Hepatitis C in Prisons

—By Alan Franciscus

Estelle v. Gamble ruled that prisons are legally responsible for treating inmates’ health conditions.

About 30% of all people with hepatitis C in the U.S. spend part of their lives in a prison

20% to 55% of inmates have a history of injection drug use

The topic of hepatitis C in prisons has always been hotly debated. But like it or not, if we are ever going to eliminate hepatitis C, we are going to have to test and treat prisoners. In this article, I will discuss what we know, and what we don’t know. I will discuss screening, prevalence and treatment of incarcerated people infected with hepatitis C. Finally, I will discuss some solutions that have been suggested to solve the problem of hepatitis C in American jails and prisons.

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Jails
Jails are funded and staffed by local and state governments. People are housed in jails for being accused of a crime or who are waiting for a trial whether they are innocent or guilty. The length of time that people are held in jails can be up to one year or longer. Jails typically have a more transient population. Jails offer educational, substance abuse, and vocational (work) programs.

Jails do not routinely screen for hepatitis C and seldom, if ever, offer treatment. But jails would be a good place to test and provide referrals to local agencies.

Prisons
People who are convicted of a felony and generally sentenced for a year or more, are sent to a prison. State and federal governments operate prisons or contract with the private prison industry. A person who is convicted of a crime and who is incarcerated in a prison is a felon. Prisons can have a minimum, medium, and maximum security. There are also halfway houses, work related programs, and community restitution programs.

The average length of time a person who is incarcerated is a couple of years.

Screening
The Federal Bureau of Prisons (FBOP) recommends opting-out of hepatitis C testing for all inmates during the prevention baseline visit. See complete guideline https://www.bop.gov/resources/pdfs/hepatitis_c.pdf Screening for hepatitis C in state prisons is not uniform and it is conducted on a state-by-state basis.

Prisons offer an optimal place to test, manage and treat hepatitis C.

Prevalence
Hepatitis C is the most common blood-borne pathogen in the United States and the Correctional Systems. In a study conducted by the Centers for Disease Control and Prevention (CDC) it was estimated that 9.6% to 41.1% of inmates in the prison system are infected with hepatitis C. The CDC took these numbers, averaged them out and estimated the number at 17.4% nationally.

New York and Maryland contributed to the CDC study and noted that their hepatitis C rates in prisons were declining. Two states that were not included in the CDC report, California and Rhode Island, also reported declining rates of hepatitis C infections in prisons.

The Annals of Epidemiology published a study on the ethnic and racial prevalence of the hepatitis C populations in correctional facilities. Non-Hispanic whites had the highest percentage of entrants followed by Hispanics then non-Hispanic Blacks. The racial comprise reported in the Annals of Epidemiology is in stark contrast to the racial and ethnic make-up of the groups who make up the general prison population. This difference may reflect the emergence of the new HCV infections from the current opioid epidemic.

Treatment
There are many reasons that prisons do not treat every prisoner with hepatitis C. In the past the cost of hepatitis C medications, the length of treatment, lack of prison medical staff, and the public reaction to spending large sums of money on the general prisoner health budget.

Now, the cost of treatment is coming down. The most recent treatment approved was AbbVie’s Mavyret. The most common treatment period is 8 weeks. The indication for the 8-week treatment period is for people with mild cirrhosis or no cirrhosis. The cost for the 8-week treatment period is $26,400. This is before negotiations that could drive down the cost even further. The other treatment periods are 12 and 16 weeks. Still public opinion, the number of prisoners times the cost of the HCV medications, and the lack of medical staff are major barriers to treating all prisoners.

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Some Possible Solutions

Changing Public Opinion: Most people believe that all prisoners are hardened criminals, but many people who are incarcerated are convicted for crimes such as using drugs or committing crimes to support their drug use. As previously mentioned, the average time spent in prison is 2 years.

Ex-prisoners are all around us in the community and we are interacting with them on a daily basis.

