

**PODIUM SESSION II:
INFECTIOUS DISEASE OUTCOMES RESEARCH STUDIES**
IN1
**INTERVIEWS WITH PATIENTS WITH CHRONIC HEPATITIS C (CHC) VIRUS
INFECTION DOCUMENT UNMET NEEDS, CONTENT VALIDITY, AND
COMPREHENSION OF PROS FOR CLINICAL TRIALS**

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OBJECTIVES: Recent advances in treatment for chronic hepatitis C (CHC) virus infection have shortened duration of treatment and increased the likelihood of treatment success. To understand what unmet needs remain with available CHC treatments, patient interviews explored what it is like to live with CHC infection and undergo CHC treatment. A subset of interviews also evaluated the content validity and comprehension of patient-reported outcome (PRO) questionnaires for use in CHC clinical trials. **METHODS:** Sixty-five patients with clinician-confirmed diagnosis of CHC infection provided informed consent and completed interviews in Germany (n=15), France (n=15), the USA (n=16), and Canada (n=19). Targeted sampling enrolled a demographically and clinically diverse sample. Concept elicitation (CE) interviews (n=58) using in-depth, open-ended questioning encouraged spontaneous discussion of patients' experience of CHC and its treatment. Patients in the USA and Canada also completed cognitive debriefing (CD) interviews using a 'think aloud' protocol to evaluate content validity and comprehension of the Fatigue Severity Scale (FSS, n=34), Work Productivity and Activity Impairment questionnaire for Hepatitis C (WPAI:Hepatitis C, n=7) and the SKINDEX-16 (n=12). Verbatim transcripts were translated to English and analyzed using thematic analysis. **RESULTS:** Treatment-related symptoms cause a significant burden for patients during treatment with tiredness (60.0%), sleep problems (57.5%), fatigue (50.0%), depression (45.0%) and itchy skin (40.0%) among the most commonly reported symptoms mentioned in CE interviews. In the 40 patients with CHC treatment experience, treatment-related symptoms led to discontinuation or lack of adherence in 25% and 10%, respectively. CD interviews confirmed that the questionnaires were relevant, understandable and easy to complete. Patients suggested minor wording changes that may make these questionnaires easier to complete. **CONCLUSIONS:** Treatment-related symptoms cause a significant burden for CHC patients and affect their adherence to treatment. The FSS, WPAI:Hepatitis C, and SKINDEX-16 are valid tools for PRO assessment in CHC clinical trials.

IN2
**CLINICAL CHARACTERISTICS AND TREATMENT DURATION AMONG PATIENTS
WITH CHRONIC HEPATITIS C VIRUS (HCV) INFECTION INITIATING DIRECT-
ACTING ANTIVIRAL THERAPY IN A LARGE COMMERCIAL INSURANCE
DATABASE IN THE UNITED STATES**

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OBJECTIVES: To describe patient characteristics and treatment duration among patients initiating telaprevir (T) or boceprevir (B) combination treatments with pegylated interferon and ribavirin (T/PR; B/PR) using administrative claims data. **METHODS:** A retrospective analysis of data from patients initiating T/PR or B/PR (index date) was conducted (MarketScan Research Databases 2011-2012). Study criteria included 7 months of continuous enrollment pre-index, 6 months post-index, diagnosis of chronic HCV and claim for PR within 40 days of index date. Pre-index comorbidities were ascertained using ICD-9-CM codes. Indicated T duration is 12 weeks (84 days); and minimum indicated B duration is 24 weeks (168 days; maximum 44 weeks). Medication Possession Ratios (MPR, adherence indicator) and persistence were estimated over the indicated duration of treatment for each drug respectively. **RESULTS:** A total of 3288 patients met the study criteria (T/PR, n=2582 [79%]; and B/PR, n=706 [21%]). Age (mean±SD) and gender were similar between cohorts (T/PR=53.7±8.4 years, 35% female; B/PR=53.7±8.7 years, 39% female). Patients treated with T/PR were more likely to have a claim for liver cirrhosis in the pre-index period (T/PR=24%; B/PR=18%, p=0.002). Prevalence rates of other comorbidities were similar between cohorts: diabetes (T/PR=14%; B/PR=13%), hypertension (T/PR=12%; B/PR=12%), and anxiety or depression (T/PR=11%; B/PR=11%). MPR (mean±SD) was 0.91±0.2 for T/PR patients in the first 84 days post-index and 0.78±0.3 for B/PR in the first 168 days post-index (p<0.001). At 84 days, 82% (95% confidence interval [CI]: 80%-83%) of T/PR patients were on therapy compared with 84% (CI: 81%-87%) of B/PR patients; 54% (CI: 51%-58%) of B/PR patients were still on therapy at 168 days. **CONCLUSIONS:** Chronic HCV-infected patients initiating telaprevir or boceprevir combination treatment had similar demographic characteristics and non-liver comorbidities. Cirrhosis was more prevalent among patients receiving telaprevir combination treatment. Data suggest adherence to indicated duration of treatment was higher among telaprevir patients than boceprevir patients.

