Communities across the country are struggling to gain control over the growing rates of opiate addiction, injection drug use, overdose and Hepatitis C (HCV) infection. Those affected by substance use issues, mental health issues and HIV/Hep C run into daily challenges on the path to recovery and health care. Many say their experiences of social and structural stigma has an impact on their willingness to access healthcare. The importance of addressing patient reported barriers to treatment will continue to be crucial in the pursuit of improving poor overall health outcomes.

Socioeconomic factors such as poverty, education, race and gender increase the likelihood of HCV contraction, and despite the fact that baby boomers are the majority of persons living with HCV (i.e. prevalence), young persons who inject drugs (PWID) are contracting it at uncontrollable rates (i.e. incidence), and have proven difficult to help and cure. These two groups are often front and center when discussing HCV treatment and care, and for good reason. However, it is important to highlight other vulnerable populations affected by hepatitis C.

Women with substance use issues seem to be viewed and treated by society more critically than men who have substance use issues. A primary cause for this is the underlying fact that women have been historically marginalized in our society. Over time, this has influenced how women are perceived, responded to, and ultimately treated.

Women battling opiate addiction face social stigma that is, for lack of a better term, brutal. When women also identify as injecting drugs, and are...
pregnant, the social and structural stigma is more pointed and biting. Unfortunately, many individuals who have opiate addictions are injecting and sharing equipment, which means there is a higher chance of contracting hepatitis C.

Across the U.S., there are a growing number of babies born addicted to drugs and opiates. This phenomenon is so prevalent it is medically identified as Neonatal Abstinence Syndrome (NAS). A diagnosis that includes many different complications and health issues that arise from babies becoming addicted to opiates in the mother’s womb. In recent weeks, I have heard individuals detail their experiences seeing an infant going through withdraw. One individual described the chilling sound of a newborn shrieking in agony, another described the heart wrenching experience of placing their hand on an infant who is shaking uncontrollably.

Such experiences are undoubtedly jarring, and elicit emotions such as sadness, frustration, anger and resentment. Harsh emotions are often aimed at the mother of the child, “How could a mother do that to her baby, she is a terrible person,” might be the nicest thing I’ve heard said about mothers battling addiction. The truth is, however, that if this is the only lens we are looking through then there is likely no other viewpoint we will reasonably end up at.

Consider this; would you respond differently if you knew that between 2009-2013, 20% of women continuously enrolled in New York’s Medicaid program filled a prescription for opiates, and in case you were wondering, this occurrence isn’t isolated to New York State, or women on Medicaid. In a large study from 2008-2012, 29% of women with private insurance between the ages of 15-44 filled a prescription for opiates. These findings are especially important when looking more broadly at the experience of women and substance use issues. Keeping all of this in mind one of the best things we can do is to frame the situation in a light that reflects addiction as a mental health issue, rather than a character flaw.

Many women battling substance use issues experience intimate partner violence and sexual coercion. In fact, about 9% of women in one study reported they experienced reproductive coercion in the previous 3 months. These acts of sabotage to reproductive health add to domestic violence issues and might lead to higher probabilities of unplanned pregnancies that may go undiscovered till late in the gestation period.

We don’t ask these questions enough, but we need to be asking them now more than ever. Women who have substance use issues are often aware of how they are perceived. A fact I didn’t fully understand until recently when I began leading group sessions with women who have substance use issues. Often, there are deep rooted feelings of shame, fear of losing their child, of law enforcement, of treatment, hopelessness and anger.
It is important to change the lens through which we view women with substance use issues to address the growing epidemic of hepatitis C and opiate addiction. Doing this means we will need to ask ourselves hard questions and explore difficult answers to a complex problem.

Vertical transmission of hepatitis C is the most common route of infection from mother to child. In a research study out of Philadelphia, data shows that 84% of infants born to hepatitis C positive mothers were not being adequately tested for hepatitis C. Further, prenatal and perinatal screening of hepatitis C is severely lacking, leading to increasing numbers of infants born with hepatitis C. Something that is completely preventable.

When vertical transmission occurs things like viral load and history of injection drug use may have an effect on the likelihood of mother to infant transmission. Increasingly, women living with hepatitis C & substance use issues represent a growing area that needs special attention. Physical dependency on opiates or other substances can lead to complex problems that limit the likelihood of seeking help. Seeing a baby born addicted to opiates who is hepatitis C positive is difficult, and something we all want not to happen; but to truly make progress we must replace our anger, disgust and resentment with empathy, compassion and tenacity.

