would enter the Medicare system. Of the cumulative 1,823,298 individuals with chronic HCV currently in or entering Medicare from 2010-2024, with NT we forecast that 661,060 (36.2%) would die from HCV or other causes while in a diagnosed state of DCC, HCC, or transplant/post-transplant. Treatment with PRPI reduced deaths in these states by these states by 29,720, and increased undiscounted QALYs by 1,562,119. Treatment with AO reduced deaths in these states by 126,163 and increased undiscounted QALYs by 7,692,906. The incremental costs of non-antiviral HCV treatment were higher in chronic HCV and cirrhosis than values used in prior cost-effectiveness models while costs for advanced stages were similar. Medicare contained more diagnoses for advanced disease in 2009 Medicare population than predicted by previous simulation. Treatment, especially treatment with interferon free, all oral regimens could substantially reduce morbidity and mortality from HCV within Medicare. Because of the large proportion of Medicare patients that enter the program in advanced stages of disease, treatment prior to Medicare entry is likely to be more effective in mitigating the health consequences of HCV.

Disclosures:
David B. Rein - Grant/Research Support: Gilead Sciences, Inc.
The following people have nothing to disclose: John S. Wittenborn, Danielle Liffmann, Joshua M. Barton

**74 Minimum target prices for production of Direct Acting Antivirals and associated diagnostics for developing countries**

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Background: Several combinations of Direct Acting Antivirals (DAAs) can cure Hepatitis C (HCV) in the majority of treatment-naïve patients, in a range of genotypes. Mass treatment programmes to cure HCV in developing countries are only feasible if the costs of treatment and monitoring are very low. This analysis aimed to estimate minimum costs of DAA treatment and associated diagnostic monitoring. Methods: Clinical trials of HCV DAAs were reviewed to identify combinations with consistently high rates of Sustained Virological Response (SVR) in different genotypes. For each DAA, molecular structures, doses, treatment duration and components of retro-synthesis were used to estimate costs of mass production. Manufacturing costs per gram of DAA were projected as formulated product cost, based upon treating at least 5 million patients/year (to arrive at volume demand) and a 40% margin for formulation. Costs of diagnostic support were estimated based on published developing country prices of genotyping, HCV antigen tests (to confirm infection pre-treatment and identify relapse/re-infection post-treatment), plus full blood count/clinical chemistry: Results: Predicted minimum costs for 12-week courses of HCV DAAs (patent expiry dates) were: US$50 for ribavirin 1200mg/day (generic), US$20 for daclatasvir 60mg/day (2027), US$102 for sofosbuvir 400mg/day (2029), US$90 for ledipasvir 90mg/day (2030), US$44 for MK-8742 (2028), and US$71 for MK-S172 (2030). Predicted minimum costs for 12 week courses of combination DAAs with the most consistent efficacy results were: US$122 per person for sofosbuvir+daclatasvir, US$152 for sofosbuvir+daclatasvir+ribavirin (US$304 for 24 weeks), US$192 for sofosbuvir+ledipasvir and US$115 for MK-8742+MK-S172. Diagnostic testing costs were estimated at US$90 for genotyping (if treatment not pan-genotypic), US$34 for two HCV antigen tests (lower detection limit 2000 IU/mL) and US$22 for two full blood count, ALT and creatinine tests (before and during treatment). Conclusions: Minimum costs of treatment and diagnostics to cure HCV were estimated at US$171-360 per person, without genotyping or US$261-450 per-person with genotyping. These cost estimates assume that similar large-scale treatment programmes for HIV/AIDS can be established for HCV. Treatments with proven pan-genotypic activity will be required to avoid expensive pre-treatment genotyping. Further reductions in price could be achieved through shorter durations of treatment, if efficacy is shown in future trials.

Disclosures:
75 Cost-Effectiveness of Novel Hepatitis C Drug Regimens Among Treatment-Experienced U.S. Veterans

