INFECTION—Methods & Concepts

PATTERNS OF ANTIVIRAL THERAPY USE AMONG CHRONIC HEPATITIS C PATIENTS ENROLLED IN MEDICAID

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OBJECTIVES: To describe medication use patterns among patients with chronic Hepatitis C virus (HCV) infection in a Medicaid population. METHODS: Florida Medicaid claims from January 2000 through December 2004 were analyzed for persons with a diagnosis of HCV infection (ICD-9 codes: 70.50 or 70.54). The date of the first pharmacy claim for ribavirin, interferon, peg-interferon, or peg-interferon plus ribavirin served as the index date. To be included in the analysis, patients had to be enrolled for 3 months prior to the index date and "Y12 months after the index date. Patients with enrollment gaps exceeding 3 months (cumulative) were excluded. Treatment patterns assessed included: duration of treatment, number of refills, and treatment persistence. Duration of treatment was defined as days (date of last claim minus the index date) plus days' supply of the last claim. Treatment was considered discontinued if the number of uncovered days (based on last claim date and days' supply) exceeded 34. Treatment persistence was defined as days from the index date to the first event of treatment discontinuation in the treatment duration. A Kaplan-Meier plot provided the probability of remaining persistence with drug over time. RESULTS: Of 10,016 patients with HCV diagnosis, 1,127 antiviral therapy users met study inclusion criteria. The majority of patients (90.9%) was treated with combination therapy and had multiple interferon claims in the study period. Mean duration of treatment was 7.1 (±4.33) months. 25.7% of patients received therapy <3 months; 25.9%, 3–6 months; 27.2%, 7–12 months; and 21.1%, >12 months. Mean number of refills was 6.2 (±4.0). Median time to discontinuation was 203 days (6.8 months). CONCLUSION: Half of patients beginning antiviral therapy for chronic hepatitis C discontinued treatment within 24 weeks. Although some patients likely discontinued therapy because of non-response or HCV genotype, additional research to identify reasons for treatment discontinuation is warranted.

ANALYSES FROM ROUTINE PATIENT CARE SETTINGS FOR CLINICAL RESEARCH PURPOSES

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OBJECTIVES: Comparative effectiveness research using real-world patient data collected outside of clinical trials is expected to increase dramatically in the coming decade as electronic medical records (EMRs) are more widely adopted in routine patient care settings. Retrospective analyses of such data to answer clinical questions will be easier than ever to perform, but with greater ease comes greater threats to validity. Our objective here is to describe a methodology we developed to move beyond the traditional chart review towards a way to use clinical practice data for reliable comparative effectiveness assessments. METHODS: We recently planned and performed an analysis of retrospective data from routine patient care settings from several liver clinics (with varying use of clinical databases) to compare the relative effectiveness of two commonly used treatment regimens in adults with chronic HCV infection. Participating clinicians in Europe and the US were initially identified via authorship of published abstracts of single center case series of HCV patients. A project protocol was prospectively developed to define site and patient eligibility criteria, and to provide sites with a template for transmission of specific data elements for analysis. Data privacy, security, and IRB issues were addressed, and a statistical analysis plan included sample size calculations and hierarchical linear modeling methods to adjust both site and patient level variables concurrently. Agreement to disseminate results regardless of findings was obtained up-front from all investigators and the corporate sponsor. RESULTS: N/A CONCLUSION: A rigorous and standardized methodology is urgently needed to advance the science of clinical effectiveness research using real-world patient records, especially those obtained from EMR systems. The approach described herein could serve as a useful case in point.

ESTIMATING THE GDP SAVED DUE TO AIDS TREATMENT

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OBJECTIVES: A recent study estimated that treatment for AIDS saved 2.8 million life-years (Wielenksy, JID, June 2006). This study attempts to estimate the economic impact of those life-years saved on the U.S. economy. METHODS: Beginning with 1987, the number of life-years saved per patient was multiplied by the real per capita GDP in the U.S. (base year 2000) to determine the real per capita GDP saved. These figures were then summed for patients initiating therapy through 2003 to determine the total GDP per capita saved. This sum was also multiplied by the number of patients receiving treatment to determine the total GDP saved throughout the period. The impact on the per capita GDP for the entire U.S. population was calculated by subtracting the GDP saved from the total GDP each year and then dividing by the total U.S. population. GDP in out-years is estimated by the average increase in real GDP from 1987 to 2003. RESULTS: For patients initiating therapy from 1987 to 2003, the total GDP saved is $100.8 billion through 2015, or $166,000 GDP per capita receiving treatment. The GDP saved ranged from $289 million in 1991 to $7.6 billion in 2003. The impact on per capita GDP for the entire U.S. population ranged from less than $0.81 saved in 1991 to nearly $26.55 in 2003. CONCLUSION: The impact of AIDS drug treatment on the U.S. economy is significant and should be considered during analysis of the costs and benefits of AIDS treatment in U.S. Further analysis is needed to assess similar impact of AIDS treatment in other countries.

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