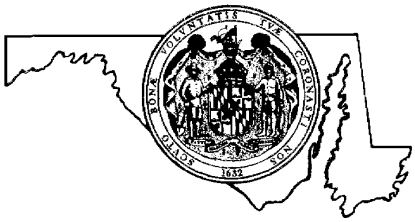
Craig Tanio, MD
CHAIR

Ben Steffen
EXECUTIVE DIRECTOR

STATE OF MARYLAND



MARYLAND HEALTH CARE COMMISSION

4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215
TELEPHONE: 410-764-3460 FAX: 410-358-1236

October 24, 2012

The Honorable Thomas Middleton, Chairman
Senate Finance Committee
Miller Senate Office Building, 3 East Wing
11 Bladen Street
Annapolis, MD 21401

The Honorable Peter A. Hammen, Chairman
House Health and Government Operations Committee
Room 241, Taylor House Office Building
Annapolis, MD 21401

Dear Chairmen Middleton and Hammen:

During the 2012 session of the General Assembly, House Bill 641 (Chapter 669, Acts of 2012)- Hepatitis B and Hepatitis C Viruses- Public Awareness, Treatment, and Outreach was passed which requires the Department of Health and Mental Hygiene to take certain steps to increase public awareness of Hepatitis B and Hepatitis C. The bill had an effective date of October 1, 2010.

The Commission is required to examine existing research findings related to health disparities in the effectiveness of medical treatment of African Americans with hepatitis C. The report is due to the Governor and General Assembly by December 1, 2012.

Due to staffing shortages at MHCC the completion of this report has been delayed. MHCC is requesting an extension until July 1, 2012.

If you have any concerns please do not hesitate to contact me at 410-764-3565.

Sincerely,

Ben Steffen
Executive Director

cc: Patrick Carlson
Erin Hopwood

Craig Tanio, M.D.
CHAIR

STATE OF MARYLAND

Ben Steffen
EXECUTIVE DIRECTOR

MARYLAND HEALTH CARE COMMISSION

4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215
TELEPHONE: 410-764-3460 FAX: 410-358-1236

June 9, 2014

The Honorable Joan Carter Conway
Chair
Education, Health and Environmental Affairs
2 West Miller Building
Annapolis MD 21401

The Honorable Peter A. Hammen
Chair
Health and Government Operations
Room 241 House Office Building
Annapolis MD 21401

RE: House Bill 641 of 2012

Dear Chairwoman Conway and Chairman Hammen:

Please find the enclosed report requested in House Bill 641 of 2012, Treating Hepatitis C in the African American Community Recommendations from Experts in the Field.

Please do not hesitate to contact me at 410.764.3565 if you have any questions.

Sincerely,

Ben Steffen
Executive Director

Enclosure

cc: President Miller
Speaker Busch
Sarah Albert

Treating Hepatitis C in the African American Community

Recommendations from Experts in the Field

Report to the Maryland General Assembly

June 2014

Maryland Health Care Commission

Craig Tanio, MD, MBA
Chair

Ben Steffen
Executive Director

House Bill 641 of 2012 requires the Maryland Health Care Commission to examine existing research on health disparities that exists in the treatment of hepatitis C. Specifically, the legislation states; *"The Maryland Health Care Commission shall examine existing research findings related to health disparities in the effectiveness of medical treatment of African Americans with hepatitis C and collect recommended protocols for treating African Americans who have hepatitis C from experts in the field."*

Commission staff interviewed David Thomas, MD, Director of the Division of Infectious Diseases, Johns Hopkins Medicine; reviewed a presentation by Charles D. Howell, MD, Professor of Medicine, University of Maryland School of Medicine; and conducted a literature review. The following report presents background information on Hepatitis C, overviews of screening protocols and treatment, the impact of the disease in the African American community, and recommendations from the field on how to improve outcomes for this population.

Background

Hepatitis C, or HCV, is a virus which affects the liver and can lead to cirrhosis, liver cancer, or liver failure. According to the American Liver Foundation there are approximately four million people in the United States living with Hepatitis C[1] making HCV the most common chronic blood borne infection in the U.S[2]. After exposure, some people are able to clear the virus, on their own or through treatment, within six-months; however, approximately 75% of those infected will develop chronic or long-term Hepatitis C[3].