IN3
**THE BURDEN OF HCV TO INSURERS IN THE UNITED STATES: TRENDS IN
HEALTH CARE RESOURCE UTILIZATION 2002-2012**

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OBJECTIVES: Trends in health care utilization among HCV patients have demonstrated marked increases between 1994 and 2001, particularly among individuals aged 40 to 60 years. Furthermore, the proportion of treated individuals who achieve disease cure remains relatively low. This has potentially

resulted in a large economic burden, as HCV leads to costly liver disease and other morbidity. The objective of this study was to examine trends in HCV-related health care utilization by insurer between 2002 and 2010 in the US. **METHODS:** Years 2002-2010 of the National Inpatient Sample (NIS) data set of hospital admissions from the Healthcare Cost and Utilization Project (HCUP) were utilized in order to determine the number of adult hospital admissions occurring to HCV-infected patients (identified by ICD-9 codes). These data included a total of 71.7 million hospital admissions from 1,051 US hospitals. The number of admissions occurring to HCV-infected patients was recorded for each year, as well as total charges. Trends over time were compared for three insurers: Medicaid, Medicare, and private. **RESULTS:** Of the 71 million admissions examined over the study period, 5,350,991 were admissions for HCV-infected adults. More HCV-related admissions were covered by Medicaid and Medicare than private insurance. In 2002, total HCV-related charges were \$693M for admissions covered by Medicare, \$708M for Medicaid, and \$579M for private insurance (costs adjusted to 2010 values). Between 2002 and 2010, total HCV-related charges increased most for Medicare (84%), followed by Medicaid (77%) and private insurance (16%). HCV-related admissions covered by Medicare, Medicaid and private insurance increased commensurately by 84%, 77% and 16%, respectively. **CONCLUSIONS:** Use of inpatient care for HCV-infected patients has increased rapidly. Increases in the number of HCV patients who seek care, as well as possible increases in the intensity of care and/or escalation in hospital charges has resulted in nearly doubling HCV-related charges from 2002-2010.

IN4
**DIRECT AND INDIRECT COST BURDEN OF CHRONIC HEPATITIS C INFECTION IN
PRIVATELY-INSURED PATIENTS, STRATIFIED BY LIVER DISEASE SEVERITY**

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OBJECTIVES: To assess the direct health care and indirect work-loss cost burden of chronic hepatitis C virus (HCV) infection and stratify the economic burden by disease severity. **METHODS:** Health insurance claims from 60 self-insured US companies and disability data for employees in 29 of these companies covering the period 01/2001-09/2011 were analyzed. Adult patients with ≥2 diagnosis claims of chronic HCV infection and no HIV diagnosis were selected. A 6-month baseline period of continuous eligibility preceding HCV diagnosis was imposed. HCV patients were stratified into groups of non-cirrhotic, compensated cirrhotic, and end-stage liver disease (ESLD). HCV patients were matched 1:1 with non-HCV controls using an exact factors and propensity score matching algorithm. Matched cohorts were compared for direct (pharmacy dispensings and medical services) and indirect (disability and medically related absenteeism) costs using per-patient per-year (PPPY) cost differences. **RESULTS:** Both cohorts (N=9,841 for each) were well matched with respect to age (mean=52 years), gender (female=39%), Quan-Charlson comorbidity index (mean=0.5), share of employees with disability coverage (26%), and non-HCV related co-morbidities. HCV patients incurred significantly greater direct and indirect costs relative to non-HCV patients (PPPY direct costs: \$16,721 vs. \$6,063, cost difference [95% CI] = \$10,503 [9,683-11,361], P<0.001; PPPY indirect costs: \$3,310 vs. \$1,723, cost difference [95% CI] = \$1,523 [1,248-1,794], P<0.001). The direct incremental cost burden associated with HCV increased with disease severity (incremental direct cost [95% CI]: non-cirrhotic HCV = \$5,536 [4,844-6,333]; compensated cirrhotic = \$6,833 [5,326-8,474]; ESLD = \$22,466 [20,182-24,729], P<0.001 for all comparisons versus matched non-HCV controls in each sub-category). Among the subset of employees with disability coverage, the incremental indirect cost burden associated with HCV also increased with disease severity. **CONCLUSIONS:** Chronic HCV infection was associated with significant direct health care and indirect work-loss cost burdens. The magnitude of the cost burden increased with disease severity.

PODIUM SESSION II:**MEDICATION ADHERENCE STUDIES****MA1**
**IMPACT OF A VALUE-BASED COPAYMENT WAIVER BENEFIT ON MEDICATION
ADHERENCE AND SPENDING**

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OBJECTIVES: Most copayment waiver (value-based benefit design) programs have been applied at the individual level. In this study we evaluate the impact of a family-based copayment waiver at a large employer. **METHODS:** Enrollees with diabetes in eligible health and all of their family members (regardless of health status) were automatically enrolled in a copayment waiver (\$0 copay) benefit beginning January 2011 for diabetes, cardiovascular, and lipid lowering medications, screenings, and related medical services. The study included 708 enrollees who were propensity score matched to a comparison group (total n=1416) within nine similar companies without these benefits. An enrollee-calendar quarter panel data set was constructed from 2009-2011. Program impact was measured as the change in outcomes (medication adherence and health care spending) post-program in the copayment waiver group relative to the change in the comparison group (difference-in-differences). Adherence was defined as percent of days covered by a medication class greater than or equal to 80%. A falsification test of adherence to asthma and migraine medications, where copayments did not change, was conducted. **RESULTS:** Prior to program implementation, enrollees in the value-based program had a similar level of