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Background: It remains unclear whether treatment-experienced patients (partial- or null-responders) with hepatitis C (HCV) should begin treatment with current sofosbuvir (SOF)-based regimens or wait for all-oral, interferon-free regimens expected in 2015. Methods: We used a Markov model with one-year cycle length for a cohort of 50-year old Veterans with genotype 1, 2, or 3 HCV to compare treating: (1) all with current SOF regimens using American Association for the Study of Liver Disease recommendations; (2) METAVIR F3-4 disease with AASLD recommendations; and F0-2 disease in one year with future all-oral regimens; (3) all with SOF regimens using Veteran’s Health Administration guidelines; (4) all with future all-oral regimens in one year; or (5) only cirrhotic (F4) patients. For comparison, we included the previous standard of care (PEG/RBV ± telaprevir/boceprevir) and no treatment. We modeled the natural history of HCV and cirrhosis, assuming progression, morbidity, and mortality risks were lower after sustained virologic response (SVR). Analyses used a VHA perspective, with a 3% annual discount rate and lifetime horizon. We varied model inputs in one-way sensitivity analyses. Results: Preferred strategies included AASLD guidelines for genotypes 1 ($33,281/QALY) and 3 ($24,724/QALY), and VHA guidelines for genotype 2 ($38,853/QALY) [see Table], which were dominant (less costly, more effective) compared to waiting for all-oral regimens or treating based on fibrosis score. Results were sensitive to SVRs for SOF/PEG/RBV, SOF/simeprevir ± RBV and SOF/RBV, costs of future all-oral regimens, and strategies for treating genotype 3. Conclusion: For treatment-experienced U.S. Veterans, using current SOF-based regimens cost less and was more effective than current all-oral regimens, and strategies for treating genotype 3.

Cost-Effectiveness of Treatment Strategies for Treatment-Experienced Veterans with HCV

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Strategy</th>
<th>Costs (QALYs)</th>
<th>Incremental Cost-Effectiveness</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Treat None</td>
<td>$81,735/11.6</td>
<td>--</td>
</tr>
<tr>
<td></td>
<td>VHA</td>
<td>$83,222/17.8</td>
<td>$242/QALY</td>
</tr>
<tr>
<td></td>
<td>AASLD</td>
<td>$95,715/18.0</td>
<td>$53,281/QALY</td>
</tr>
<tr>
<td>2</td>
<td>Previous Standard of Care</td>
<td>$62,836/14.3</td>
<td>--</td>
</tr>
<tr>
<td></td>
<td>VHA</td>
<td>$66,167/18.2</td>
<td>$1,050/QALY</td>
</tr>
<tr>
<td></td>
<td>AASLD</td>
<td>$75,011/18.4</td>
<td>$38,853/QALY</td>
</tr>
<tr>
<td>3</td>
<td>Previous Standard of Care</td>
<td>$74,495/13.5</td>
<td>--</td>
</tr>
<tr>
<td></td>
<td>VHA</td>
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<tr>
<td></td>
<td>AASLD</td>
<td>$130,035/16.5</td>
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Disclosures: Vinod K. Rustgi - Grant/Research Support: Abbvie, BMS, Gilead, Achillion

The following people have nothing to disclose: Alexis P. Chidi, Shari S. Rogal, Cindy L. Bryce, Michael J. Fine, Chester B. Good, Larissa Myaskovsky, Allan Tsung, Kenneth J. Smith

76 Clinical efficacy of highly effective interferon-free therapy in patients with chronic HCV infection and compensatedadvanced hepatic fibrosis

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INTRODUCTION Independent of host characteristics, 95% of patients with chronic HCV infection attain SVR with interferon-free therapy. We aimed to assess the clinical efficacy of such therapies for the individual patient with compensated advanced fibrosis. METHODS A multicenter cohort study including all consecutively treated patients with chronic HCV infection and advanced hepatic fibrosis was performed. Clinical efficacy of therapy was assessed as the number needed to treat (NNT) to prevent 1 death in 5 years, which was calculated with the adjusted hazard ratio (HR) of SVR for all-cause mortality and the individual’s estimated 5-year survival based on our externally validated mortality risk score (including solely objective variables). [NNT = 1/([estimated 5y-survival without SVR]/[HR of SVR]) – estimated 5y-survival without SVR])RESULTS In total, 530 patients were followed for a median of 8.4 (IQR 6.4-11.4) years. Median age was 48 (IQR 42-56) years, 143 (27%) patients had bridging fibrosis and 387 (63%) had cirrhosis. SVR was attained by 192 (36%) patients. Cox analyses showed that SVR was independently associated with reduced all-cause mortality (adjusted HR 0.25, 95%CI 0.12-0.53), without significant interactions with any baseline variables. Among patients without SVR, the 5-year mortality rate was 8.6 (95%CI 5.7-11.5). For calculating the NNT, the HR of SVR was fixed at 0.25 and the SVR rate at 95%. The NNT to prevent 1 death in 5 years was 29, 15, 10
Treatment with Interferon (IFN) and Ribavirin (RBV)-Free Regimens with Ledipasvir (LDV) and Sofosbuvir (SOF) Improves Patient-Reported Outcomes (PRO) for Patients with Genotype 1 (GT1) Chronic Hepatitis C (CH-C): Results from the ION-1,2 and 3 Clinical Trials

