The Hepatitis C Mentor & Support Group

PATIENT SUPPORT NEWSLETTER

Vol. 5 - 2019

WELCOME from Ronni Marks, Founder & Director HCMSG

I have been working to raise awareness for Hepatitis C for over twenty years. I started my journey as a patient, became a patient advocate, and the facilitator of one of the longest running support groups at NYU Medical Center. Seeing a lack of education and supportive services for Hepatitis C, I founded the organization, **The Hepatitis C Mentor and Support Group, Inc. - HCMSG** in 2010.

After several unsuccessful attempts with other treatments, five years ago after treating with the new DAA's, I was told the Hepatitis C virus was no longer detected in my body. This has reinforced my mission to help others to have the same opportunity.

My hope is that this newsletter will be a form of education and support to those newly diagnosed, those living with Hepatitis C or co-infected with HIV, those having to make decisions, those on treatment and even post treatment. We welcome your suggestions on what you would like to see in upcoming issues and any stories you want to share. We can be contacted at hepatitisCmsg@gmail.com.

HEPATITIS C TREATMENT UPDATE:

Matthew Akiyama, MD, MSc - Assistant Professor of Medicine, Montefiore Medical Center
Medical Advisor to HCMSG

Much progress has been made since the emergence of Direct Acting Antivirals (DAAs) for the treatment of Hepatitis C. DAAs were developed to improve the tolerability and efficacy of Hepatitis C treatment regimens by targeting proteins on the Hepatitis C viral genome including the NS3/4A protease, NS5A, and NS5B polymerase. Inhibiting these proteins during viral replication prevents the virus from reproducing and leads to eradication of the virus from the liver.

The first single-tablet combination DAA regimen, Harvoni (ledipasvir/sofosbuvir), was approved for use in October 2014. Many developments have occurred since that time including the approval of two single-tablet regimens in 2016: Zepatier (grazoprevir/elbasvir) – an NS3/4A, NS5A inhibitor approved for genotypes 1 and 4, and Epclusa (velpatasvir/sofosbuvir) – an NS5A, NS5B inhibitor, which was the first approved all oral, pan-genotypic regimen.

In 2017, two new pan-genotypic regimens were approved: Vosevi (voxilaprevir/velpatasvir/sofosbuvir), an NS3/4A, NS5A, NS5B inhibitor combination therapy, and Mavyret (glecaprevir/pibrentasvir) an NS3/4A, NS5A inhibitor combination therapy. Both new therapies are approved for patients with genotypes 1-6 with no or mild cirrhosis. Vosevi was the first treatment approved for patients who have been previously treated with Sofosbuvir or NS5A inhibitors. Mavyret is approved for patients with genotype 1 who have been previously treated with Sofosbuvir, NS5A or NS3/4A inhibitors. Mavyret is the first treatment of 8 weeks duration approved for all Hepatitis C genotypes 1-6 in patients without cirrhosis who have not been previously treated. Standard treatment length was previously 12 weeks or more. Mavyret is also approved for patients with moderate to severe kidney disease and those who are on dialysis.

Since several all-oral DAA options are now available prices have been falling due to market competition in recent years. This year, Gilead Sciences announced it plans to sell lower-priced generic versions of ledipasvir/sofosbuvir and velpatasvir/sofosbuvir. This development has raised hopes that decreased prices will improve access to treatment among populations that have faced barriers to date.

The following is a timeline of DAA combinations from 2014-2018:

Trade name	Generic name(s)	Class	Use/efficacy	FDA status
Harvoni	ledipasvir/sofosbuvir	NS5A/NS5B	Genotype 1,4,5,6 (up to 100%[1])	Approved 10/10/14
Viekira Pak	parataprevir/ritonavir, obitasvir, dasabuvir	NS3/4A, NS5A, NS5B	Genotype 1 (up to 100%[2])	Approved 12/19/14
Daklinza + Sovaldi	daclatasvir + sofosbuvir	NS5A + NS5B	Genotype 3 (up to 98%[3])	Approved 7/24/15
Technivie	parataprevir/ritonavir, obitasvir	NS3/4A, NS5A, NS5B	Genotype 4 (91%[4])	Approved 7/24/15
Zepatier	grazeprevir/elbasvir	NS3/4A/NS5A	Genotype 1,4 (up to 100%[5])	Approved 1/28/16
Epclusa	velpatasvir/sofosbuvir	NS5A/NS5B	Genotype 1,2,4,5,6 (99%[6])	Approved 6/28/16
Vosevi	voxilaprevir velpatasvir/sofosbuvir	NS3/4A, NS5A, NS5B	Genotype 1,2,3,4,5,6 (99%[7])	Approved 7/18/17
Mavyret	glecaprevir/pibrentasvir	NS3/4A, NS5A	Genotype 1,2,3,4,5,6 (99%[8])	Approved 8/3/17

References:

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2. Poordad F, Hezode C, Trinh R, et al. ABT-450/r-ombitasvir and dasabuvir with ribavirin for hepatitis C with cirrhosis. N Engl J Med. 2014;370:1973-82.
3. Sulkowski MS, Gardiner DF, Rodriguez-Torres M, et al. Daclatasvir plus sofosbuvir for previously treated or untreated chronic Hepatitis C infection. N Engl J Med. 2014;370:211-21.
4. Hézode C, Asselah T, Reddy KR, et al. Ombitasvir plus paritaprevir plus ritonavir with or without ribavirin in treatment-naive and treatment-experienced patients with genotype 4 chronic hepatitis C virus infection (PEARL-I): a randomised, open-label trial. Lancet. 2015;385:2502-9.
5. Zeuzem S, Ghalib R, Reddy KR, et al. Grazoprevir-Elbasvir Combination Therapy for Treatment-Naive Cirrhotic and Noncirrhotic Patients With Chronic Hepatitis C Virus Genotype 1, 4, or 6 Infection: A Randomized Trial. Ann Intern Med. 2015;163:1-13.
6. Feld JJ, Jacobson IM, Hézode C et al. Sofosbuvir and Velpatasvir for Hepatitis C Genotype 1, 2, 4, 5, and 6 Infection. N Engl J Med. 2015 Dec 31;373(27):2599-607.
7. Bourlière M, Gordon SC, Flamm SL et al. Sofosbuvir, Velpatasvir, and Voxilaprevir for Previously Treated Hepatitis C Infection. N Engl J Med. 2017 Jun 1;376(22):2134-2146.
8. Forns X, Lee SS, Valdes J et al. Glecaprevir plus pibrentasvir for chronic hepatitis C virus genotype 1, 2, 4, 5, or 6 infection in adults with compensated cirrhosis (EXPEDITION-1): a single-arm, open-label, multicentre phase 3 trial. Lancet Infect Dis. 2017 Aug 14. pii: S1473-3099(17)30496-6.

Diannee Carden Glenn – Harm Reduction Consultant for HCMSG and Founder of ekiM For Change

I became an advocate for harm reduction and treatment for Hepatitis C following the heroin overdose death of my son Michael in 2012. Michael was a well-respected pioneer in the harm reduction movement as a Social Worker and Substance Use Counselor. As a person who was "in recovery" he was able to connect and understand the special needs of this population. Although Michael did not have Hepatitis C he was passionate about advocating for those who used drugs with Hepatitis C not be excluded from the treatment and cure provided to those who did not have substance use disorder. Through his guidance I became his voice after his death. First advocating for the Good Samaritan Law, Syringe Exchange and continuity of care. This led me to share his passion to provide treatment for hepatitis C for this population.

I am the founder of ekiM For Change, LLC a syringe exchange program that provides compassionate care and supplies that prohibit the spread of disease, Hepatitis C and HIV testing, linkage to supportive services and education using HCMSG's "The Circle" group models for participants in programs such as syringe exchange. These are provided in a non-hostile environment where the participants are given hygiene safety kits to reduce the harm of infection and to encourage a healthy lifestyle. There is no judgment of lifestyle in these programs and participants are treated with respect encouraging them to make healthy choices.

My hope is that my collaboration with HCMSG and this newsletter will provide another form of education and a better understanding of the struggles and obstacles those suffering from substance use disorder face while making life decisions involving their health when infected with Hepatitis C or co-infected with HIV/Hepatitis C.

Hepatitis C and people who inject drugs – A dilemma

We know that Hepatitis C is directly affecting people who inject drugs. They are currently the group most likely to be infected and/or to become infected. It is critical that we develop strategies for testing and treatment that are effective and available. To date few people who inject drugs have access to treatment for hepatitis C. Until 2002, in the US, the National Institute of Health Guidelines actually recommended against offering treatment to people who actively use drugs.

In 1997 a Consensus Development Conference on treating hepatitis C in people who use drugs specifically stated that treatment for people who are drinking significant alcohol or actively using illicit drugs should be delayed until their habits are discontinued for at least six months.
In 1997 there still was no good evidence to show that people who use drugs could not be treated. A significant number of advocates lobbied for a change in this policy as a violation of ethical principles, good medical practice citing the lack of data that suggested that people who use drugs couldn't successfully have anti-viral treatment.

In 2002 there was another Consensus Development Conference in which people who use drugs diagnosed with Hepatitis C was discussed again resulting in the reversal of the previous decision. The new statement said that actively injecting drugs, in and of itself, is not a reason to exclude patients from anti-viral therapy and that treatment decisions for people who use drugs should be done on a case by case basis. 1. Active injection drug users can be treated for Hepatitis C. 2. Methadone is not a contra indication for treatment.
3. treatment for drug and alcohol dependence should be available for all those who want and need it and 4. Hepatitis C and substance use experts should collaborate.

The guidelines changed 16 years ago. Unfortunately care is still not readily available. The question is - How can we have an impact on that practice and how can we enhance treatment for Hepatitis C for people who are actively using drugs? We agree there are numerous barriers that exist to Hepatitis C treatment for this patient population. Some barriers have to do with physicians who lack training in working with people who use drugs.

There are other reasons that physicians give for not treating persons who use drugs – some are concerns about poor adherence to the treatment medicine, relapse or an increase in drug use as well as a concern about re-infection after being successfully treated for Hepatitis C. We need to come up with a solution for those who are not already receiving medical care, for one reason or another, to have access to treatment for Hepatitis C. It is important to look at methods that have been successful in treating people with substance use disorder and also diagnosed with Hepatitis C. What were the critical elements of programs that have been successful? What were the characteristics of those who were successfully treated? Were there issues with adherence and side effects? What were the rates of re-infection as compared to the general population? Where there adverse interactions between Hepatitis C and illicit drugs, Methadone and/or Buprenorphine? What is the estimated number of people who can't get Hepatitis C treatment because of their drug use? It is important to determine the cost effectiveness in order to make the argument that treating this population is worth doing on a social level.

The HCMSG model is a collaborative, multidisciplinary, integrated care program. Collaborative because of the importance of partnerships between medical providers such as Medical Centers and programs such as syringe exchange. Multi-disciplinary to partner with people who provide care in multiple disciplines like mental health, psychiatry, substance use services, and people who specialize in Hepatitis C care. Primary care integration to cross institutional boundaries (i.e. syringe exchange staff would sometimes come to the medical center) and when necessary the medical center would provide care at programs such as syringe exchange to enhance continuity of care.

Having a peer and/or case manager that will provide linkage of care individually for the participant as well as between the providers of each discipline is important. This individual makes sure that communication happens among each of the different providers and that the participant is included in the decision making. This individual also works closely with the participant providing pertinent education, encourages the participant to make healthy decisions, provides hope and motivation for the participant as well as explaining the results of their lab work, escorting them to medical appointments, and attending HCMSG's "The Circle" groups. Hepatitis C treatment, without stigma or shame, is within our grasp for everyone. Our voice matters.

WHO SHOULD GET TESTED

- Baby Boomers (1945-1965)
- People who received blood transfusions before 1992
- People who inject drugs, hormones/ steroids
- People who have tattoos & body piercings
- People infected with HIV
- Children born to mothers infected with Hepatitis C

RISK FACTORS

- Sharing syringes or other equipment to inject drugs
- Occupational needle stick
- Sharing personal care items such as razors, nail clippers or toothbrushes
- Sexual transmission (not common, however, some sexual practices may involve blood)

HOW LONG HEPATITIS C VIRUS STAYS ON EQUIPMENT

Cotton Filters	24-48 Hours
Cookers	14 Days
Syringes	63 Days
Water	21 Days
Surfaces	16 Days

References:
http://jid.oxfordjournals.org/content/202/7/984.full.pdf
http://www.projectinform.org/pdf/pwidtoolkit_whatkillsHepatitis C.pdf
http://harmreduction.org/issues/hepatitis-c/overview/hepatitis-c-transmission/

”The Circle” Group Model

HCMSG’s “The Circle” groups address the basic needs of all people affected by Hepatitis C and those co infected with HIV, including people who currently and formerly injected drugs. After gaining their trust, we encourage each person to be tested for Hepatitis C in response to what is clearly a connection between the use of injection drugs and Hepatitis C.

The participants who test positive are then navigated through the system with the goal of receiving treatment for Hepatitis C and to endeavor to reduce the harm of injection drug use through The Hepatitis C Education and Support Group Assistance Program. The clients are identified through programs, such as weekly syringe exchanges.

