The 2018 Liver Meeting took place this November. It’s a longstanding tradition of the HCV Advocate to highlight the latest research from this annual meeting of the American Association for the Study of Liver Diseases (AASLD). Alan Franciscus and I divide the task, providing capsule summaries of our favorite presentations. Be sure to check out HCV Advocate’s News and Pipeline Blog to keep abreast of the latest hepatitis C-related news.

I’ve been reporting on The Liver Meeting for more than 20 years. I remember a presentation I heard years back, predicting that fatty liver disease would someday be a bigger problem than hepatitis C. That day is here as presentations on fatty liver diseases dominated this year’s Liver Meeting.

Below are some of my favorite hepatitis C-related posters from the nearly 2400 abstracts. Next month, I will present the latest research on hepatocellular carcinoma (liver cancer). Note that conference posters are preliminary investigations, and are not conclusive until the data are published in a peer-reviewed journal.


The increase in injection drug use among younger people is driving an increase in the number of hepatitis C virus (HCV) infections. To prevent and treat hepatitis C, epidemiologists need to know where the highest prevalence exists in the United States. This study updated existing surveillance methods to obtain an accurate assessment.

These researchers estimated that during 2013-2016, nearly one percent of adults (2.5 million persons) in the United States had hepatitis C. Half of these infections were in nine states: Alaska, Arizona, Kentucky, Louisiana, New Mexico, Oklahoma, Oregon, Tennessee, West Virginia plus Washington, D.C.

Conclusion: These prevalence estimates support evidence-based evaluation and planning for HCV prevention, treatment, and ultimately elimination.
Editorial Comments: These high prevalence regions mirror many of the areas where there is a huge opioid problem. If effective measures are not put in place, hepatitis C transmission and reinfection rates will continue to climb. So will opioid-related injuries and deaths.


The purpose of this research was to better understand the mechanisms of HCV transmission among men who have sex with men (MSM). This prospective study enrolled 34 subjects with acute or chronic HCV infection. Researchers analyzed HCV RNA (viral load) obtained from rectal and nasal swabs from all participants. Fecal occult blood tests were performed to rule out rectal bleeding. Participants completed questionnaires to assess risk behavior related to recreational drug use and sexual practices.

Here are the results: The mean age of participants was 43 years; all but one were HIV-positive; 82% were male of whom 64% were MSM. Acute HCV was observed in 32% (11/34) with all subjects being HIV+MSM. Twenty-three (68%) patients had at least one positive swab sample (56% nasal and 52% rectal), whereas blood contamination was never detected. Individuals with positive swab samples had significantly higher HCV-RNA levels vs. those with negative swab samples.

Conclusion: Despite the absence of blood, HCV-RNA is readily detectable in rectal and nasal fluids in patients with acute and/or chronic hepatitis C. This suggests that unprotected anal intercourse and sharing of drugs via nasal route may be high-risk practices for HCV transmission, especially in patients with high HCV viral levels.

Editorial Comments: First, this is a small study. Second, we need more studies like this. Third, this research has the potential to shed light on transmission routes for which we need more information.


Approximately one to three percent of pregnant women in the US are infected with HCV. Despite this, the rate of vertical transmission between mother and fetus is quite low at four to eight percent. Researchers wanted to know why.

Conclusion: Looking at mother-child pairs with and without HCV, they found an aspect of fetal immunity by identifying HCV-specific T cells at the maternal/fetal interface. Further, the T cell responses at the maternal/fetal interface are highly active in patients with active HCV infection. Researchers speculated as to whether in the future this understanding can lead to reduced transmission rates of not only HCV, but also of hepatitis B.

Editorial Comments: This is very exciting. Few things break my heart more than hearing about women who learn that their child has hepatitis C because of vertical transmission.


Liver biopsy is an important diagnostic tool used to evaluate the condition of the liver. There are no universal guidelines on recovery times following percutaneous biopsy. Using a consistent liver biopsy protocol
and follow-up procedure, these researchers evaluated
recovery times after 456 liver biopsies were performed. Less than 8% of subjects reported a pain level above 5 on a 0-10 scale; 13% required post-procedure pain medications. There were three serious complications: two cases of hemorrhage and one pneumothorax. There were no deaths. All complications were detected during the 1-hour recovery time. Nearly 80% of subjects were discharged in less than 90 minutes post-procedure, and 50% of subjects were discharged 1-hour post intervention. Overall complication rate after 24 hours was less than 1%. There were no mortalities.

