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Community Health Centers

### **Important Content Note:**

This technical assistance resource was developed prior to the August 2017 release of the Health Center Compliance Manual by the Health Resources and Services Administration's (HRSA) Bureau of Primary Health Care (BPHC). The BPHC Compliance Manual, issued August 2017, indicates where PINS, PALs and other program guidance are now superseded or subsumed by the BPHC Compliance Manual.

See: <https://bphc.hrsa.gov/programrequirements/pdf/healthcentercompliancemanual.pdf>

# A New Era in Management of Hepatitis C in Health Centers

## Background

*“The ease of administration, short duration of treatment, and minimal side effects of all -oral [Hepatitis C] regimens will probably mean that most persons will qualify for therapy. Collectively, these regimens promise to transform Hepatitis C from a condition requiring complex, unsatisfactory therapies and specialist care to one that can be effectively and easily managed by a general physician with few contraindications and side effects.”<sup>1</sup>*

- About 3 to 4 million Americans are chronically infected with Hepatitis C (HCV); approximately half are unaware of their infection.<sup>2,3</sup>
- The majority of HCV infections are among individuals born between 1945 and 1965 (referred to as the birth cohort).<sup>4</sup>
- The highest risk for HCV exposure is injection drug use.<sup>5</sup>
- About 15 to 25 percent of people spontaneously clear the infection without treatment.<sup>6</sup> For the 75 to 85 percent who develop chronic HCV infection, if left untreated, many will develop advanced liver disease and/or hepatocellular carcinoma (HCC).<sup>7</sup>
- Given that all-oral HCV regimens are shorter in duration, better tolerated, and more effective than previous interferon-based therapies, HCV management in primary care is essential to help ensure that every patient infected with HCV is offered the opportunity to access these curative treatments.

## Role for Health Centers

In this new era of HCV care, health centers may find that more patients are interested in and eligible for treatment. The following information will help clinical and administrative leadership consider how to integrate HCV management into the primary care setting. With a team-based approach, the following steps can be performed over several visits prior to treatment or specialty referral.

- 1. HCV Screening:** The Centers for Disease Control and Prevention (CDC) and the United States Preventive Services Task Force (USPSTF) recommend risk-based and one-time birth cohort screening with a serum HCV antibody (Ab).<sup>4,8</sup> Patients who require screening can be identified by the medical assistant (MA), nurse (RN), or provider and a standing order can be implemented for the HCV Ab test.
- 2. Confirmation of HCV Infection:** Quantitative HCV RNA testing is recommended for any positive HCV Ab to confirm infection and to establish baseline viral level prior to initiation of treatment. Positive HCV Ab results can be reflexed to immediately test for quantitative HCV RNA through the laboratory.
  - Detectable HCV RNA < 6 months post exposure = acute infection
  - Detectable HCV RNA > 6 months post exposure = chronic infection
  - Undetectable HCV RNA = clearance of HCV infection or false positive HCV Ab

### For all patients confirmed to be infected with HCV

- 3. Counseling:** Individuals should be counseled on a) HCV transmission/prevention and b) risks of alcohol use.
- 4. Important Screenings:** Individuals should also be screened for 1) HIV, 2) Hepatitis A (HAV) and B (HBV) infection and immunity, and 3) alcohol and drug disorders and referred for treatment when necessary.
- 5. Vaccination:** Individuals should be vaccinated against Hepatitis A and B if not immune.
- 6. Baseline Liver Assessment:** As part of a baseline work-up, at a minimum, a CBC, INR, albumin, AST/ALT, bilirubin, alkaline phosphatase, and GFR should be considered.
- 7. Treatment and Referral:** With all-oral regimens now available for every HCV genotype, every HCV-infected individual should be informed of current, highly effective, and well-tolerated therapies and referred to a provider with HCV treatment expertise. HCV genotyping is required to help guide selection of HCV therapy.

## Key Clinical Challenges and Strategies

1. **Prescribing HCV Treatment in Primary Care:** With more patients interested in and eligible for HCV treatment, access to specialists may become an issue, if not already a barrier, for many health center patients. Fortunately, these new all-oral regimens can be safely administered in the primary care setting with guidance from providers with HCV expertise. Such relationships can be established with local specialists or through programs like Project ECHO™ (<http://echo.unm.edu/>) that provide videoconferencing consultation and guidance from HCV experts. Updated guidelines for what regimens to use in which patient circumstances and for monitoring prior to and during treatment are available at <http://www.hcvguidelines.org/>