Treating prisoners accomplishes many goals. If we can treat and cure prisoners we can stop the HCV epidemic from spreading into the community at-large. It will help to lower the future disease burden and overall future health care costs. It will also be a big step to eventually eliminating hepatitis C.

Lack of Prison Medical Staff: There have been studies showing that telemedicine can successfully manage and treat prisoners. The ease of treatment of hepatitis C, one-pill-once-a-day for 8, 12 or 16 weeks is relatively easy for most patients. People with more advanced liver disease will need more care and support that will require an in-house physician that could consult with a telemedicine expert, an in-house expert or a local expert.

Cost of HCV Medicines: There was an interesting idea put forth in an article that appeared in the National Academy of Sciences. The authors proposed buying licensing rights to hepatitis C drugs that could cost $2 billion dollars. The states would pay roughly 140 million dollars each to treat 700,000 Medicaid beneficiaries and prisoners. This is just one innovative idea. We need more ideas like this to solve such an important and expensive problem.

A final note

There is contradicting information coming from the White House. The Justice Department led by the Attorney General, Jeff Sessions, is basically reinstituting the “War on Drugs.” This will mean that there will be mandatory minimum sentences for drug offenses even small ones. These policies will increase the number of people incarcerated, and the government will spend large sums of money on law enforcement, trials, jails, prisons and prisoners instead of services to help people with addiction.

In August, the Trump Administration announced that there was a national emergency due to the opioid crisis. The declaration should mean that more resources will be allocated towards fighting the opioid epidemic.

Resources:
- He, Tianhua “Prevention of Hepatitis C by Screening and Treatment in U.S. Prisons” Annuals of Internal Medicine (2016): 84-92

Alan Franciscus is the Executive Director of the Hepatitis C Support Project and the Editor-in-Chief of the HCV Advocate Website.
A new combination treatment has entered the hepatitis C (HCV) market that could revolutionize the treatment landscape. In August 2017 the Food and Drug Administration (FDA) approved AbbVie’s Mavyret (glecaprevir plus pibrentasvir) to treat genotype(s) 1, 2, 3, 4, 5 and 6. It is three tablets, taken once-a-day.

In clinical trials, the cure rates were 92% to 100% of patients treated for 8, 12 or 16 weeks. Mavyret is approved for treatment in people without cirrhosis or people with compensated cirrhosis—that is in individuals with mild to moderate cirrhosis. Mavyret is FDA approved for use in patients with kidney impairment. Mavyret is not approved to treat people with decompensated cirrhosis (severe cirrhosis).

The most common side effects in the clinical trials were headache, nausea, and diarrhea.

Mavyret is approved to treat patients for 8, 12 or 16 weeks. The length of treatment is determined by cirrhosis status, whether or not someone was previously treated and cured, or what HCV medications were already used to treat HCV. The typical treatment period is 8-weeks.

The Wholesale Acquisition Cost (WAC) of Mavyret is $26,400 for an 8-week course of therapy. This price is substantially lower than the other hepatitis C medications on the market. We finally have a low-cost hepatitis C drug and short treatment duration.

Last month I wrote about Gilead’s Vosevi that has a near perfect cure rate to retreat the people not cured with other HCV therapies. And still, we have more HCV drugs in the pipeline.

Now we just need to push for more access to care and advocate for research dollars to develop a vaccine so that we can indeed eliminate hepatitis C in our lifetimes.

It will be interesting to see if the other companies follow suit in dropping the price of HCV therapies.

Visit our Hep C Medications Blog to learn more about Mavyret. http://hepatitiscmedications.hcvadvocate.org/
Article: Ethnic disparities in progression to advanced liver disease and overall survival in patients with chronic hepatitis C: impact of a sustained virological response—A. K. Le et al.

SOURCE: Aliment Pharmacol Ther. DOI: 10.1111/apt.14241

Study Aims and Results
The authors undertook the study to understand two questions:

1. The difference in the development of cirrhosis and liver cancer among different ethnic and racial groups.
2. How curing HCV affected the development of cirrhosis and liver cancer among the same group of people in the ethnic and racial groups.

The study conducted a chart review from two medical centers in California between January 1997 and June 2016. There were 8,039 patients included—59% were Caucasian, 20% were Hispanic, 9% were African American and 13% were Asian. Of note, the majority of Asians were foreign born.

• Before Treatment & Cure
When the researchers looked at the participant’s disease progression before treatment their analysis revealed that Asians and Hispanics had a significantly higher rate of cirrhosis and liver cancer compared to participants who were Caucasians. The same study showed that the African Americans participants did not have an increased risk of cirrhosis and liver cancer compared to Caucasian participants.

• After Cure
In the analysis of the patients cured after treatment, the rates of cirrhosis and liver cancer and survival were the same as the other races who were treated and cured.

Conclusions
There are clear differences in the development of cirrhosis and liver cancer among racial and ethnic groups. Asians and Hispanics have increased rates of cirrhosis and liver cancer compared to Caucasians and African Americans. But the differences disappear once hepatitis C is cured.

Editorial Comments
This study is encouraging, but it is important to know that it is a chart review (retrospective study) that means it doesn’t provide a high standard of research that a prospective study provides. I would like to see a prospective study that was well-designed ahead of time that has a larger population of racial and ethnic groups.

Still, the current study validated previous studies that found similar results—a faster disease progression in Asians and Hispanics compared to Caucasians and African Americans. And this study does provide some valuable information. The higher rates of disease HCV progression in Asians and Hispanics prior to treatment of hepatitis C is another reason why we should expand screening of hepatitis C and treat everyone as early as possible.

“Asians and Hispanics have increased rates of cirrhosis and liver cancer compared to Caucasians and African Americans. But the differences disappear once hepatitis C is cured.”
Hepatitis C is the most common bloodborne virus in the U.S. More people die every year from hep C than all 60 reportable infectious diseases combined, including HIV. Historically, hepatitis C virus infection (HCV) was considered a baby boomer disease; a legacy that we hoped would die with us. However, we got that wrong. Today’s opioid crisis is causing a new wave of HCV infections, and is threatening our youth.

Last month, Alan Franciscus wrote about hepatitis C in children. He discussed our national failure to accurately gauge the prevalence of HCV in kids. Franciscus points out that women in their childbearing years are not exempt from the ravaging effects of substance use. In short, the number of hep C cases is rising again. However, it’s a different era than when my fellow baby boomers and I were infected. When I was infected, HCV wasn’t yet identified. Not only have we identified and named hepatitis C, we know how it is transmitted, how to prevent it from spreading, and how to cure it.

The Risk of HCV in Young People
The reported prevalence of hepatitis C infection in children and teens ranges from 0.05 percent to 0.36 percent in the United States. However, James Squires and William Balistreri suspect that the prevalence of hepatitis C in children and adolescents is grossly underestimated. (Hepatology Communications) The opioid crisis is causing a surge in the number of hepatitis C cases. Squires and Balistreri write, “A recent study demonstrates a 364% increase in HCV infection among people 12 to 29 years of age living in the Appalachian region of the United States. These findings show that a new wave of young individuals will require HCV-specific treatment or risk the development of progressive liver disease and its complications.”

The rise in new hepatitis C infections isn’t solely due to drug use. HCV is associated with other high-risk activities, including receiving tattoos in an unregulated setting, body piercing, and engaging in sexual practices that involve multiple partners and/or sexual activity with trauma. When the Twilight movies were big, nurses and public health workers saw a wave of teens practicing vampire play. Outside of medical blood transfusions, sharing blood is never a harmless activity, and I shuddered when they told me about vampire play. It sounded to me like a vampire nightmare.
For the record, hepatitis C is not limited to cities. In fact, young people in the suburbs and rural parts of the U.S. are discovering what used to be more of an urban problem. If you think that your kids can’t be infected, you may be deluding yourself.

