Senate HCV Drug Pricing Investigation

On December 1st Senate Finance Committee Ranking Member Ron Wyden, D-Ore., and senior committee member Chuck Grassley, R-Iowa, released a 144-page report detailing the results of their 18-month investigation of Gilead Science’s pricing and marketing of Hepatitis C Virus (HCV) drugs sofosbuvir (Sovaldi) and sofosbuvir/ledipasvir (Harvoni). The full report, as well as the various appendices, and a recording of the press conference can be found here. Sovaldi was FDA approved in December of 2013 and had an initial cost of $84,000 for a 12-week regimen. Harvoni was approved by the FDA in October of 2014 with a price of $94,500 for the 12-week course.

The report’s primary finding was that Gilead priced its HCV drugs to maximize revenue and was not necessarily concerned with the public health impact and access issues that resulted from a high sticker price. Indeed, internal documents obtained by the investigators showed that Gilead had projected that a lower drug cost would allow more patients to be treated. Ultimately, public health institutions like Medicaid, Medicare, the Bureau of Prisons, and the Veteran’s Affairs Administration felt the brunt of the drug pricing. As a result, many institutions put access restrictions on Gilead’s HCV drugs. Rebates offered by Gilead were often inversely proportional to the number of restrictions imposed by insurance providers (e.g. the more restrictions the less the rebate). In 2014, despite a marketed increase in the amount of Medicaid dollars spent on HCV medications (a total of $1.3 billion in 2014 alone), only 2.4% of the nation’s HCV-infected Medicaid beneficiaries were treated.

The clinical effectiveness of new HCV medications like Sovaldi, Harvoni, and Abbvie’s Viekira Pak are undeniable, but the price is clearly limiting access to care. The Senators’ report of Gilead’s pricing strategy raises some important issues, but the authors stopped short of making any regulatory or legislative proposals.

—Janelle Stokely
As the public’s awareness of viral hepatitis increases, so do the number of calls for services received by State and Local Health Departments (LHDs). The MDHHS Viral Hepatitis Prevention Workgroup set out to create a comprehensive Viral Hepatitis Resource Guide and Directory to be used by the public, providers, and local health officials throughout Michigan. The objective was to create a one-stop-shop for all related viral hepatitis health service questions. The first version of the resource guide was recently published to [www.mi.gov/hepatitis](http://www.mi.gov/hepatitis) and covers hepatitis A and B vaccination, viral hepatitis testing, resources for treatment, patient assistance, how to enroll in health insurance, and substance abuse treatment services.

To gather the information included in this Directory, Viral Hepatitis Workgroup members contacted each Local Health Departments (LHDs) communicable disease staff by phone to ascertain the LHD referral process and the agencies providing hepatitis services in the various jurisdictions. Additionally, LHDs were encouraged to complete an online survey that included questions about the health departments internal hepatitis services such as immunizations, testing, care and treatment as well as substance use services and access to health insurance.

Our goal is to make the guide as comprehensive as possible. Therefore, if you are aware of viral hepatitis resources not included in the directory, please let us know. The resource guide is a “living document” and we will continuously update as more information comes in. The fourth page of the resource guide contains a form which can be completed and e-mailed to us at MDHHS-Hepatitis@michigan.gov.

-Chardé Fisher

Happy New Year!

Toward a Better Estimate of National HCV Prevalence

The National Health and Nutrition Examination Survey (NHANES) is often used to derive an estimate of how many people living in the United States are infected with hepatitis C. NHANES assesses the health of approximately 5000 adults and children in the United States each year. However, NHANES does not survey some populations that might be at increased risk of being HCV infected such as those in the military, the homeless, incarcerated, hospitalized, institutionalized, those that reside in a nursing home or live on an Indian reservation.