I think we would all benefit from understanding that a woman before us battling substance use isn’t an opiate addicted, selfish, waste of space person. It’s your sister, your mother, your wife, your grandmother, your aunt, your friend, and they need you; they need us. They deserve our efforts in understanding their plight.

Matthew Zielske currently works as a HIV/HCV special populations prevention specialist at an HIV services organization. He utilizes a harm reduction model in his work with the substance use population focusing pointedly on persons who inject drugs. He is currently conducting research on Health Literacy and hepatitis C for his Master's Thesis in Communications.

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**Article: Efficacy of the Combination of Sofosbuvir, Velpatasvir, and the NS3/4A Protease Inhibitor GS-9857 in Treatment-naïve or Previously Treated Patients with HCV Genotype 1 or 3 Infections—EJ Gane et al.**


**Study Aims and Results**

This was a phase 2 study conducted September 2014 through March 2015 to understand the effectiveness of sofosbuvir, velpatasvir and GS-9857 to treat HCV genotype 1 and 3. There were 161 treatment naïve (29%) and, treatment-experienced (61%) patients. The study was conducted in New Zealand. All the patients were white. The patients were treated for 4, 6 or 8 weeks.

**Conclusions**

The 4-week treatment group only cured 27% of the patients treated. Therefore, I am only listing the treatment results for the 6 and 8-week treatment groups.

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**Editorial Comments**

This small study is encouraging. The promising part is that this regime will successfully treat genotype 1 and genotype 3 people who have not responded to a prior course of treatment including those with cirrhosis, and it may do so in 8 weeks. This combination is currently in phase 3.

Eclusa (sofosbuvir plus velpatasvir) is expected to be approved by the Food and Drug Administration (FDA) by the time this article is published.

If the combination of Sofosbuvir, Velpatasvir, and the NS3/4A protease inhibitor GS-9857 result in the same safety and effectiveness as they have shown in phase 2 studies, this combination will be another regime to treat hepatitis C especially those patients who have been the most difficult to treat and cure.
Article: Racial diversity in mortality and morbidity in urban patients with hepatitis C—A Stubbs et al.  

Study Aims and Results
The authors wanted to understand the differences in hepatitis C (HCV) disease progression between African Americans and Caucasians. The current study included 3,724 patients seen in an urban clinic between 1995 and 2008—2,879 African Americans, 758 Caucasians and 87 other people who belonged to a different race. The majority were not treated with HCV medications.

Conclusions
The average age from first death was 5 years, and the average age at death was 55 years old among Caucasians and African Americans. The death rate was similar in African Americans (23%) and Caucasians (22%). Achieving a treatment cure increased survival in both groups.

The authors commented that their study found that African Americans with kidney disease and low albumin counts were at highest risk for death and should be treated with HCV medications soon after testing positive for the hepatitis C virus. Not surprisingly, African Americans who were treated with antiviral medications but who did not respond to HCV antiviral medications still had better overall health outcomes.

Editorial Comments
The early death scenario in this urban clinic setting is frightening. The typical patient that visits an urban clinic is uninsured or underinsured, and as a result, their hepatitis C related disease has been neglected for years and decades. This study points to the terrible outcome that can result —after first visiting an urban health center the average death in 5 years at age 55 years old regardless of race.

“The typical patient that visits an urban clinic is uninsured or underinsured, and as a result, their hepatitis C related disease has been neglected for years and decades.”
**Article: Alcohol intake increases the risk of hepatocellular carcinoma in patients with hepatitis C virus-related compensated cirrhosis: a prospective study—A Vandenbulcke et al.**


### Study Aims and Results

The current study looked at the effect of alcohol consumption and hepatitis C (HCV) treatment cure on the risk of the development of liver cancer (hepatocellular carcinoma (HCC)). The study authors collected information on the amount of alcohol consumed by 192 HCV patients with HCV-related compensated cirrhosis.

