Hepatitis Headlines

Issue 11
January
2016

Viral Hepatitis Surveillance and Prevention Unit, Michigan Department of Health and Human Services
www.michigan.gov/hepatitis

In this issue

Federal Needle Exchange Ban Lifted

The relationship between injection drug use and Hepatitis C Virus (HCV) is well understood and something we have highlighted in previous newsletters. With the outbreak of HCV and HIV in southern Indiana the role of needle exchange programs in combatting the transmission of blood-borne pathogens has been garnering a lot of attention. It has been known for some time that needle exchange programs are an effective way to mitigate HIV transmission among people who inject drugs, but since 1998 the use of federal funding for these programs have been banned. The fear has been that providing clean needles in exchange for dirty/used needles would encourage drug use, but data exists to prove that needle exchange programs do not lead to increases in drug use. **(continued on page 3)**

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

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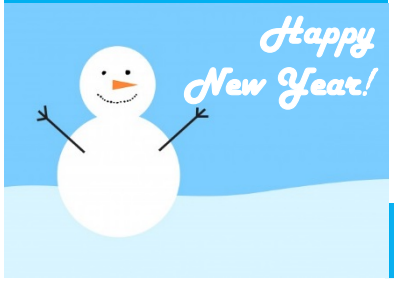
MDHHS Michigan Department of Health & Human Services

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.

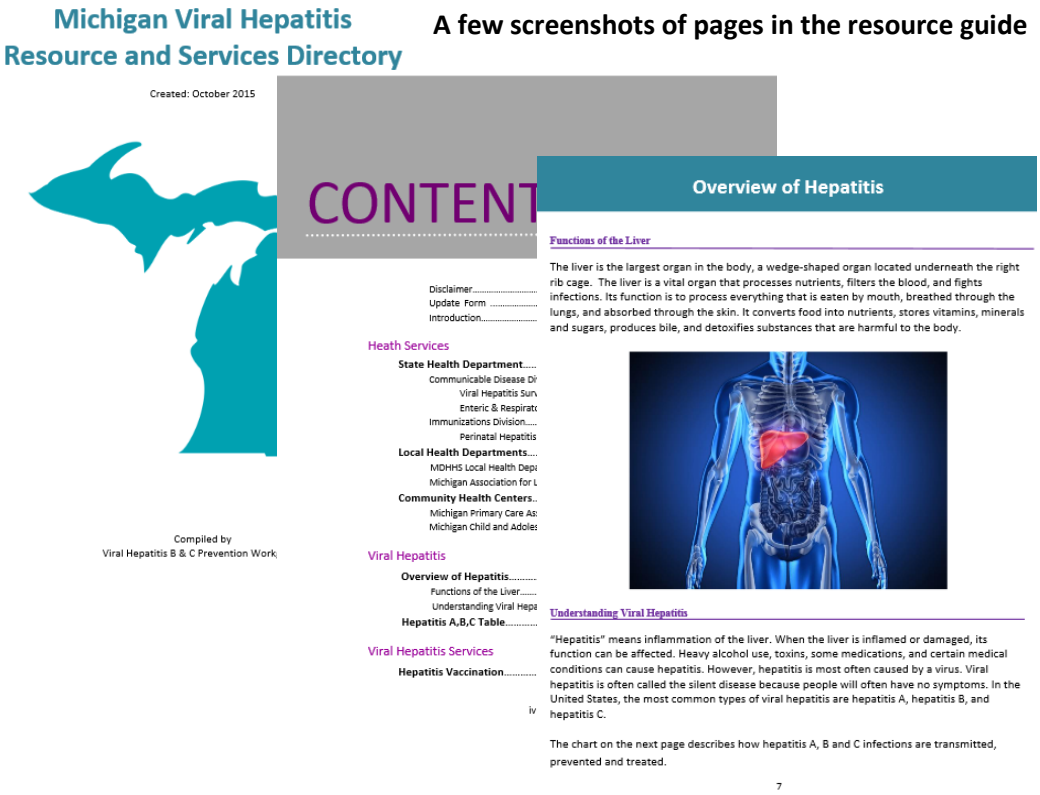
Brian Edlin and colleagues recently published an article in Hepatology which seeks to improve the overall estimate of hepatitis C prevalence in the United States by estimating the prevalence of hepatitis C in the populations excluded from NHANES. They conclude that the true seroprevalence of hepatitis 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



Michigan Viral Hepatitis Resource Guide and Directory

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** 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.

A few screenshots of pages in the resource guide


Michigan Viral Hepatitis Resource and Services Directory

Created: October 2015

Compiled by
Viral Hepatitis B & C Prevention Work

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Overview of Hepatitis

Functions of the Liver

The liver is the largest organ in the body, a wedge-shaped organ located underneath the right rib cage. The liver is a vital organ that processes nutrients, filters the blood, and fights infections. Its function is to process everything that is eaten by mouth, breathed through the lungs, and absorbed through the skin. It converts food into nutrients, stores vitamins, minerals and sugars, produces bile, and detoxifies substances that are harmful to the body.