The Circle groups provide a non-hostile environment where they are given hygiene safety kits to reduce the harm of infection and to encourage a healthy lifestyle. There is no judgment of lifestyle in these groups and participants are treated with respect encouraging them to make healthy choices. There is a generation of young people who have become infected with Hepatitis C through injecting opiates and other drugs sharing syringes. Education in regard to transmission is necessary for this population in a non-judgmental environment. Using HCMSG's mission and goals, we provide insight and direction into providing options and developing effective ways to educate, engage and retain people in care and treatment. Our goal is to empower them to be in charge of their overall health.

If you are interested in starting “The Circle” at your organization, please follow the steps below:

1. **Register at** *www.hepatitiscmsg.org/circleregistration.html*
2. **Discuss specifics needs of your organization with HCMSG**
3. **Provide necessary feedback using the questions below:**

- How many participants came into group as a result of a program like syringe exchange?
- Were incentives necessary to encourage them to attend “The Circle” group?
- How many stayed in group, attended more than once, referred others?
- How many had already been tested? How many were you able to get tested? How long did it take to get them to agree?
- How many were linked to care? How long did it take for their first appointment? Were they prepared because of knowledge gained in group? How many were adherent to Hepatitis medication?
- Cured and beyond- Have many have been informed on follow up and risk of re-infection?
- How has being cured impacted their health and life after cure?

"The Circle" impacts communities in New York
and Nationwide through the collaboration of organizations such as:

Hawaii Department of Health
Hep Free Hawaii
Hawaii Health and Harm Center
ekiM for change syringe exchange Greenville, NC
Positively Living/Project Act, Knoxville, TN.

*** SITE FOR CHECKING DRUG-INTERACTIONS***
http://www.hep-druginteractions.org

TREATMENT SIDE EFFECT MANAGEMENT TIPS

For nausea. Ginger can be taken to decrease the nausea. It can be eaten raw or in foods that contain ginger, such as ginger tea, ginger ale, and ginger candy.

SEVEN QUESTIONS TO ASK ABOUT MEDICATIONS:

Doctors should communicate these basic points whenever they prescribe a new medication. Unfortunately, research shows they usually deliver only about four of them. For the full story, ask these critical questions when you are given a new drug:

1. What's the name (trade) of the medication?
2. Why are you prescribing it for me?
3. What are the potential side effects?
4. How much should I have (how many pills, squirts, teaspoons, etc.)?
5. How many dose(s) do I need each day, and what time should I take them?
6. Will this medication interact with my current medications or with over the counter products I currently take, such as antacids and others?
7. For how long should I take the medication?

**MANY PATIENTS SAY THEY ARE HANDED THEIR LAB WORK RESULTS,
BUT DO NOT UNDERSTAND THEM. HOPEFULLY THE FOLLOWING WILL HELP:**

LAB DEFINITIONS:

WBC- "White Blood Cell Count" - Normal Range (4.5-11 x 10^9 per µL)
White Blood Cells are cells that fight infection and can cause inflammation. This number can be elevated or decreased in a new infection. It may present low in infections harming the immune system such as HIV.

ANC- "Absolute Neutrophil Count" - Normal Range (>500 cells)
The ANC is a number representing the specific number of neutrophils within the white blood cell count (WBC). Neutrophils are the main infection fighting cell in a new infection. In situations where the total WBC is low, the ANC indicates the body's ability to fight an acute infection.

Hg- "Hemoglobin" - Normal Range (Male- 13.5-17.5g/dL / Female- 12-16 g/dL)
Hemoglobin is a protein component of red blood cells that uses iron to carry oxygen. When hemoglobin is low, this is called "Anemia."

Hct- "Hematocrit"- Normal Range (Male- 39-49% / Female - 35-45%)
Hematocrit represents how much blood volume is made up of red blood cells (RBC). If elevated, this indicates an increased production of red blood cells or a decreased amount of fluid without a change in red blood cells such as in dehydration. If lower, this indicates a decrease in red blood cell production.

PLT- "Platelet" - Normal Range (150-450 x 10^3 per µL)
Platelets are necessary to form clots in the body. Low platelets can indicate a tendency for bleeding. A low platelet count is called "thrombocytopenia," this may be seen in HIV, Hepatitis C, or blood disorders.

BUN- "Blood Urea Nitrogen" - Normal Range (7-18 mg/dL)
Blood Urea Nitrogen is a break down product of normal human metabolism. It is excreted by the kidney. If elevated, it can indicate non-specific status changes including changes to blood volume or kidney function.