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IFN+RBV negatively impacts patient-reported outcomes (PROs) in CH-C. AIM: To assess PROs in CH-C patients treated with RBV-free SOF+LDV regimens. METHODS: PRO questionnaires [Chronic Liver Disease Questionnaire-HCV (CLDQ-HCV), Short Form-36 (SF-36), Functional Assessment of Chronic Illness Therapy-Fatigue (FACT-F), and Work Productivity and Activity Index: Specific Health Problem (WPAI:SHP)] were administered at baseline, during, and post-treatment to GT1 CH-C subjects treated with SOF+LDV+RBV or SOF+LDV. RESULTS: 1,952 subjects were enrolled: age 53.1±10.2, 60.2% males, 11.5% with cirrhosis, 77.5% treatment-naïve. Duration of treatment consisted of 8 (N=431), 12 (N=867) and 24 weeks (N=654). Baseline demographics and psychiatric disorders were similar between treatment arms (all p>0.05). During treatment with the RBV-containing regimens, some PRO decrements (compared to baselines) were observed (up to -6.7% on a normalized 0-100% scale in 8 weeks, -6.3% in 12 weeks, -4.9% in 24 weeks; all p<0.05). On the other hand, patients receiving SOF+LDV regimens showed significant improvement of PRO during treatment (up to +7.4%, +7.0% and +6.7%, respectively; all p<0.0001). In fact, in the RBV-free arm, improvements in some of the PROs were observed starting as early as 2 weeks and maximized by the end of treatment. Throughout treatment, most of the PRO (HRQL, vitality, fatigue, work productivity) were superior for RBV-free regimens: up to +10.3% [8 weeks], +10.3% [12 weeks], and +7.4% [24 weeks] (p<0.0001). Receiving RBV was also an independent predictor of PRO impairment in multivariate analysis (beta up to -5.8%, p<0.005). Patients who achieved sustained viral eradication showed significant improvement of their PROs (up to +8.3%, p<0.0001). CONCLUSION: Ribavirin-free SOF+LDV regimen is associated with both high efficacy and significant improvement of PROs during treatment and after eradication of HCV.

Figure 1. PROs at the last day of treatment with RBV-containing regimen vs. RBV-free regimen.
Disclosures:
Patrick Marcellin - Consulting: Roche, Gilead, BMS, Vertex, Novartis, Janssen, MSD, Abbvie, Allos BioPharmaceuticals, Akenon, Akrion, Grant/Research Support: Roche, Gilead, BMS, Novartis, Janssen, MSD, Allos BioPharmaceuticals; Speaking and Teaching: Roche, Gilead, BMS, Vertex, Novartis, Janssen, MSD, Boehringer, Pfizer, Abbvie
Nezam H. Afdhal - Consulting: Merck, Vertex, Idenix, GlaxoSmithKline, Springbank, Gilead, Pharmasset, Abbott; Grant/Research Support: Merck, Vertex, Idenix, GlaxoSmithKline, Springbank, Gilead, Pharmasset, Abbott
Kris V. Kowdley - Advisory Committees or Review Panels: AbbVie, Gilead, Merck, Novartis, Tria Health, Boehringer Ingelheim, Ikaras, Janssen; Grant/Research Support: AbbVie, Beckman, Boehringer Ingelheim, BMS, Gilead Sciences, Ikaras, Janssen, Merck, Machida, Vertex
Stefan Zauzem - Consulting: Abbvie, Boehringer Ingelheim GMBH, Bristol-Myers Squibb Co., Gilead, Novartis Pharmaceuticals, Merck & Co., Idenix, Janssen, Roche Pharma AG, Vertex Pharmaceuticals
The following people have nothing to disclose: Zobair Younossi, Maria Stephanova, Sharon L. Hunt

78 Direct Care Costs for Hepatocellular Carcinoma in Patients with Hepatitis C Cirrhosis
Andreea M. Catana, Daniel Mansuri, Nidhi Sethi, Annie Vong, Saurabh Sethi, Nezam H. Afdhal; Hepatology, Beth Israel Deaconess Medical Center, Boston, MA