Seventy-four patients consumed an average of 15 grams of alcohol a day—the equivalent of a little more than one 12-ounce beer a day. Sixty-eight patients were cured of HCV. The patients in the study were followed for an average of 58 months. Thirty-three patients developed liver cancer. Fifty-three patients experienced at least one decompensation event (varices, ascites, etc.).

The 5-year cumulative incidence rate of liver cancer was 10.6% in alcohol abstainers vs. 23.8% in alcohol consumers. In persons who were treated and cured of HCV, the liver cancer was 2.0% compared to 21.7% in the patients not cured of HCV.

Those who did not drink alcohol and were cured of HCV had the lowest incidence of liver cancer—0% followed by those who did drink alcohol but were cured of HCV (6.2%).

Patients who did not drink alcohol and who did not achieve a cure of HCV had a cancer rate of 15.9% compared to those who had consumed alcohol and not cured of HCV had a cancer incidence of 29.2%.

Importantly, it was noted that alcohol intake did not influence the risk of decompensation or death.

### Editorial Comments

This was a small study, but it is important because it does point to the fact that alcohol combined with HCV-related cirrhosis can contribute to the development of liver cancer. The people who drank alcohol in the study consumed small amounts of alcohol. This study makes it clear that people with cirrhosis should abstain from alcohol.

There is a need for more studies on the role of alcohol and liver cancer.

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**“This study makes it clear that people with cirrhosis should abstain from alcohol.”**

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Alan Franciscus is the Executive Director of the Hepatitis C Support Project and the Editor-in-Chief of the HCV Advocate Website.
In 1998, nurse practitioner Ginny Morrow and I launched the Redwood City Hepatitis C Support Group. Our first meeting surpassed our expectations, merely because people showed up. Far more people showed up for future meetings than we had anticipated. As the group grew, other leaders emerged, including another nurse named Brooke Clark. A second group was added for the often neglected family and friends of those with hepatitis C, facilitated by Amanda Newsom. In 2006, I moved out of the area, leaving behind dear friends and an important part of my life.

The Redwood City Hepatitis C Support Group met for the last time on June 9. More than 40 people attended this bittersweet occasion; not a single person had hepatitis C any longer. One of our youngest group members went to nursing school and is now working with hepatitis patients. There was much to celebrate.

In eighteen years, countless people with hepatitis C were served. I was one of them, having gone through one of my treatments as a group member/facilitator. In the years we met, many had been cured, some in the hell days of interferon. At least four died. The causes were liver cancer, a failed liver transplant, a drug overdose, and a motorcycle accident. Each death tore us apart and brought us closer together.

As hepatitis C treatments improved, group attendance dropped. The explanations for this are easy to guess. When the group began, hepatitis C was rarely curable. The treatment had low response rates, was long, and was fraught with side effects. It took Herculean efforts to endure. Support groups made it easier to endure. When I was on 48 weeks of peginterferon and ribavirin, the only place I remember ever laughing was when I attended the support group. I felt like I was a bumbling mess, and it was the one place I felt understood.

Now that treatment for hepatitis C is short and fairly easy to endure, it makes sense that group attendance has fallen. Does that mean that hep C support groups...
have outlived their usefulness? Not at all. I believe that the need for shared information and support is as great as ever. What has changed is the group format. Web-based groups are flourishing. For instance, the HEP Forum has over 4500 members. Despite the numbers, the group is able to share good information while offering compassionate support.

So if hep C is curable, why do people flock to them? Because hepatitis C is scary and complicated. With a menu of medications to consider, people want to understand what their treatment options are. Further, support groups work. They may sound touchy-feely, but a good group empowers people to make choices about their health, by providing solid information and insight on how to live with their disease. The potential value of support groups is not just theoretical—there is evidence for it.

In the 1970’s and 80’s, Harvard-trained psychiatrist David Spiegel became interested in the emotional aspect of illness, specifically cancer. “…Dr. Spiegel was troubled by the assertion that you one could “wish-away-your-illnesses.”…In the 1980’s his well-designed study of women with breast cancer shocked the medical community. Those in support groups lived on average twice as long as those who had not been in a group - an 18-month extension. (Published in The Lancet, 1989) However, the group model emphasized confronting cancer and death rather than “wishing it away.” The focus was on living better, not on living longer.” (David Spiegel, Living Beyond Limits; Fawcett Columbine 1993)

Somewhat stunned, Spiegel conducted further research and concluded:

1. Support groups can improve quality of life — reduce anxiety and depression, increase coping skills, and help symptom management
2. A thorough understanding of illness affects physical and psychosocial factors that affect response to treatment and resistance to disease progression
3. The most effective techniques involve facing the illness directly
4. There is no evidence that these techniques will cure an illness, but there is evidence that these may prolong life with cancer, heart disease, and other chronic diseases
In this era of short medical appointments, support groups provide an opportunity for participants to share tips with each other. Patients who have personal experience with treatment bring perspective and a streetwise expertise that is highly valuable to those who are newly diagnosed or on treatment.

All groups are not alike. Some may be positive and upbeat; others may be unnecessarily negative. The quality of a support group is influenced by its leadership as well as its regular members. Try a group a few times, and if it doesn’t feel supportive, look for another one. The benefit of web-based support groups is that there are so many of them that if you don’t like one group, you can easily find another. Another benefit is that you don’t need to reveal your identity in order to participate and you can wear your pajamas to meetings.

Web-based support groups have characteristics that may be both useful and harmful. They are more anonymous than in-person groups, so this makes it easier for people to say things that they may not say in face-to-face discussions. Open communication can foster genuine compassion, which is a good thing, but it can also lead people to say whatever is on their minds, without thinking it through, and that can lead to comments perceived as tactless or hurtful.

Another problem with electronic conversations is that there is no body language. Communication is more than the spoken word; it involves gestures, facial expression and other body language, all of which are missing online. When we read words on a page, we hear the message in our own voice, adding meaning and interpretation from our own perspective that perhaps wasn’t intended by the “speaker.”

If you are interested in participating, search for web-based support groups on Facebook, Google, Yahoo, etc, and as mentioned earlier, HEPmag.com. Janis and Friends and the Hepatitis Central groups on Delphi Forums have been around for a very long time. The size of the group doesn’t matter; it’s all about quality.

As for face-to-face support groups, they still exist. You can search the HCV Advocate for one in your area. I hope you find the experience as rewarding as I did.

I end with a toast to all those who have facilitated and participated in hepatitis C support groups. Thank you for all that you have contributed. Someday, may we meet in a world free from hepatitis C.

“Patients who have personal experience with treatment bring perspective and a streetwise expertise that is highly valuable to those who are newly diagnosed or on treatment.”

Lucinda K. Porter, RN, is a long-time contributor to the HCV Advocate and author of “Free from Hepatitis C” and “Hepatitis C One Step at a Time.” She blogs at www.LucindaPorterRN.com and HepMag.com.
The current drugs to treat hepatitis C have high cure rates and minimal side effects (compared to the older therapies). This has created a dilemma for drug developers who must develop new drugs that somehow improve upon the current drugs. This is a difficult task, but not impossible. Probably the biggest achievement will be shorter treatment duration and lower cost. There is a percentage of patients who are more difficult to treat, such as those with genotype 3 who have cirrhosis and have not achieved a cure with a previous course of therapy. The race is on for new, better and cheaper therapies—this is very good news for people living with chronic hepatitis C.

You will see below that the need for these new therapies has narrowed the pharmaceutical companies to a number that you can count on your fingers! As a result I have decided to rework our pipeline and list it by the pharmaceutical company. I am also just listing the major studies. This is also a new pipeline that will grow as information is released. The pipeline is a brief overview. More extensive information is listed in our newsletters and in our blog.

A brief overview of how this pipeline is laid out:

**Date:** The Pipeline will be updated on a monthly basis and will be included with the HCV Advocate Newsletter

**Genotype (s):** This lists the drugs or combination of drugs and the particular genotype or genotypes that the drug is active against.

**Comments:** This section will list the study results. Within this section, I will list the genotype(s) being studied and the phase of the study with a brief recap of the study.

You will note that many of the drugs or combinations of drugs are pan-genotypic—that is they work on many or most of the HCV genotypes. **Note:** Many of the drugs listed below have been updated with the latest information from the Liver Meeting 2015 and the International Liver Congress 2016. More detailed information about drugs in development is available in our blog and reported in the HCV Advocate newsletters.
AbbVie | Genotype(s): 1, 2, 3, 4, 5, 6 (Pan-genotypic)

**COMMENTS:**

**Genotype 1 – Phase 2 Study:** Information from the International Liver Congress 2016: AbbVie’s once-daily therapy of ABT-493 (protease inhibitor) and ABT-530 (NS5A inhibitor).

**Non-cirrhotic patients Treatment period - 8 weeks:**
- Genotype 1: 85% were treatment-naive; 15% were pegylated interferon (PEG)/ ribavirin (RBV) experienced, cure rates—97% (33 of 34 patients)
- Genotype 2: 87% were treatment-naive; 87% were PEG/RBV treatment experienced: cure rate—98% (53 of 54 pts)
- Genotype 3: 100% were treatment-naive: cure rate—97% (28 of 29 pts)

**Treatment period 12 weeks:**
- Cirrhotic treatment-naive patients, genotype 3 – cure rate —100% (24 of 24 patients)
- Non-cirrhotic treatment-naive patients (85%), PEG/RBV (15%); genotype 4 (22 pts), genotype 5 (1 pt), genotype 6 (11 pts)—cure rate—100% (34 of 34 pts)

**Bottom line:** cure rates were 97% to 100%.

Gilead | Genotype 1,2,3,4,5,6, (Pan-genotypic)

**COMMENTS:**

- **Genotype 1 – Phase 3:** Sofosbuvir plus velpatasvir (GS-5816) In Phase 3 clinical trials (ASTRAL-1-4), the cure rates in genotypes 1 through 6 ranged 97% to 100%. In January 2016 the combination received priority review status and Gilead stated that FDA approval is expected by June 28, 2016. To view the Phase 3 data go here: [http://hcvadvocate.org/news/NewsUpdates_pdf/Advocate_2016/advocate0116_mid.pdf](http://hcvadvocate.org/news/NewsUpdates_pdf/Advocate_2016/advocate0116_mid.pdf)

The results from a phase 2 study of the combination of sofosbuvir, velpatasvir and GS-9857 are listed below:

<table>
<thead>
<tr>
<th>Genotype 1: 6 - 8 weeks</th>
<th>Treatment-naive no cirrhosis 6 weeks</th>
<th>Treatment-naive cirrhosis 6 weeks</th>
<th>DAA-experienced with &amp; without cirrhosis 6 weeks</th>
<th>PEG-RBV-experienced with cirrhosis 8 weeks</th>
<th>PI-experienced with &amp; without cirrhosis 8 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cure rates</td>
<td>93% (14/15 pts)</td>
<td>87% (13/15 pts)</td>
<td>67% (20/30 pts)</td>
<td>100% (17/17 pts)</td>
<td>89% (25/28 pts)</td>
</tr>
<tr>
<td>Genotype 3: 6 – 8 weeks</td>
<td>Treatment-naive with cirrhosis</td>
<td>PEG/RBV-experienced with cirrhosis</td>
<td>DAA experienced cirrhosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cure rates</td>
<td>83% (15/18 pts)</td>
<td>100% (19/19 pts)</td>
<td>100 (4/4 pts)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: DAA experienced: direct-acting antiviral treatment-experienced patients; PEG – pegylated interferon; RBV: ribavirin; PI experience: Protease inhibitor treatment-experienced; Treatment-naive: patients who have never been treated

The most common side effects were a headache, nausea, and fatigue.
### Comments:

- **Genotype 1 – Phase 1:** In a small study of samatasvir, it was found to be safe and have antiviral properties against genotype 1, 2, 3 and 4. There is now a phase 2 study of samatasvir plus Olysio (simeprevir) in treatment-naïve patients with genotype 1b or 4.

- **Genotype 1:** Janssen (Alios Pharma) has initiated a phase 2a study of AL-335, odalasvir, and simeprevir to treat HCV genotype 1 treatment-naïve patients. There will be 60 patients divided into three treatment arms who are treated for 4, 6 or 8 weeks.

- **Genotype 1 – Phase 2 Study:** ACH-3422 and Odalasvir (ACH-3102) and Sovaprevir are in studies with various combinations. Recently, Johnson & Johnson Innovation – JJDC, INC (Janssen) made an investment in Achillion for co-development and distribution.

