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**TITLE:** Patients Meeting 'Highest' or 'High' Priority for HCV Treatment in the Chronic Hepatitis Cohort Study (CHeCS)
**PRESENTER:** Fujie Xu
**AUTHORS/INSTITUTIONS:** F. Xu, J.W. Ward, S.D. Holmberg, Division of Viral Hepatitis, CDC, Atlanta, Georgia, UNITED STATES|S.C. Gordon, Henry Ford Health System, Detroit, Michigan, UNITED STATES|
**ABSTRACT BODY: Sponsorship<br>This study was sponsored by:<br>If this abstract was not sponsored please indicate 'none'. (Late-Breaking Submission):** CHeCS was funded by the CDC Foundation, which currently receives grants from AbbVie, Gilead Sciences, and Janssen Pharmaceuticals, Inc. Past funders include Genentech, A Member of the Roche Group and Vertex Pharmaceuticals. Past partial funders include Bristol-Myers Squibb. Granting corporations do not have access to CHeCS data and do not contribute to data analysis or writing of manuscripts.
**ABSTRACT BODY:**
**Abstract Body:** Objective: The new AASLD/IDSA treatment guidelines (August 2014) formalized criteria for prioritizing care among patients seeking treatments for hepatitis C virus (HCV) infection. We sought to quantify the number and percentage of patients meeting the criteria of 'highest' or 'high' priority for HCV treatment, using data from an ongoing cohort study. Methods: Data were drawn from the Chronic Hepatitis Cohort Study (CHeCS), an ongoing observational cohort study of patients receiving care for chronic HBV or HCV infections at 4 integrated US healthcare systems: Geisinger Health System, Danville, PA; Henry Ford Health System, Detroit, MI; Kaiser Permanente-Northwest, Portland, OR; and Kaiser Permanente-Honolulu, HI. We analyzed clinical data for HCV-infected patients still living as of December 2011, excluding those who had died, had achieved sustained virologic response, or had received a liver transplant. Patient's fibrosis stage was based on FIB-4 scores derived from serum tests or biopsy results, if available. The FIB-4 scores cutoff values of 2.5 and 1.6 were the upper limits of mean FIB-4 scores in CHeCS patients who had biopsy-confirmed Metavir F3 or F2 stage of fibrosis, respectively. Laboratory tests and ICD-9 codes were used to identify patients with extrahepatic manifestations and qualifying comorbidities. Some conditions, like severe cryoglobulinemia and debilitating fatigue, were not assessed due to lack of a reliable laboratory test or ICD-9 code. Results: Of 10,786 patients with HCV infection, 2,339 (21.7%) had a biopsy in 2004 or later, and 7,777 (72.1%) had no biopsy but had laboratory results available to a calculate FIB-4 score; only 6.2% had neither. Of the 10,116 patients that could be staged by biopsy or FIB-4 score (Table), 3,364 (33.3%) were staged at F3 or higher based on the latest biopsy or FIB-4 score (Table), using a cutoff of FIB4 ≥2.5. Only 3271 (32.3%) had less than F2 fibrosis and did not have comorbid conditions we could assess, thus these patient did not qualify for 'highest' or 'high' priority for treatment. Conclusions: In a large U.S. cohort of patients with HCV infection at least two-thirds of patients would meet the 'highest' or 'high' criteria for treatment according to the new treatment guidelines. However, these patients' immediate access to new therapies is challenged by treatment costs and other barriers.
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**TABLE TITLE:**

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|---|---|
| Patients staged by biopsy or FIB-4 score | n=10 116 |
| F3 (biopsy staged F3 or higher or FIB-4 score ≥2.5) | 3 364 (33.3) |
| Less than F3 with chronic kidney disease | 475 (4.7) |
| F2 (biopsy stage F2 or FIB-4 score ≥1.6 but <2.5) | 2 139 (21.1) |
| Less than F2 with HIV co-infection | 70 (0.7) |

| | |
|---|---|
| Less than F2 with HBV co-infection | 22 (0.2) |
| Less than F2 with NASH | 135 (1.3) |
| Less than F2 with Diabetes | 640 ( 6.3) |
| Not meeting ‘highest or high’ priority criteria | 3 271 (32.3) |

TABLE FOOTER: