



The Hepatitis C Mentor & Support Group

PATIENT SUPPORT NEWSLETTER

Vol. 2 Summer 2014

WELCOME from Ronni Marks, Founder & Director HCMSG

I was diagnosed with Hepatitis C in 1997, a time when the internet was new and there were no Hepatitis C support groups. My friends and family didn't understand what I was going thru. I made a promise that if possible, I would never let anyone else endure this experience alone!

My organization HCMSG-the Hepatitis C Mentor and Support Group, was formed to address the lack of awareness, support and services for people living with Hepatitis C, co-infection, pre and post liver transplant. HCMSG provides resources and services nation-wide to hospitals, clinics, and other organizations who want to establish or run Hepatitis C and co-infection patient support groups.

My hope is that this newsletter will be a form of support to those newly diagnosed, those living with HCV, 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 reached at hepatitisCmsg@gmail.com.

HCV TREATMENT UPDATE:

Mary Olson, DNP, ANP – Research Nurse Manager

In 2013 a protease inhibitor, Olysio (simeprevir) and a nucleotide polymerase inhibitor, Sovaldi (sofosbuvir), were approved, with each to be given in combination with pegylated interferon and ribavirin for genotype 1 patients. Sofosbuvir with pegylated interferon and ribavirin was also approved for genotype 4 patients. Sofosbuvir with ribavirin was approved for treatment of patients with HCV genotypes 2 and 3.

Interferon free HCV treatment regimens for HCV genotype 1 are anticipated in the Fall of 2014.

Combinations of two or three Direct Acting Antivirals (DAA) have been developed to improve the tolerability and efficacy of HCV treatment regimens.

DAAs have been developed that target proteins on the viral genome; the NS3/4A protease, NS5A, and the polymerase. Inhibiting these proteins during viral replication prevents the virus from being able to reproduce and causes eradication of the virus from liver cells.

DAA combinations include all oral combinations of 2 or 3 DAAs from different classes. The combinations evaluated in large trials thus far include: a protease inhibitor with a NS5A inhibitor,

a protease inhibitor with a polymerase inhibitor, a NS5A inhibitor with a polymerase inhibitor, and a protease inhibitor, NS5A inhibitor and a non-nucleotide polymerase inhibitor with or without ribavirin.

The following are anticipated interferon free DAA combinations that are expected the fall of 2014. These regimens are those for which filings have been made to the FDA for approval.

Status	Protease Inhibitor	NS5A inhibitor	Polymerase Inhibitor	Guanosine (ribonucleic) analog
Pending FDA approval	N/A	ledipasvir	sofosbuvir (nucleotide)	
Pending FDA approval	ABT450/Ritonavir	ombitasvir	dasabuvir (non-nucleotide)	With or without ribavirin
Pending FDA approval	Asunaprevir	daclatasvir	N/A	N/A
Off-Label, pending FDA approval	Simeprevir	N/A	sofosbuvir	With or without ribavirin
Pending FDA approval		daclatasvir	sofosbuvir	

The all oral combinations of 2 or 3 DAAs with or without ribavirin will increase the tolerability and efficacy of HCV regimens and decrease the duration of treatment for genotype 1 patients to either 8 weeks, 12 weeks or 24 weeks depending on the patient population. The response rates to these regimens have proven to be >90%.

REFERENCE

Afdahl, N., Zeuzum, S., Schooley, R., et. al. The new paradigm of hepatitis C therapy: integration of oral therapies into best practices. *Journal of Viral Hepatitis*, 2013; 20: 745-760

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

TREATMENT SIDE EFFECT MANAGEMENT TIPS
 Interferon and Ribavirin can cause 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.

*Dark chocolate can help for metallic taste.

SIX MUST-ASK QUESTIONS ABOUT MEDICATIONS:

Doctors should communicate six 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 six 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. For how long should I take the medication?

LAB DEFINITIONS:

WBC- "White Blood Cell Count" - Normal Range ($4.5-11 \times 10^9$ 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 ($150-450 \times 10^3$ 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.

HCV 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 Zieve"Complete Blood Count:MedlinePlus Online Encyclopedia. " U.S National Library of Medicine. National Institutes of Health, 19 Mar. 2012.

CLINICAL TRIALS

New HCV treatment options in development may be available through participation in clinical trials. Clinical trials require that you meet the inclusion and exclusion criteria. To inquire about participation contact one of the centers below. These centers generally complete an intake interview and perhaps collect records. If you are a candidate for clinical trials, you will be offered a trial if one is available or contacted at a future date when a trial is available. TAG (Treatment Action Group) provides an excellent overview to clinical trials entitled: Guide to Clinical Trials for People with Hepatitis C - Second Edition by Matt Sharp and Tracy Swan. Please access it at the following address: <http://www.treatmentactiongroup.org/hcv/publications/2011/hcv-clinical-trials-guide>

ClinicalTrials.gov (a service of the National Institutes of Health-NIH) Provides regularly updated information about federally and privately supported clinical research in human volunteers. The Website gives information about a trial’s purpose, who may participate, locations, and phone numbers. For more details, visit: www.clinicaltrials.gov

CURRENT CLINICAL TRIAL CENTERS in the NYC Region:

NYU LANGONE MEDICAL CENTER

Dr. Samuel Sigal
Therese Capobianco 212-263-3643

CONCORDE MEDICAL GROUP

Drs. Hillel Tobias/Edward Brettholz
Juanita Clinical Trial Coordinator 212-889-5544

NYU LANGONE MEDICAL CENTER

Mary Lea Johnson Richards Transplantation Center
Dr. Lewis Teperman
Christelle Clinical Trial Coordinator 212-263-8391

WEILL CORNELL MEDICAL COLLEGE

Dr. Ira Jacobson
Marlene Feron-Rogodon, RN 646-962-4372

MOUNT SINAI MEDICAL CENTER

Dr. Douglas Dietrich
Michele Cohen 212-241-7734

COLUMBIA UNIVERSITY MEDICAL CENTER

Dr. Robert Brown
Theresa Lukose, Pharm.D.
Claudia Musat- cm2065@cumc.columbia.edu 212-305-3839

NORTHSHORE MEDICAL CENTER

Dr. David Bernstein
Radica Palmer, RN 516-562-2082

MONTICELLO, NY

Dr. Gary Good
Jane Koskey 845-794-6813

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.

For more information about patient assistance programs and fair pricing, please check out the following two excellent resources: www.fairpricingcoalition.org and <http://www.hepatitisCmsg.org/assistance-programs.html>.

PATIENT ACCESS NETWORK (PAN) Foundation: is 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

Olysio (Simeprevir)- Janssen

Patients who lack adequate financial resources and do not have prescription coverage can apply to the Johnson & Johnson Patient Assistance Foundation, Inc., to determine if they meet eligibility criteria for financial assistance for OLYSIO:

For additional information, please visit the JJPAF Web site at www.jjpaf.org or call and speak to one of our patient assistance program specialists at 1-800-652-6227

Sovaldi (Sofosbuvir)- Gilead

Gilead is committed to ensuring that people with hepatitis C can access Sovaldi and has launched Support Path(tm) (www.MySupportPath.com) to provide assistance to patients who are uninsured, underinsured or who need financial assistance to pay for the medicine. Information about how to apply can be found at www.MySupportPath.com or by calling 1-855-7MyPath (1-855-769-7284) between 9 a.m. - 8 p.m. EST.

Merck commitment to care for:

PegIntron (peginterferon alpha 2b)

1-800-521-7157, www.Merckhelps.com

Kadmon Pharmaceuticals

K.E.Y.S. Program

Ribasphere/RibaPak (ribavirin)

1-888-668-3393

www.RibaPak.com

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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