Understanding Viral Hepatitis

"Hepatitis" means inflammation of the liver. When the liver is inflamed or damaged, its function can be affected. Heavy alcohol use, toxins, some medications, and certain medical conditions can cause hepatitis. However, hepatitis is most often caused by a virus. Viral hepatitis is often called the silent disease because people will often have no symptoms. In the United States, the most common types of viral hepatitis are hepatitis A, hepatitis B, and hepatitis C.

The chart on the next page describes how hepatitis A, B and C infections are transmitted, prevented and treated.

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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.

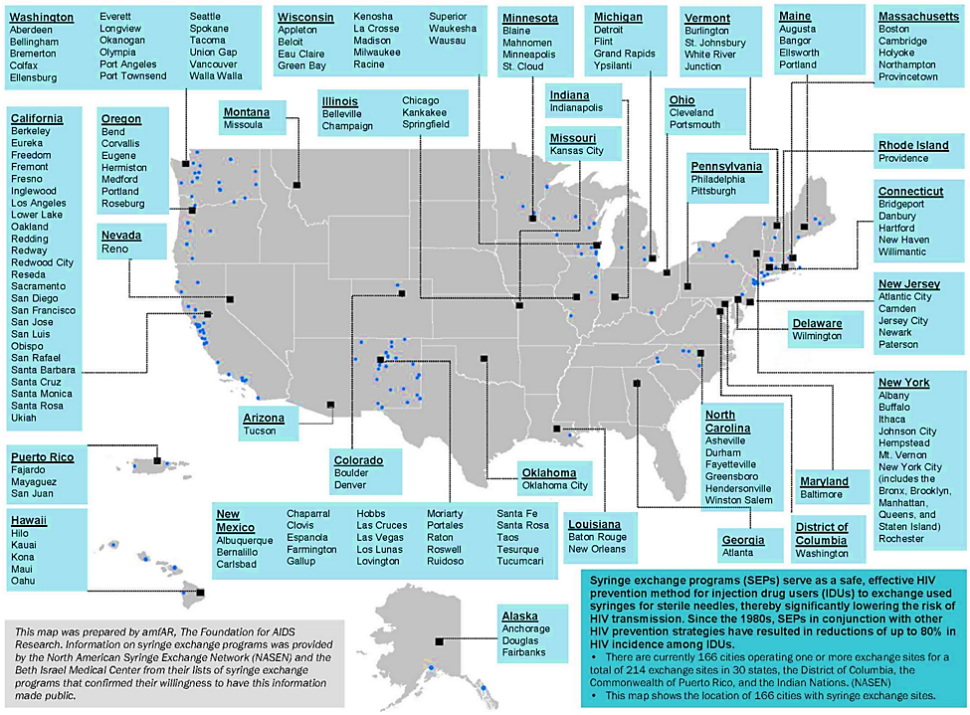
Our goal is to make the guide as comprehensive as possible. Therefore, if you are aware of viral hepatitis resources not included in the directory, please let us know. The resource guide is a "living document" and we will continuously update as more information comes in. The fourth page of the resource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

-Chardé Fisher

Federal Ban on Needle Exchange Lifted

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.

Syringe Exchange Program Coverage in the United States –July 2013



While needle exchange has proven effective had 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

December 8th Michigan Medicaid P&T Committee

Michigan Medicaid's Pharmacy and Therapeutics Committee recommends what drugs are added to the Medicaid formulary. Up to this point, no criteria had existed for coverage of newer HCV direct acting antivirals (DAAs). On December 8th it was decided that newer HCV DAAs should be added to the formulary. While no specific drugs were discussed or the timeline for implementation, criteria for coverage were voted on and approved. To be considered for treatment with newer HCV DAAs the following criteria must be met:

- **Patients must have an F3 or F4 Metavir score**
- **Patients must be evaluated by a specialist**
- **Patients must abstain from intravenous drugs and alcohol abuse**

The P&T Committee expressed interest in closely monitoring drug utilization and conducting modeling studies to better understand the impact this decision will have. We hope to be able to share additional details as Medicaid works to operationalize these new criteria.

-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.

2016 Hepatitis C Case Classification Table	Discrete Onset of at least one Symptom[1] **AND** either Jaundice **OR** ALT>200 IU/L	
	No **OR** Unknown	Yes
HCV Antibody Positive **ONLY**[2]	Probable, Chronic	Probable, Acute
Any HCV Nucleic Acid Test Positive[3] **OR** HCV Antigen Positive	Confirmed, Chronic	Confirmed, Acute[4]

[1] Symptoms include either fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, or abdominal pain
[2] Any antibody result, regardless of the signal-to-cutoff ratio; includes rapid tests
[3] Nucleic Acid Tests for HCV include Quantitative HCV RNA tests, Qualitative HCV RNA tests, and HCV Genotype tests
[4] Automatically classify as Confirmed, Acute for a seroconversion; if a negative HCV lab test is followed within 12 months by a positive HCV lab test

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**

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.michigan.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

ISSUE #11 January 2016 (Issued 2/1/2016)

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