Cr- "Creatinine" - Normal Range (0.6 – 1.2 mg/dL)
Creatinine is a break down product of normal human metabolism. It is excreted by the kidney. If elevated, this number indicates damage to the kidney itself.

Albumin – Normal Range (3.5 – 5.5 g/dL)
Albumin is a protein made in the liver and found in the blood. It is an indicator of liver function.

AST- "Aspartate Aminotransferase" - Normal Range (7-40 U/L)
AST is a marker used to indicate damage to the liver cells. It is compared with ALT.

ALT- "Alanine Aminotransferase" - Normal Range (7-40 U/L)
ALT is a marker used to indicate damage to the Liver. It is compared with AST.

Bilirubin – Normal Range (.2-1.0 mg/dL)
Bilirubin is a breakdown product of red blood cells. It is also an indicator of liver function.

Hepatitis C Viral Load- "Hepatitis C Viral Load" - Normal Range (Not detected)
Hepatitis C Viral Load being elevated indicates an active infection because the viral load is a measurement of the presence of the virus in the bloodstream.

HIV Viral Load- "Human Immunodeficiency Virus Viral Load"- (Not detected)
HIV Viral load indicates the current state of the infection.

TSH- "Thyroid Stimulating Hormone"- Normal Range (<10 µU/L, >60yo Men 2-7.3 / Women 2-16.8)
TSH is a marker of thyroid function.

AFP - "Alpha-Fetoprotein"
AFP is a non-specific marker that may indicate liver cancer.

INR- "International Normalized Ratio"
Is a measurement of bleeding time, which is an indication of liver function?

Tarek Aly –Medical student, Ross University School of Medicine *sourced the lab definitions from*
Dugdale, David C., and David Ziev" Complete Blood Count: *MedlinePlus Online Encyclopedia. "US National Library of Medicine*. National Institutes of Health, 19 Mar. 2012.

PATIENT ASSISTANCE PROGRAMS

Most pharmaceutical companies offer help to patients who cannot afford the medications needed to treat Hepatitis C. You should work with your medical provider to select and contact programs for assistance.

Patient Access Network (PAN) Foundation:
An independent non-profit organization that provides assistance to underinsured patients for their out of pocket medical expenses. PAN assistance covers multiple Hepatitis C medications and a patient's choice of medication does not influence the amount of assistance a patient is able to receive.
To learn more or to apply, visit www.panfoundation.org or call 1866-316-7263

Patient Advocate Foundation
To provide Hepatitis C patients with hands-on case management support
H**epatitis C Co-Pay Relief fund award**
HIV, AIDS and Prevention Co-Pay Relief fund
Learn more at www.patientadvocate.org
Hepatitis C CareLine -1-800-532-5274

Healthwell Foundation
Patients, providers, and pharmacies can apply by visiting HealthWell at www.HealthWellFoundation.org or by calling 1- 800-675-8416 Monday through Friday 9:00 a.m. to 5:00 p.m. to speak with a HealthWell representative.
Here's a link to our Hep C fund page that includes all of the fund information and eligibility requirements:
https://www.healthwellfoundation.org/fund/hepatitis-c

HEPATITIS C TREATMENT MEDICATIONS

Most pharmaceutical companies offer help to patients who cannot afford the medications needed to treat Hepatitis C. You should work with your doctor to select and contact programs for assistance.

For more information about Patient Assistance Programs, please check out the two following resources:
www.fairpricingcoalition.org and http://www.hepatitisCmsg.org/assistance-programs.html

Gilead
Vosevi (sofosbuvuir/valpatasvir/voxilaprevir)
Epclusa (sofosbuvuir/valpatasvir)
Harvoni (ledipasvir/sofosbuvir)
Sovaldi (sofosbuvir)
Gilead Patient Assistance Program
1-855-7-MYPATH (1-800-769-7284)
http://www.mysupportpath.com

Abbvie
MAVYRET (glecaprevir/pibrentasvir)
Patient Support Program
www.mavyret.com
1877-6289-9738

Merck
Zepatier (grazoprevir/elbasvir)
Merck Patient Assistance Program
http://merckhelps.com/Programs.aspx
Please call 1-800-727-5400

If you wish us to email you the newsletter and/or just want to contact us with news, questions, thoughts, etc., Please contact us at hepatitisCmsg@gmail.com.

Check out our website www.hepatitisCmsg.org for more information, support, and assistance.

Thank you!

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