**Conclusion:** Following a liver biopsy, a 1-hour recovery time appears to be adequate to identify major complications and shorten post procedure stay.

**Editorial Comments:** I’ve had 5 liver biopsies, all requiring a 6-hour stay following the very brief procedure. One-hour biopsies seems like a vast improvement.

**Abstract: #1582** Chronic Hepatitis C and Autoimmune Hepatitis Overlap Syndrome: Fact or Fiction? – Juan Putra, et al.

In addition to having hepatitis C, some patients are also diagnosed with autoimmune hepatitis (AIH), leading to a diagnosis of overlap syndrome (HCV-AIH). Not only is this an uncommon diagnosis, it is controversial since both diseases share common features. This study evaluated biopsies from 2011 to 2018 of 5 patients with HCV-AIH who were treated with direct-acting antiviral agents (DAAs).

**Conclusion:** Even without immunosuppression, most patients showed improvement in liver tissue following DAA treatment. Researchers state that the results suggest that the autoimmune component is a secondary phenomenon of HCV. They recommended using the term “HCV with autoimmune features” instead of HCV-AIH to prevent overtreatment with immunosuppressants.

**Editorial Comments:** Although this is a very small study, it opens the door wider to examining the role of HCV on the immune system, particularly when autoimmune features appear to be present.


Recent data show an increasing number of younger HCV-infected individuals, presumably due to the opioid epidemic. Because HCV can be transmitted vertically during pregnancy, this study assessed the HCV infection rate in pregnant American Indian and Alaska Native (AI/AN) women from 2011 through 2015.

They found that between 2013 and 2015, more than 12% of non-Native women and nearly 17% of AI/AN women of reproductive age self-reported ever having been tested for HCV. The percentage of pregnant women who were known to have HCV infection increased between 2011 and 2015 in both the AI/AN population (0.57% to 1.19%) and the non-Native population (0.21% to 0.36%).

**Conclusion:** This study found a significant increase in the proportion of pregnant AI/AN and non-Native women with known HCV infection between 2011 and 2015. Only a small percentage of women reported having ever been screened, raising the possibility that the true prevalence of infection is higher. The majority of women with HCV did not have medically documented history of injection drug use. The researchers state that the data suggest reassessing risk-based HCV testing and prevention programs in high-risk pregnant AI/AN women.

**Editorial Comments:** Universal HCV testing of all pregnant women is an economic and logical alternative to risk-based HCV testing. The cost-effectiveness of this strategy was reported in another presentation: #87

Abstract: #1591 The Cedar Project: Childhood Sexual Abuse Is a Risk Factor for Hepatitis C Infection Among Young Indigenous People Who Use Drugs in Canada – Margo Pearce, et al.

Indigenous people in Canada are disproportionately affected by HCV. The Cedar Project is a cohort of young Indigenous people (14-30 years) using street drugs in Vancouver and Prince George, British Columbia, Canada. Indigenous communities struggle with a higher than average amount of sexual and physical trauma. This study looked at the effects of childhood physical abuse or sexual abuse on HCV risk among young Indigenous people who use street drugs.

Conclusion: Researchers noted that childhood physical and sexual abuse experiences continue to negatively affect the well-being of young Indigenous people. Each increase in sexual abuse severity was associated with 3.5-fold higher odds of HCV infection. Researchers noted the HCV infection may be a marker of previous sexual abuse among Indigenous patients.

Editorial Comments: In this #MeToo age, we must remember the children plus those who are trapped in a cycle of violence. It isn’t enough to support children, we need to reach out to those who abuse, developing effective ways to stop violence before it occurs.

Briefly…
These three abstracts illustrate the benefits of successful HCV treatment.

Abstract: #766 Cure of Hepatitis C Virus Infection with Direct Acting Antiviral Drugs Improves Work Place Performance – Ciara Bosh, et al. This study demonstrated that successful HCV treatment had a beneficial effect on participants’ ability to be fully engaged in the work place, unhindered by illness. This improved capacity for effective functioning in the work place is expected to enhance job retention, increase pay, and promote career advancement.

