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Treating Hepatitis C in Indian Country: Specialist Support is Available

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How do you treat Hepatitis C virus (HCV) when there aren't enough specialists? This is the question that clinicians at the University of New Mexico Health Sciences Center (UNMHSC) posed 13 years ago. UNMHSC, located in Albuquerque, serves the entire state and is located far from most community health centers which lack specialty care. The lack of treatment capacity for HCV meant that most patients would never get treatment.

To respond to this clinical need, UNMHSC initiated a program called Project ECHO (Extension for Community Healthcare Outcomes), a telehealth program designed to educate clinicians in rural areas to allow them to treat complex conditions such as HCV locally. In a prospective cohort study, Project ECHO demonstrated that the ECHO model is a safe and effective way to treat HCV in the primary care setting.¹ ECHO programs for HCV have been replicated in other states with large rural populations such as Washington, Utah, and Arizona. A tribal nation has even replicated an ECHO program in Oklahoma.

HCV is now curable in > 90% of persons who treatment. The new HCV drug regimens are simple, oral only, well tolerated, and with minimal side effects. Diagnosing and treating HCV in the primary care setting has never been more feasible. Similarly, it has never been more urgent: most cases occur among baby boomers (born 1945-1965)

who have been infected for decades without symptoms, and many now have advanced liver disease. These patients need to be fast tracked for treatment to reduce their risk of complications from HCV including cirrhosis, hepatocellular cancer and death.

The IHS HCV TeleECHO Clinic provides HCV specialist access for IHS sites. Primary care physicians, nurse practitioners, physician's assistants and pharmacists participate in teleECHO clinics which are web-based teleconferences where community clinicians present their own HCV cases and learn from a multi-disciplinary team at Project ECHO. The cases are de-identified. The technology needed to participate is very simple and all that is needed is an internet connection and a webcam [using a desktop computer, laptop or mobile device]. Participants do not need to be currently treating HCV to participate. They can observe, learn, and receive CMEs or CPEs for their attendance. The IHS HCV TeleECHO Clinics are on the first Wednesday of the month at noon Mountain Time. The Project ECHO monthly IHS HCV TeleECHO Clinic was established in March 2013. Since the launch of the IHS

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HCV clinic, there have been 19 teleECHO clinics held with 78 unique attendees from 25 IHS and tribal sites from Alaska to White Earth in Minnesota. To receive an invitation for these events, contact Brigg Reilley at brigg.reilley@ihs.gov. Join a teleECHO clinic to hear how other IHS sites are diagnosing and treating HCV and saving lives in their communities.

Reference

Arora S, Thornton K, Murata G, et al. Outcomes of treatment for hepatitis C virus infection by primary care providers. *N Engl J Med* 2011;364 (23): 2199-207

Did you know that IHS has an STD and an HIV Listserv?

The IHS STD and HIV Programs use two Listservs to disseminate relevant scientific and programmatic information related to STDs and HIV to interested I/T/U staff and partners. You can subscribe by simply going to these links:

STD Listserv

http://www.ihs.gov/listserv/topics/signup/?list_id=167

HIV Listserv

http://www.ihs.gov/listserv/topics/signup/?list_id=182

For more details or to share information to be posted on the Listservs please contact for the STD Listserv Andria Apostolou, PhD, MPH (IHS STD Surveillance Coordinator) at andria.apostolou@ihs.gov and for the HIV Listserv Lisa Neel, MPH (Program Analyst) at lisa.neel@ihs.gov



Indian Health Service
National Pharmacy and Therapeutics Committee
Hepatitis C
NPTC Formulary Brief
February 2015



Background:

In February 2015, the IHS National Pharmacy and Therapeutics Committee (NPTC) reviewed Hepatitis C management and guidelines by the American Association for the Study of Liver Disease and the Infectious Diseases Society of America. Jonathan Iralu, MD, IHS Chief Clinical Consultant in Infectious Disease, and LCDR Amy Nguyen, PharmD, served as subject matter experts for this review. New direct-acting antivirals (DAA) reviewed at this meeting include the fixed combination products, ledipasvir/sofosbuvir (Harvoni®) and ombitasvir/paritaprevir/ritonavir/dasabuvir (Viekira Pak®), as well as the individual products sofosbuvir (Sovaldi®) and simeprevir (Olysio®).