Screening

Hepatitis C is most commonly transmitted through repeated injection drug use; however, the Centers for Disease Control and Prevention (CDC) recommends the following screening protocols:

- Those with a history of IV Drug use;
- Those who had a blood transfusion or solid organ transplant prior to July 1992;
- Anyone who received clotting factor concentrates made before 1987;
- Patients who have ever received long-term hemodialysis treatment;
- Persons with known exposure to hepatitis C, such as
    - A health care worker after needle sticks involving blood from a patient with hepatitis C; or,
    - A Recipient of blood or organs from a donor who later tested positive for hepatitis C;

[1] American Liver Foundation, *Hep C 1,2, 3, Diagnosis, Treatment and Support.*http://hepc.liverfoundation.org/what-is-hepatitis-c/

[2] Centers for Disease Control and Prevention. *Hepatitis C Information for Health Professionals* http://www.cdc.gov/hepatitis/HCV/index.htm

[3] American Liver Foundation, *Hep C 1,2, 3, Diagnosis, Treatment and Support.*http://hepc.liverfoundation.org/what-is-hepatitis-c/

- People living with HIV;
- People with signs or symptoms of liver disease;
- Children born to mothers who have hepatitis C; and
- Anyone born between 1945 and 1965.

The CDC added the recommendation in 2012 that anyone born between 1945 and 1965, or Baby Boomers, be screened at least once, even if they do not have other risk factors/ More than 75% of individuals living with Hepatitis C are Baby Boomers and this generation is five times more likely than other American adults to be infected.[4] Further, the U.S. Preventative Task Force, which evaluates clinical evidence on preventative services, recommends offering a onetime screening for HCV infection to all adults born between 1945 and 1965.[5]

Treatment

Approximately 30% of individuals diagnosed with HCV will spontaneously clear the acute infection.[6] It is suspected that differences in the genetic makeup of the individual diagnosed with HCV account for the differences in the rates of spontaneous clearance because there are variations among ethnic groups even after exposure to the same HCV variation.[7] However, the primary causes for the differences in spontaneous clearance have not been proven via peer-reviewed scientific studies.[8]

There are treatment options for those individuals who do not spontaneously clear the virus. The goals of any treatment are to remove all traces of the hepatitis C virus from the individual's body, stop or slow the damage to the liver, or reduce the risk of liver damage advancing to cirrhosis.[9]

There are currently two main treatments available for individuals living with chronic hepatitis C. Treatment outcomes can vary depending on the genotype, or strain, of the virus[10]. Dual therapy treatment is treatment with pegylated interferon and ribavirin. Pegylated interferon is administered through a weekly injection and ribavirin administered in pill form. This treatment

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[4]Centers for Disease Control and Prevention. *Hepatitis C Information for Health Professionals. Hepatitis C FAQs for Health Professionals* http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm#section2

[5] U.S. Preventive Services Task Force. *Screening for Hepatitis C Virus Infection in Adults. U.S. Preventive Services Task Force Recommendation Statement* http://www.uspreventiveservicestaskforce.org/uspstf12/hepc/hepcfinalrs.htm

[6] Thomas D Et al "Genetic Variation in IL28B and Spontaneous Clearance of Hepatitis C Virus" *Nature* Vol 461 October 2009

[7] Thomas D Et al "Genetic Variation in IL28B and Spontaneous Clearance of Hepatitis C Virus" *Nature* Vol 461 October 2009

[8] Thomas D Et al "Genetic Variation in IL28B and Spontaneous Clearance of Hepatitis C Virus" *Nature* Vol 461 October 2009

[9] U.S. Department of Veterans Affairs. *Viral Hepatitis* www.hepatitis.va.gov

[10] U.S. Department of Veterans Affairs. *Viral Hepatitis* www.hepatitis.va.gov

is generally administered to people with genotype 2 or genotype 3. Triple therapy, which adds either boceprevir or telprevir, is usually given to those with genotype 1 hepatitis C.[11]

As the science behind treatment improves and practitioners gain a better understanding of the various viral genotypes, the Food and Drug Administration (FDA) continues to approve new treatments. In 2011, the FDA approved boceprevir and telprevir, which is usually given to those with genotype 1 hepatitis C.[12] In late 2013, the FDA approved a new therapy to treat chronic Hepatitis C infection, Olysio, or simeprevir. It would be used as a component of a combination antiviral treatment regimen.[13]

Hepatitis C in African Americans

Despite decreases in acute HCV, an infection lasting less than six months, chronic hepatitis infection continues to affect about 2.7 to 3.9 million Americans.[14] In the U.S., chronic hepatitis is estimated to be two to three times more prevalent in African Americans than in whites.[15] It is difficult to determine exactly how many individuals are infected with HCV because approximately 75% of those infected are unaware of their infection.[16]

Studies have confirmed a lower response rate to treatment in African Americans compared to the white population. In one study, overall treatment response to three different treatment regiments was 22% in African Americans compared to 44% in non-African Americans.[17] Some explanations for these differences include viral dynamics, dosing mistakes, non-adherence to treatment, and lack of access to treatment options. These explanations can be divided into two basic categories: patient related factors and disease related factors.