### 2. Potential Costs Associated with HCV Care:

- **HCV Medications:** Given the high cost of HCV medications, many insurers may restrict coverage, e.g. based on disease severity or prescriber specialty. Prior authorizations (PAs) may be required and are typically time-consuming. Utilizing MAs/RNs as members of the care team to assist with PAs may be helpful in streamlining clinical workflows. Pharmaceutical companies, such as Gilead and AbbVie, offer Patient Assistance Programs for uninsured patients.
- **Laboratory Tests, Imaging, and Biopsies:** These costs tend to be covered by insurance. Agreements between health centers and laboratories may allow services without charge for the uninsured. Similarly, hospitals and agencies providing imaging and biopsies may offer reduced costs and/or payment plans through agreements established with the patients or the health center.
- **Medical Visits:** The number of visits tends to be low (about 3) during the short (usually 12 week) treatment. This has particular significance for patients who self-pay.

3. **Liver Fibrosis Assessment:** Liver biopsy can usually be ordered through Interventional Radiology. Non-invasive alternatives are increasingly accepted, e.g. serum fibrosis markers, transient elastography. Some insurers require a biopsy despite lack of medical need; however, most accept the non-invasive assessments.

### 4. Medication-related Issues:

- **Medication Adherence** is essential for treatment success and fortunately is easier with the new all-oral regimens.
- **Drug-drug Interactions** exist with some HCV medications and must be checked (e.g. through a website like <http://www.hep-druginteractions.org>) prior to prescribing HCV treatment. As an example, acid suppressants such as TUMS and proton pump inhibitors interfere with absorption of one HCV medication.
- **Side Effects** with the new regimens tend to be mild but, as with all medications, should be reviewed with the patient. Ribavirin, if used, is teratogenic; men must not take it if their partner is pregnant and must not get anyone pregnant during and for 6 months after treatment; women must not take it during pregnancy and must not get pregnant during and for 6 months after treatment.

5. **Ongoing alcohol and drug use:** At a minimum, abstinence from heavy alcohol use should be encouraged in patients with no or mild fibrosis; in advanced fibrosis, complete abstinence should be the goal. Active drug use, especially through injection, is a risk for HCV reinfection after successful treatment. Safer injection and drug use practices and abstinence should be encouraged. Treatment for alcohol and substance use disorders is essential.

6. **Cirrhosis:** Regular screening for HCC is recommended with an abdominal ultrasound every 6 months.<sup>9</sup> Individuals with decompensated cirrhosis should be referred to a liver specialist.

## Special Considerations

**HIV-HCV co-infection:** Same guidelines apply. Drug interactions, particularly with HIV medication, are a concern; consultation with an expert prior to prescribing is recommended.

**Other liver conditions:** Screening may be warranted for conditions such as non-alcoholic steatohepatitis (NASH), hemochromatosis, Wilson's disease, and autoimmune hepatitis.

**Prescribing other medications:** Use of hepatotoxic medications should be avoided; adjusting dose of medications when indicated in hepatic disease is important.

**Acute HCV infection:** Monitoring for spontaneous clearance with HCV RNA every 4-8 weeks for 6-12 months is recommended. If earlier treatment is required, it should be delayed for 12-16 weeks for potential clearance. Counseling and treatment follow the same guidelines as for chronic infection.

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## Key Strategic Documents, Websites, and Information

- CDC's A Guide to Comprehensive Hepatitis C Counseling and Testing: <http://www.cdc.gov/hepatitis/Resources/Professionals/PDFs/CounselingandTestingPC.pdf>
- CDC patient education resources for HCV: <http://www.cdc.gov/hepatitis/hcv/patienteduhcv.htm>
- CDC recommendations for HCV screening: <http://www.cdc.gov/hepatitis/HCV/GuidelinesC.htm>
- USPSTF recommendations for HCV screening: <http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/hepatitis-c-screening#consider>
- AASLD/IDSA/IAS–USA recommendations for testing, managing, and treating HCV: <http://www.hcvguidelines.org>
- Hepatitis Drug Interactions: <http://www.hep-druginteractions.org>
- Clinical Care Options: <http://www.clinicaloptions.com/Hepatitis.aspx>
- American Association for the Study of Liver Diseases (AASLD): <http://www.aasld.org/>
- Infectious Diseases Society of America (IDSA): [http://www.idsociety.org/Hepatitis\\_C/](http://www.idsociety.org/Hepatitis_C/)
- Centers for Medicare and Medicaid Services ICD-9-CM code for HCV screening: V69.8 ([http://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/Downloads/MPS\\_QuickReferenceChart\\_1.pdf](http://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/Downloads/MPS_QuickReferenceChart_1.pdf))

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## References

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