Hepatitis C virus (HCV) affects more than 3.2 million people and is the leading cause of cirrhosis, liver cancer and liver transplantation in the United States (US). High risk patient populations for HCV infection include injection drug users, incarcerated persons, blood transfusion recipients prior to 1992, dialysis patients, as well as “baby-boomers” born between 1945-1965. Since 2012, the addition of “baby-boomers” to the Centers for Disease Control and Prevention (CDC) screening recommendations is anticipated to identify an additional 800,000 HCV infected US patients. American Indian/Alaska Natives (AI/AN) ethnic groups are particularly at risk for HCV infection and death according to the CDC. Between 2011-2012, AI/AN ethnicities were 3-20 times more likely to develop acute hepatitis when compared to other ethnic groups and had a death rate of 10.6 deaths per 100,000 US population.

Guidelines:

HCV genotypes 1, 2 and 3 are the most common genotypes in the US, with genotype 1 accounting for ~70%.

Treatment Naïve

Genotype	Regimen	Duration: Non Cirrhotic	Duration: Compensated Cirrhotic
1a	Ledipasvir/sofosbuvir (Harvoni®)	12 wks	12 wks
	----- ----- Ombitasvir/paritaprevir/ritonavir + dasabuvir (Viekira Pak®) + ribavirin	12 wks	24 wks
	----- ----- Sofosbuvir + simeprevir ± ribavirin	12 wks	24 wks
1b	Ledipasvir/sofosbuvir (Harvoni®)	12 wks	12 wks
	----- ----- Ombitasvir/paritaprevir/ritonavir + dasabuvir (Viekira Pak®) <i>If cirrhotic: add ribavirin</i>	12 wks	12 wks
	----- ----- Sofosbuvir + simeprevir ± ribavirin	12 wks	12 wks
2	Sofosbuvir + ribavirin	12 wks	16 wks
3	Sofosbuvir + ribavirin	24 wks	24 wks

Treatment experienced with peginterferon + ribavirin

Genotype	Regimen	Duration: Non Cirrhotic	Duration: Compensated Cirrhotic
1a	Ledipasvir/sofosbuvir (Harvoni®) <i>If ribavirin added</i> ----- -----	12 wks xxx -----	24 wks 12 wks -----
	Ombitasvir/paritaprevir/ritonavir + dasabuvir (Viekira Pak®) + ribavirin ----- -----	12 wks -----	24 wks -----
	Sofosbuvir + simeprevir + ribavirin	12 wks	24 wks
1b	Ledipasvir/sofosbuvir (Harvoni®) <i>If ribavirin added</i> ----- -----	12 wks xxx -----	24 wks 12 wks -----
	Ombitasvir/paritaprevir/ritonavir + dasabuvir (Viekira Pak®) <i>If cirrhotic: add ribavirin</i> ----- -----	12 wks -----	12 wks -----
	Sofosbuvir + simeprevir + ribavirin	12 wks	12 wks
2	Sofosbuvir + ribavirin	12 wks	16 wks
3	Sofosbuvir + ribavirin	24 wks	24 wks

Treatment experienced with peginterferon + ribavirin + HCV protease inhibitor

Genotype	Regimen	Duration: Non Cirrhotic	Duration: Compensated Cirrhotic
1a and 1b	Ledipasvir/sofosbuvir (Harvoni®) <i>If ribavirin added</i>	12 wks xxx	24 wks 12 wks

Discussion:

HCV infection has a significant impact on morbidity, mortality and healthcare resources. New DAA treatment options for HCV offer cure rates up to 99%, 95% and 84% for genotypes 1,2, and 3, respectively. Curing HCV has been shown to decrease liver inflammation and reduce progression to liver fibrosis, carcinoma and transplantation. This in turn reduces hospitalizations and liver transplants (costing ~\$600,000), providing much needed healthcare cost savings.