Abstract: #1553 “If I Get Cured, My Whole Quality of Life Will Change:” an in-Depth Qualitative Analysis of Patients’ Anticipated Benefits if Cured from Hepatitis C Viral (HCV) Infection – Donna M. Evon, et al. This study examined some of the hopes and expectations that 28 patients had about HCV treatment. In addition to improving liver health and life expectancy, they hoped that HCV cure would improve many areas of life functioning, especially emotional well-being.

Abstract: #1566 Risk of Cardiovascular Disease Events after HCV Treatment: Results from Erchives – Adeel Ajwad Butt, et al. This large study (32,575 subjects) found that HCV treatment is associated with a reduction in cardiovascular events, especially when direct acting antiviral regimens (vs. PEG/RBV) are used.

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The main part of my review will concentrate on hepatitis C (HCV) treatment and abstracts awarded special designations:

- **American Association for the Study of Liver Disease (AASLD) Foundation Abstract** recognizes excellence and promotes the professional development of young investigators by enabling them to travel to The Liver Meeting® and present their work to an international audience.

- **Recipient Posters of Distinction** are considered to be particularly noteworthy and represent the top 10% of all accepted poster presentations.

### AASLD FOUNDATION Abstract Award Recipient

**Abstract: #148 Sustained Virologic Responses Reduces the Incidence of Extrahepatic Manifestations in Chronic Hepatitis C Infection - Carmine Ross, et. al.**

This study evaluated the effect of hepatitis C (HCV) treatment with interferon-based therapies on extrahepatic manifestations (diabetes, chronic kidney disease, stroke, heart disease, osteoporosis and mood disorders such as depression). The results compared patients cured and not cured. Included in the analysis were 10,566 HCV patients that were followed for up to 10 years. The overall cure rate in this interferon-based therapy was 57%. All extrahepatic manifestations (diabetes, chronic kidney disease, end-stage kidney disease, stroke, osteoporosis with fractures, and mood disorders) improved except heart disease.

**Conclusion:** Treatment and cure of HCV significantly reduced extrahepatic manifestations of HCV.

**Editorial Comments:** This was a retrospective study of people treated with interferon-based therapies. Still, since this is a large long-term study it provides valuable information that treatment and cure significantly reduce many extrahepatic manifestations of HCV.

### AASLD Presidential Poster of Distinction

**Abstract: #583 Retreatment with SOF/VEL/VOX in Treatment-Experienced Patients with and without HIV: The Resolve Study – Emily Covert, et. al.**

Retreatment of people who have not achieved a cure with a direct-acting antiviral (DAA) therapy is uncommon but an important unmet need. Retreatment is even more important in people coinfected with HIV or hepatitis B (HBV) or in people who had prior poor medication adherence. Additionally, some providers may not want to re-treat these ‘difficult-to-treat’ patients. In the current study (RESOLVE), the authors’ re-treated patients with a combination of sofosbuvir/velpatasvir/voxilaprevir (Vosevi) for 12 weeks.

There were 77 people enrolled—most were male, black and genotype 1a, 17 patients were coinfected with HIV, and two patients were co-infected with HBV. The majority of the patients in the trial (89%) had failed prior treatment with ledipasvir/sofosbuvir (Harvoni), but all DAA therapies were represented in the study.

The cure rate was 91% (70 of 77 patients). Two patients had not reached their cure determination results by the study completion date; five people discontinued treatment. The most common side effects were fatigue, headache, diarrhea, abdominal pain, and constipation.

**Conclusion:** In this ‘difficult’ treatment population, a cure rate of 91% was achieved.

**Editorial Comments:** In my opinion, this is one of the most important studies on HCV treatment to come out of The Liver Meeting. Retreatment of the people who did
not achieve a cure with DAA therapy will continue to be a problem even if it is a minority of people. I would like to understand what can be done to help the people who discontinued treatment early. Perhaps we could have reached 100% if there were other adherence strategies put in place.

Editorial Comments: This is a well-conducted study that should prompt earlier treatment of people newly diagnosed with hepatitis C. I would hope that insurance companies would consider this when evaluating approval of treatment.

AASLD Presidential Poster of Distinction

Abstract: #584 Early Treatment with Direct-Acting Antivirals (DAAs) Saves Medical Costs in Non-Cirrhotic Patients with Chronic Hepatitis C (CHC) Virus Infection in the United States (US)- Patrice Cacoub, et. al.