Empower Young People
I would not have been cured if I didn’t know that I had hepatitis C. Knowing is the most important part, because then you can do something about it. If you suspect that your teenager or adult children were exposed, talk to them about being tested.

Better yet, talk to your kids about staying safe before they are at risk for hepatitis C. Let’s face it, we don’t want to have the birds and the bees conversation, let alone one about hepatitis C and blood and needles. However, that talk is critical because it may save your child from acquiring this virus or others. Here is what everyone needs to know:

• You may be at risk for hepatitis C if your blood comes in contact with blood that is infected with hepatitis C. Don’t get a tattoo or piercing at a party or other unprofessional setting. Skip the vampire “play” or “blood brother/sister” rituals.

• Sharing needles, syringes, and everything associated with injection drugs is a risk factor for hepatitis C transmission. Straws used for inhaling drugs may also be contaminated.

• Don’t share personal care items that may have been in contact with another person’s blood, such as razors, toothbrushes, and cuticle scissors.

• Having sexual contact with a person infected with hepatitis C is a very low risk, but it is a risk. Teaching your children about safer sex does not mean they are going to have sex. It means that when they do, they will have some information that may help them stay safer. It also means that they are more likely to talk to you about hard-to-talk-about subjects.

It’s worth noting that the hepatitis B vaccine does not protect against hepatitis C. Hep B and C are completely different viruses. If your child missed the hep B vaccine, talk to their medical provider about getting immunized.

In addition to talking to your child or children, talk to other parents of school age children. It’s never too soon to start teaching about not sharing blood. Young children can be taught to wash their hands, report cuts, avoid touching blood, and to tell an adult if blood needs to cleaned up.

Kids don’t need to be frightened by blood. Keep the conversations factual, like talking about seat belts and brushing their teeth. But don’t wait until they are teens and less open to your guidance.

References:
• Hepatitis C in Children by Alan Franciscus HCV Advocate August 2017
• Hepatitis C Virus Infection in Children and Adolescents by James E. Squires and William F. Balistreri Hepatology Communications April 2017

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
Many of us have heard the phrase, “Knowledge is power,” and understand the idea that comes along with it. The more we know about the world around us, the more power we have to move ourselves through it, and to change it. Of course, having correct information is important, but even having incorrect information initially, and then making mistakes or missteps, is valuable. Information alone can transform a person and give them the ability to alter their own life.

Along the hepatitis C treatment cascade there are many points of focus for improvement. Many of us rightly focus on testing, surveillance and linkage to care. Education often comes as an addendum to any of these things, but hardly ever stands alone. “What good is education if I can’t provide a test?” might be a question you’ve asked yourself before, or struggle with daily. It’s a topic that came up at a recent training which led to a good conversation about the value of education by itself.

Even if all you can do is provide education in the form of brochures or presentations there is value in this. Of course, education’s potential is unlocked through purposeful action, but the initial stages of realization, understanding and motivation are important. Education...
isn’t only for people who we are trying to get tested. As you can see on the HCV Advocate’s website, education is important at all stages of the treatment cascade. It helps people learning about how the virus is transmitted and how to keep themselves safe. Or those preparing for their first doctor’s visit and anxious about what to expect and what to ask. Maybe they are even beginning to take a certain medicine and they want to learn more about what they are taking, the side effects and what to expect. These points along the treatment cascade are spots for education, but not as a passing addition. They are points where full, robust and dedicated education can be provided apart from the testing, linkage to care and treatment.

I’ll admit that funding is hard to come by for education alone, but there are many resources including the HCV Advocate where materials can be downloaded and redistributed for free. We all want to make the greatest impact possible on our communities and those we care about. We must not lose hope or become discouraged just because we can’t do it all. Networking opens the doors for us to provide what we can and then direct people to our partners and friends who can provide what we can’t.