Brian Edlin and colleagues recently published an article in Hepatology which seeks to improve the overall estimate of hepatitis C prevalence in the United States by estimating the prevalence of hepatitis C in the populations excluded from NHANES. They conclude that the true seroprevalence of hepatitis C may be as high as 6 million and the number of people infected with hepatitis C may be up to 4.7 million. –Kim Kirkey

Happy New Year!
In December, the Congressionally-approved budget lifted the ban thus giving permission for federal dollars to be spent on needle exchange programs. Interestingly enough, that portion of the spending bill was spearheaded by Kentucky Republicans Rep. Hal Rogers and Sen. Mitch McConnell, showing the growing bipartisan support for this evidence-based intervention. The language stipulates that federal dollars cannot be used to purchase needles themselves, but can be used for everything else (e.g. staffing, mobile vans, gas, rent). Needles, in fact, are only a small piece of a needle exchange program. Co-location of services such as substance abuse counseling and treatment referral, testing for communicable diseases, safe-sex education, and provision of clean works are also important components of the programs. These other services are particularly important for HCV.

While needle exchange has proven effective in thwarting the spread of HIV among persons who inject drugs, multiple interventions may be required to stem the transmission of HCV in this population, largely due to the higher transmissibility of HCV. For instance, some modeling studies have suggested that needle exchange plus clean works plus HCV testing and treatment plus opioid substitution therapy are all necessary to fully combat the HCV epidemic among persons who inject drugs.

In order to warrant the use of federal funds for syringe exchange programs, jurisdictions will have to work with the state and CDC to justify a need (i.e. document an increase in HIV and HCV in the population related to injection drug use). We hope, in the future, that we can assist jurisdictions in making the case for needle exchange programs and improving drug user health in Michigan and ultimately reducing the burden of HCV in the population.

–Joe Coyle
Viral Hepatitis Reporting and Case Classification, 2016

As many of probably heard already, there are some changes coming to viral hepatitis reporting and case classification coming in 2016. One such change is the new CDC/CSTE case classification criteria for acute and chronic Hepatitis C Virus (HCV). We will be replacing the old case classification flow chart with the 2016 case classification table below. Please look for this to be uploaded to www.mi.gov/hepatitis and www.mi.gov/cdinfo before the end of the year. We hope that you find this tool helpful and intuitive.

In addition, in 2016 we are asking that laboratories and providers report pregnancy status on any individual being reported with Hepatitis B Virus (HBV) or HCV if possible. The major commercial laboratories already report pregnancy status on positive HBsAg results. CDC and MDHHS are now encouraging all labs and providers to do the same. Pregnancy status on HCV results is also requested due to increases in perinatal HCV infection which we have previously discussed. Automation of reporting of pregnancy status will increase the number of HBsAg-positive pregnancies identified and will improve the timeliness of public health response.

Finally, MDHHS is also requesting all HBsAg and anti-HBs results be reported for children 5 years old and younger (including positive, negative, and indeterminate results). This information will help the MDHHS Perinatal Hepatitis B Prevention Program track post-serologic testing in children that were potentially exposed to HBV. MDHHS is encouraging this reporting in 2016 with the plan for a hard roll out in 2017.

If there are questions or concerns please do not hesitate to contact your regional epidemiologist or the Viral Hepatitis Unit.

-Joe Coyle and Pat Fineis

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Save the Date
4/1 – Michigan Epi Conference
5/18 – MDHHS CD Conference
6/19-6/23 - CSTE Conference
2016 – MDHHS Viral Hepatitis Unit Local Health Department Trainings (email us for more info at: MDHHS-Hepatitis@michigan.gov)

Helpful Links
www.michigan.gov/hepatitis
www.michigan.gov/injectionsafety
www.michigan.gov/hepatitisb
www.mi.gov/cdinfo
www.michigan.gov/hai
CDC Hepatitis
CSTE HCV Subcommittee
Know More Hepatitis Campaign
Know Hepatitis B Campaign
CDC Hepatitis Risk Assessment
Hepatitis A
Hepatitis B
Hepatitis C
USPSTF
AASLD
Institute of Medicine Report
One and Only Campaign
Injection Safety Resources
Hepatitis Occupational Exposure Guideline
Blood Glucose Monitoring
ACIP Hepatitis B Vaccination Guide