The study evaluated whether DAA therapy was cost-effective in people infected with chronic hepatitis C without cirrhosis. Prior interferon and/or ribavirin-treated patients were excluded from this retrospective study. Two patient groups were identified and evenly matched by patient characteristics—one group received DAA treatment, one group did not (control group). The treated patients received DAA treatment between 2013 and 2015. Both groups were followed for a maximum of 3 years, and their medical costs were estimated. The medical costs of the two groups were compared including expenses from HCV extrahepatic manifestations (EH). The most common EH’s included fatigue (13%), type 2 diabetes (11%), and heart disease (9%). There were 3,069 patients evaluated and 852 (28%) patients treated with DAAs.

The cost savings in the DAA-treated group was significantly lower on average ($6,379 per patient, per year). The savings were mainly from a reduction in costs attributed to the care and treatment of extrahepatic manifestations.

Conclusion: Starting DAA treatment within the first three years of diagnosis of HCV is associated with significant cost savings.

Editorial Comments: This is a well-conducted study that should prompt earlier treatment of people newly diagnosed with hepatitis C. I would hope that insurance companies would consider this when evaluating approval of treatment.
Briefly…

**Abstract: #595** Sustained Viral Response Following Treatment with Direct Acting Antiviral Regimens Is Durable in More Than 6,600 Patients: Results of the Gilead Sustained Virologic Response Registry Study - Christian Schwab, et. al.

**Summary:** The 6,600 patients received various Gilead’s direct-acting antiviral drugs including ribavirin and pegylated interferon for a treatment period ranging from 24 weeks to 144 weeks. The patients who achieved a cure within three months were eligible for the study. Eight (0.1%) had a relapse, and 22 (0.3%) had reinfection. None of the patients with mild liver fibrosis (F0-F1) prior to treatment developed liver cancer. The patients who developed liver cancer based on their liver fibrosis prior to treatment was F2 (0.06%); F3 (0.25%), and F4 (0.58%). This showed a very good durable response with low liver cancer development rates.

**Abstract: #602** Durability of Sustained Virologic Response and Liver Safety in Patients Treated with Glecaprevir/Pibrentasvir: A Long-Term Follow-up Study – Franco Felizarta, et. al.

**Summary:** In a follow-up of 792 days, all 87 patients (except 2) treated with glecaprevir/pibrentasvir (Maryret) maintained their sustained virologic response or cure. Reinfection was detected in one patient who relapsed before the post-SVR24 weeks and before this study ended.

**Abstract: #681** Impact of Obesity on Treatment of Chronic Hepatitis C in Interferon-Free Direct-Acting Antiviral Era - KyDieu Tran, et. al.

**Summary:** A retrospective analysis conducted on patients with an average body mass index (BMI) of 30 kg/m² (considered to be obese). A total of 168 patient records were found. All patients were treated with direct-acting antiviral (DAA) medications for 12 weeks. The cure rate was 95%. The authors concluded that obesity defined as BMI greater than 30kg/m² does not have a negative effect on being cured with DAA medications.

**Abstract: #715A** (late breaker) Efficacy and Safety of 8-Week Glecaprevir/Pibrentasvir in Patients with HCV Genotype 1–6 Infection and Compensated Cirrhosis: The Expedition-8 Study - Robert S. Brown Jr., et. al.

Cohort 1 of 270 treatment-naïve patients treatment results were released that showed treatment with eight weeks of glecaprevir/pibrentasvir (Maryret) in hepatitis C (HCV) genotypes 1,2,4,5 and 6 patients with compensated cirrhosis achieved a 100% cure rate. Cohort B of treatment-naïve with compensated cirrhosis HCV genotype 3 patients is on going.

**Abstract #984** The Cost-Effectiveness of HCV Screening of Pregnant Women in the United States - Antoine Chaillon, et. al.

**Summary:** This study explored the cost-effectiveness to screen all pregnant women for hepatitis C (HCV) before giving birth to their babies. Based on their analysis, it was found that it is likely cost-effective to screen all pregnant women for HCV on a national level.

**Note:** Legislation for screening all pregnant women is pending in Kentucky.

Alan Franciscus is the Executive Director of the Hepatitis C Support Project and the Editor-in-Chief of the HCV Advocate Website.
WHAT’S UP!
We have updated the following HCV Advocate treatment-related fact sheets:

- **Adherence to HCV Therapy**¹
- **Treatment Response Terms**²
- **Prescription Drugs – Off-label Use**³
- **Reporting Drug Side Effects**⁴

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