Hepatitis C is primarily transmitted intravenously. African Americans are disproportionately affected by intravenous drug abuse, HIV/AIDS and hepatitis C. Efforts should continue to be made to reduce these risk factors in the African American population along with increased screening for the groups recommended by the CDC.

Further, obesity, which is more common among African Americans, can greatly reduce the effectiveness of ribavirin in treating hepatitis C,[18] The weight-based dosing of interferon and ribavirin trial compared treatment with either a fixed dosing or a weight based dosing and found

[11] U.S. Department of Veterans Affairs. *Viral Hepatitis* www.hepatitis.va.gov
[12] U.S. Department of Veterans Affairs. *Viral Hepatitis* www.hepatitis.va.gov
[13] Food and Drug Administration (2013). FDA Approves New Treatment for hepatitis C virus. [Press release]. Retrieved from www.fda.gov
[14] Centers for Disease Control and Prevention. *Viral Hepatitis Surveillance United States 2011* http://www.cdc.gov/hepatitis/Statistics/2011Surveillance/PDFs/2011HepSurveillanceRpt.pdf
[15] Jeffers, Lennox. "Treating hepatitis C in African Americans." *Liver International.* 2007
[16] Centers for Disease Control and Prevention. *Viral Hepatitis Surveillance United States 2011* http://www.cdc.gov/hepatitis/Statistics/2011Surveillance/PDFs/2011HepSurveillanceRpt.pdf
[17] Muir et al. "Hepatitis C treatment among racial and ethnic groups in the IDEAL trail" *Journal of Viral Hepatitis,* 2011, 18.
[18] Jeffers, Lennox. "Treating hepatitis C in African Americans." *Liver International.* 2007

weight based dosing to be more effective.[19] Ensuring that patients receive the proper dosage of medications could increase responses to treatment.

Other factors, including access to medical care generally, can be an impediment to seeking treatment in the African American population. In his *Racial Disparities in Chronic Hepatitis C* presentation, Dr. Charles D. Howell suggests that access (insurance status, ability to pay for care) is the most important predictor of the quality of healthcare for all racial and ethnic groups.[20] Given the known disparity in insurance coverage, increasing access to insurance coverage for African Americans would increase treatment opportunities.

Lastly, as new treatments are tested, it is important to include a diverse group of participants in any study.[21] Given that there is already a known difference in the viral response between ethnic groups, studies should look into potential differences in response rates by ethnicity.

General consensus about ways to improve outcomes for African Americans diagnosed with Hepatitis C included improving primary prevention by better screening and educating those with one or more risk factors for the disease; getting the patient into the proper treatment for their viral type and ensuring patients received the proper dose of medication; improving access to healthcare generally; and increasing representation in studies of new treatments.

[19] Jeffers, Lennox. "Treating hepatitis C in African Americans." *Liver International.* 2007

[20] Charles D. Howell, MD "Racial Disparities in Chronic Hepatitis C" Presentation to the Maryland Legislature. November 2011.

[21] Muir, Andrew; Bornstein, Jeffry; Killenberg, Paul. "Peginterferon Alfa-2b and Ribavirin for the Treatment of Chronic Hepatitis C in Backs and Non-Hispanic Whites." *New England Journal of Medicine.* 350;22 (May 27, 2004)

Recommendations from Experts

Prevention

- Engage in robust community education and outreach initiatives, including disseminating information on the disease and risk factors.
- Utilize wide a group of community organizations and venues to ensure the broadest community engagement.

Screening

- Implement screening according to CDC screening protocols foe
    - Those with a history of IV Drug use;
    - Those who had a blood transfusion or solid organ transplant prior to July 1992;
    - Anyone who received clotting factor concentrates made before 1987;
    - Patients who have ever received long-term hemodialysis treatment;
    - Persons with known exposure to hepatitis C such as:
        - A health care worker after needle sticks involving blood from a patient with hepatitis C; or
        - A Recipient of blood or organs from a donor who later tested positive for hepatitis C
    - People living with HIV;
    - People with signs or symptoms of liver disease;
    - Children born to mothers who have hepatitis C; and
    - Anyone born between 1945 and 1965.

Treatment

- Ensure proper treatment for an individual's viral genotype.
- Ensure that individuals receive proper dosage based on the individual's weight and other factors.
- Expand minority participation in the studies of new treatments.