Hepatitis C is the commonest cause of hepatocellular cancer (HCC) in the US and the incidence is expected to increase further as the HCV population ages and develops more cirrhosis. Management of HCC is very heterogenous with multiple non-surgical and surgical options. The true cost of care of the HCV patient with HCC is unknown. AIMs: To evaluate the total direct health care costs of different approaches to HCC care in HCV patients in a major referral and transplant center. METHODS: 101 patients were randomly selected by computer from a list of all HCC patients with HCV between 2003 and 2013. All patients were biopsy-proven HCC or met UNOS OPTN criteria. Patients were categorized by the primary treatment modality of TACE, Cyberknife radiotherapy, radiofrequency ablation (RFA), chemotherapy or resection. Patients could have multiple treatment modalities and also go on to liver transplant, which is considered as a separate modality for cost determination. The direct cost includes the cost of the procedure, imaging, hospitalizations and all subsequent care of the HCC patient until death or transplant including cost of HCV treatment and immunosuppression post-transplant. Costs were derived from the Medicare fee schedule abstracted from the HCUP NIS sample 2011. Medication costs used were wholesale acquisition costs [Redbook 2014]. RESULTS: 101 patients, 82 male mean age 59 years (range 49-82) were included. All had HCV cirrhosis at diagnosis with a median CTP score of 7 (range 5-11) and a median MELD of 8. Genotype 1 (74%) and genotype 3 (16%) were predominant. 31 patients were HCV treatment naive, 65 treatment failures and 4 had a prior SVR. Majority of HCC were detected through cross-sectional radiological screening programs. Liver staging using the Barcelona score was A1 20%, A2 18%; A3 16% and A4 27%; B 12% and C 7%. Tumor size was mean 2.8 cms with a range from 1 – 14 cms. Mean follow up was 32 months with a range from 4 – 118 and 37 patients have died. Initial primary treatment modalities were RFA 53%; TACE 26%; Cyberknife 10%, resection 8% and chemotherapy 2%. 43 patients went on to liver transplantation. Calculated overall cost of HCC care for this group of patients was $22,030,108 for a mean cost per patient of $218,120. The 43 patients who underwent transplant accounted for $17,025,037 of the overall costs at $395,000 per transplanted patient compared to $5,817,300 for the non transplant patients for a mean cost of $100,299 per patient. CONCLUSIONS: Pharmacoeconomic studies of HCV treatment need to model real life estimations of true direct cost of HCC care.

Disclosures:
Daniel Mansuri - Stock Shareholder: Gilead Sciences
Nezam H. Afdhal - Consulting: Merck, Vertex, Idenix, GlaxoSmithKline, Springbank, Gilead, Pharmasset, Abbott; Grant/Research Support: Merck, Vertex, Idenix, GlaxoSmithKline, Springbank, Gilead, Pharmasset, Abbott
The following people have nothing to disclose: Andreea M. Catana, Nidhi Sethi, Annie Vong, Saurabh Sethi

79 Once Daily Sofosbuvir with GS-5816 for 8 Weeks with or without Ribavirin in Patients with HCV Genotype 3 without Cirrhosis Result in High Rates of SVR12: The ELECTRON2 Study
Edward J. Gane 1, Robert H. Hyland 2, Di An 1, John McNally 1, Diana M. Brainard 2, William T. Symonds 2, John G. McHutchison 1, Catherine A. Stedman 2; 1 Auckland Clinical Studies, Auckland, New Zealand; 2 Gilead Science, Inc, Foster City, CA; 3 Christchurch Clinical Studies Trust, Christchurch, New Zealand

Background: Sofosbuvir (SOF) is approved in combination with other direct-acting antiviral agents for the treatment of chronic HCV infection. GS-5816 is an investigational inhibitor of the HCV NS5A protein with picomolar antiviral activity across all HCV genotypes 1-6. In a phase 2 study, treatment with SOF+GS-5816 at a dose of 25 or 100 mg/day with or without ribavirin (RBV) was found to be safe and effective when administered for 12 weeks. In this study, we evaluated whether this regimen would also be effective for patients with HCV genotype 3 when administered for a shorter, 8-week duration. METHODS: 104 treatment-naïve, non-cirrhotic patients with chronic HCV genotype 3 infection were randomized to receive SOF+GS-5816 25 mg, SOF+GS-5816 25 mg+RBV, SOF+GS-5816 100 mg, or SOF+GS-5816 100 mg+RBV. Results: The majority of subjects were male (63, 61%), Caucasian (79, 76%), and had IL28B non-CC genotype (59, 57%). The median BMI was 25.8 kg/m2, and the median HCV RNA was 6.1 log10IU/ml. Two patients did not complete the study treatment: one discontinued due to an adverse event, and one withdrew consent. Both withdrew before completing two weeks of treatment, prior to achieving undetectable HCV RNA, and were lost to follow-up in the posttreatment phase. SVR12 rates are included in the table below. SOF+GS-5816 with or without RBV was well tolerated. Adverse events, which were more common in the RBV arm, were generally mild, and Grade 3/4 laboratory abnormalities were infrequent and were consistent with the safety profile of RBV. There was one SAE (seizure) that occurred after treatment was completed in a patient with a history of seizure disorder and suspected nonadherence to seizure medication. No toxicity attributable to SOF+GS-5816 at a dose of 25 or 100 mg/day with or without RBV was identified. Conclusions: Treatment with SOF+GS-5816 25 mg or 100 mg for 8 weeks, with or without RBV, resulted in high rates of SVR12 in GT3 HCV-infected patients. Treatment was well tolerated with no identified safety signal due to SOF or GS-5816. These data support further development of SOF+GS-5816 without RBV for treatment of chronic HCV.