- **Genotype 1 – Phase 2 Study:** Odalasvir plus sofosbuvir (used as a proxy drug) to treat genotype 1 patients for 6 weeks achieved 100% (12 of 12 patients) cure rates. A proxy drug is a drug used to stand in for another drug. Sofosbuvir is a polymerase inhibitor so it is assumed that odalasvir plus a polymerase inhibitor that is being developed by Achillion will produce similar cure rates.

- **Genotypes 1 through 6–Phase 2b Study:** Odalasvir, AL-335, and simeprevir in treatment-naïve and treatment-experienced patients with and without cirrhosis. The trial will enroll 400 patients for six or eight weeks. The study will include four arms with different combinations of drugs. The trial will begin in June 2016 and end in July 2017.
### Merck

**COMMENTS:**

- **Phase 2** - The study was to evaluate the safety and efficacy of an all-oral therapy. There were three different groups that included treatment-naïve, non-cirrhotic patients. The patient population included 93 genotype 1 patients, 61 genotype 2 patients, and 86 genotype 3 patients. The treatment duration was 8 weeks. All of the treatment groups received MK-3682 (300 mg or 450 mg) combined with grazoprevir/elbasvir or grazoprevir /MK-8408.

Twenty-four percent of genotype 1 patients had resistant associated variants (RAVs): 59% had NS3 (protease) RAVs and 21% had NS5B (polymerase) RAVs.

The overall cure rates were 91 to 100% in the genotype 1 groups; 60 to 94% in the genotype 2, and 86 to 91% in genotype 3. The drugs were well-tolerated with no treatment discontinuations.

Part B of C-CREST 1 and 2 will evaluate the most effective dose to treat prior treatment failures, cirrhotic patients and treatment in people with HIV/HCV coinfection.

**Bottom line:** The most effective dose was associated with cure rates in the 90 to 100%.

<table>
<thead>
<tr>
<th>Time Since Treatment Completion</th>
<th>RG-101 + Harvoni</th>
<th>RG-101 + Olysio</th>
<th>RG-101 + Daklinza</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 12</td>
<td>27/27 pts (100%)</td>
<td>26/27 pts (96.3%)</td>
<td>22/24 pts (91.7%)*</td>
</tr>
<tr>
<td>Week 16</td>
<td>21/21 pts (100%)</td>
<td>19/20 pts (95.0%)</td>
<td>20/22 pts (90.9%)</td>
</tr>
<tr>
<td>Week 20</td>
<td>14/14 pts (100%)</td>
<td>13/15 pts (86.7%)</td>
<td>13/13 pts (100%)</td>
</tr>
<tr>
<td>Week 24</td>
<td>10/10 pts (100%)</td>
<td>8/10 pts (80.0%)</td>
<td>8/9 pts (88.9%)</td>
</tr>
</tbody>
</table>

* One patient missed the Week 12 visit. Viral load results for this patient at week 8 and 16 were collect and indicate that the patient was a responder at both time points.

### Regulus

**COMMENTS:**

Regulus Therapeutic Inc.

The study included 79 treatment-naive genotype 1 and 4 patients. RG-101 is a GalNAc-conjugated anti-miR targeting miR-122, a host factor for HCV infection. It is an injectable medication given at Day 1 and Day 29 plus 4 weeks of a once-a-day direct-acting antiviral medication—Harvoni (27 patients), Olysio (27 patients), Daklinza (25 patients). Regulus issued a press release on June 7, 2016 that reported through 24 weeks of follow-up an additional 4 patients relapsed.
WHAT’S UP!

WE HAVE REVIEWED AND UPDATED THE FOLLOWING HCSP FACT SHEETS:

Diagnostic Tools Series:

Fibroscan
Genotype, Quasi-species and Subtype
Viral Load

CLICK TO DOWNLOAD

CLICK TO DOWNLOAD

CLICK TO DOWNLOAD

UPDATED EXTRAHEPATIC MANIFESTATIONS GLOSSARY

I have added the following conditions to the glossary. These conditions are either caused by hepatitis C or are diseases that more commonly found in people with hepatitis C.

Erythema Multiforme
Head and Neck Cancers
Necrolytic Acral Erythema
Prostate Cancer
Rheumatoid arthritis
Scleritis

The HCV Advocate offers information about various forms of intervention in order to serve our community. By providing information about any form of medication, treatment, therapy or diet we are neither promoting nor recommending use, but simply offering information in the belief that the best decision is an educated one.

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