Potential barriers to HCV cure include financial hardship, access to healthcare and treatment adherence. Wholesale pricing for DAAs averages \$1,000 per pill and cost per treatment regimens can range from \$38,000 to \$93,000. The IHS has traditionally utilized outside resources to obtain medications for patients through state and federal insurance, private insurance as well as patient assistance programs offered by drug manufacturers. In 2011, IHS sites connected with the Extension for Community Healthcare Outcomes (ECHO) program, named Project ECHO, created by the University of New Mexico Health Science Center. Project ECHO is a system used to disseminate specialized expert medical knowledge to the rural underserved areas, including many IHS clinics and hospitals. Through Project ECHO, community clinicians (e.g., physicians, pharmacists, nurse practitioners and physician assistants) ensure patient adherence, safety and potential cure.

Findings:

Treatment for HCV has improved dramatically over recent years with better outcomes, shorter durations and fewer medication side effects. However, drug cost remains a barrier to the affordability of this treatment for our patients. Although not added to the IHS National Core Formulary, the NPTC recognizes the proven efficacy and tolerability of these agents. IHS programs should continue to work with patients to obtain HCV medications through outside resources, providing access to new DAA treatment regimens.

If you have any questions regarding this document, please contact the NPTC at IHSNPTC1@ihs.gov. For more information about the NPTC, please visit the [NPTC website](#).

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Get Yourself Tested (GYT) Campaign

Know the facts: One in two sexually active young people in the U.S. will get an STD by the time they're 25 — and most won't know it. And, unfortunately, Native populations bare a disproportionate burden of STDs. According to the Centers for Disease Control and Prevention, in 2013, the rate of chlamydia among American Indians/Alaska Natives in the United States was 3.9 times the rate among whites. The gonorrhea rate was 4.0 times the rate among whites, and the disparity was larger for native women than native men.

As April is STD Awareness Month, it's a perfect time to test your STD IQ. Here are the facts:

1. STDs impact young people the hardest. Half of all STDs are in people under 25, although they represent only a quarter of people having sex. There will be an estimated 20 million new sexually transmitted infections this year, half in people under the age of 25.
2. You can't tell by looking who has an STD. Many STDs cause no symptoms, so the only way to know for sure is to get tested. For example, 75 percent of women and 50 percent of men with chlamydia have no symptoms. And on average, people with HIV don't develop symptoms of HIV for 10 years. And STDs can still be passed on to partners, even if the person isn't showing symptoms.
3. If not treated, STDs can lead to serious health problems. Untreated STDs, like chlamydia, although easy to cure, make it difficult for about 24,000 women to get pregnant each year. Having an STD (like herpes or gonorrhea) can also increase your chances of getting HIV.

The good news is that all STDs, even HIV, are treatable and most are curable. The sooner you know your status, the better you can protect your health and the health of your partner(s). Early treatment can help prevent serious, life-long health problems that can result from untreated STDs.

NCSD is a proud partner in the Get Yourself Tested (GYT) campaign. GYT encourages testing for STDs, including HIV, as recommended by the U.S. Centers for Disease Control and Prevention (CDC), and works to empower young people to have an open dialogue about STDs. Other partners in GYT include: American College Health Association (ACHA), Kaiser Family Foundation (KFF), MTV, and Planned Parenthood Federation of America, with technical consultation provided by CDC.

Getting tested for STDs is a basic part of staying healthy and taking care of your body – like brushing your teeth and exercising regularly. STD tests are quick, simple, and painless. For example, rapid HIV tests can provide results in as fast as 20 minutes from just a swab inside the mouth.

Check with your provider to see how often you should be tested. For young people, the CDC recommends:

- HIV testing for all young adults and adolescents
- Annual testing for chlamydia and gonorrhea for all sexually active women under the age of 25
- Screening at least once a year for syphilis, chlamydia, and gonorrhea for all sexually active gay, bisexual, and other men who have sex with men (MSM)
- Some people may need more frequent testing (for example, every 3-6 months).

So, this month, GYT: Getting yourself tested for STDs. It is one of the most important things you can do to protect your health and take control of your sex life, and it's easier than ever before. To learn more about the campaign, order free materials please visit <http://npin.cdc.gov/stdawareness/GYT.aspx> and www.gytnow.org. You can listen to a PSA by Native American rap artist and actor, Litefoot, by visiting http://npin.cdc.gov/stdawareness/docs/Native_PSA_60.mp3

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