A gentleman at the training mentioned that they have many people who come to their agency to receive a test who say they were prompted by an educational brochure or talk they had received weeks or months ago. He stressed that without the education those people received, they might not ever have walked through their doors to get a test. Many other people spoke up as well about the importance of education. We can’t overlook the power of one small gesture. Giving a positive result or making a referral to the doctor will have less of an affect, and maybe no affect at all, if people aren’t equipped with the knowledge and skills to feel motivated to act. Hearing the stories and conversation of those in that training reminded me even if all we are providing is education, and feel as though unless we can also do testing and linkage to care we aren’t doing anything, we are wrong. People find comfort, strength and self-confidence in education. They find connection through conversation and bonding. They find self-confidence by taking what they’ve learned back to their friends and family who may not be ready to come in and give that education back. They find the strength to move forward with their own treatment and in doing so can move those around them forward as well.

Matthew Zielske is the Training Manager for the Hepatitis C Support Project’s Train-the-Trainer workshop. He has a Master’s in Communication with a focus on health communication and health literacy.
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:** There is more detailed information about the drugs in development in our newsletter (http://hcvadvocate.org/publications/newsletter/) and our blog (http://hepatitisc.hcvadvocate.org/) and in the HCV Advocate Hepatitis C Drug Pipeline & Conference Coverage site hcvdrugs.com

For EASL coverage see www.hcvdrugs.com

If you are interested in finding out about clinical trials visit HCV Advocate Clinical Trial Reference Guide (http://hcvclinical.hcvadvocate.org/) for a list of trials that are currently recruiting patients.

<table>
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<tr>
<th>Merck</th>
<th>Genotype(s) 1, 2, 3, 4, 5, 6 (Pan-genotypic)</th>
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<tr>
<td><strong>COMMENTS:</strong></td>
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<td><strong>• Phase 2- AASLD 2016:</strong></td>
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**C-Crest:** The trial was a phase 2 study of a 3-drug co-formulation of MK-3682 (polymerase inhibitor), grazoprevir (protease inhibitor) plus ruzasvir (NS5A inhibitor) with and without ribavirin to treat HCV genotypes 1, 2 and 3. The treatment period was 8, 12 or 16 weeks. In the people who were previously treated with pegylated interferon plus ribavirin the SVR12/cure rates were 95% to 100% in genotype 1a, 1b and 3. In people with genotype 2 the cure rate was 87% in the 8-week group and a 100% rate in the 12-week group and 96% to 98% in the 16-week groups. There was very little difference in cure rates between the groups who had cirrhosis, and who did/did not receive ribavirin.

**C-Surge:** An on-going phase 2 study to treat people with genotype 1 who had failed a previous course of a direct-acting antiviral therapy (Harvoni or Zepatier) using MK-3682, grazoprevir and ruzasvir with and without ribavirin. In the group that received ribavirin the treatment duration was 16 weeks; in the group that did not receive ribavirin the treatment duration was 24 weeks. The cure rates were 98% (43 of 44 pts) in the 16 week group that received ribavirin and 100% (49 of 49 pts) in the 24 week group that did not receive ribavirin.
EASL 2017: The results of the phase 2 study results of JNJ-4178 are included in the table below:

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<th>AL-335 (mg QD)</th>
<th>ODV (mg)</th>
<th>SMV (mg QD)</th>
<th>HCV Genotype</th>
<th>Dosing Duration (weeks)</th>
<th>Number (%) with undetectable HCV RNA at SVR24*</th>
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<td>20/20 (100%)</td>
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QD: every day; QOD: every other day; RNA: ribonucleic acid; SVR: sustained virologic response. *All results SVR24, with the exception of genotype 3 which is SVR12 **One patient did not attend SVR12 follow-up.

Note: The two drug combination of odalasvir and AL-335 for a treatment duration of 8 weeks will not proceed into phase 3 clinical trials. Clinical trial development of the combinations to treat HCV genotype 3 will also not move forward.

The combinations were generally safe and well-tolerated.

The next phase of development is to study these combinations in phase 2B studies.
Don’t want to go through this by yourself?

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- Develop a personalized plan – you set the goals, we’ll help you get there
- Find answers and accountability to get the results you want.
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