

# The A.C.D. Quarterly

#### PHILADELPHIA DEPARTMENT OF PUBLIC HEALTH

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- Unmet HCV Testing Needs in Philadelphia
- Your Role: From Screening to Linkage to Care
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# **BOX 1. HEPATITIS C RISK FACTORS**

- Injection drug use (IDU)
- Tattoos/Body piercings (in non-commercial settings)
- Dialysis
- Receipt of clotting factors prior to 1987
- Receipt of blood products prior to 1992
- Birth mother HCV+
- Multiple sexual partners

# Testing for (Current) Hepatitis C Infection: A Role for Primary Care Providers

Combating what has been termed the "silent epidemic" of hepatitis C (HCV), the nation's most common chronic blood-borne infection and leading cause for liver transplantation in adults, requires first identifying individuals who are currently infected. Of the estimated 3.2 million who have been chronically infected with HCV in the United States, as many as 50% to 75% may never have been tested, or know their status [1]. Every patient encounter is an opportunity to address this staggering unmet need. Have you considered who you should be testing for hepatitis C?

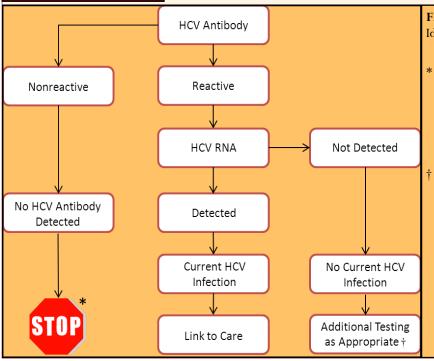


## Testing for HCV Infection: Updated CDC Guidance

Recently, the CDC broadened its recommendations for HCV testing beyond persons with risks for HCV infection (see Box 1), to one-time HCV testing for all persons born during 1945-1965 regardless of other risk factors [2]. The US Preventive Services Task Force (USPSTF) has just assigned a "Grade B" recommendation, indicating this testing will be reimbursed as preventative care! Other updates include:

- Availability of a rapid test for HCV antibody. The OraQuick HCV Rapid Antibody Test (OraSure Technologies) is a rapid assay for the presumptive detection of HCV antibody in blood (finger-stick capillary and venipuncture). Its sensitivity and specificity are similar to those of FDA-approved, laboratory conducted HCV antibody assays. In 2011, a Clinical Laboratory Improvements Amendments (CLIA) waiver was granted to the test by FDA. This provides wider testing access to persons at risk for HCV infection, permitting use of the assay in nontraditional settings such as physician offices, hospital emergency departments, health department clinics, and other freestanding counseling and testing sites.
- <u>Discontinuation of RIBA HCV</u>. National shortages of the Chiron RIBA HCV 3.0 Strip Immunoblot Assay (Novartis Vaccines and Diagnostics), that was recommended for supplemental testing of blood samples after initial HCV antibody testing, have prompted discontinuation of its use. Thus, currently, the only other FDA-approved supplemental tests for HCV infection are those that detect HCV RNA.

As a result, the recommended testing sequence has been altered to reflect these updates (see Figure 1).



**FIGURE 1.** Recommended Testing Sequence for Identifying Current Hepatitis C virus Infection [3]

- \* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.
- † To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

#### Unmet HCV Testing Needs in Philadelphia

HCV is a reportable condition in Philadelphia, and approximately 4,000 new HCV cases are reported annually among Philadelphia residents. In 2012, of 3,911 newly reported individuals (not previously confirmed), case status determinations [4] were: "Acute" – 11 and "Chronic Confirmed" – 1,623. Of the remaining reports, 49% only had HCV antibody tests, without subsequent confirmatory testing necessary to allow for definitive diagnosis of current hepatitis C infection. This mirrors national trends, indicating a lack of an HCV RNA test for approximately one half of persons screened for hepatitis C and suggests that testing and reporting must improve to detect all persons with current infection [1].

Amongst reports received by PDPH, there is a significant degree of duplicative testing (the repetition of an antibody test for an individual who has already had a positive screening test) which is clinically redundant because HCV antibodies can persist for life. So for anyone with HCV antibodies, indicating *prior exposure* to HCV, the remaining clinical need is to determine *current* infection status.

#### The Role of the Primary Care Physician

From screening, to diagnosis, to linkage to care, your involvement is critical to local efforts to address hepatitis C.

**Note**: You don't have to refer patients to a clinician experienced in hepatitis C treatment to diagnose them! Loss to follow-up, and time to referred care are significant barriers to obtaining confirmatory HCV diagnoses. Following the recommended care management sequence in Figure 2 can ensure that only those patients who require specialist care are appropriately referred.

Also, for patients who test positive for HCV:

- Determine hepatitis A and B immunization status, and offer vaccines if needed
- Provide counseling on:
  - Alcohol cessation
  - Prevention of HCV transmission

# Screen

## Screen Appropriate Patients for HCV

- Draft CDC guidelines recommend a one-time anti-HCV antibody test for all baby boomers (those born from 1945 through 1965)¹
- HCV is transmitted by blood-to-blood contact<sup>2</sup>

# Diagnose

# Diagnose Chronic HCV infection

- If a patient tests positive for anti-HCV antibodies, a confirmatory test (eg, HCV RNA) should be performed<sup>3</sup>
- If the HCV RNA test is positive, the patient is infected with HCV<sup>3</sup>

## Refer

#### Refer Patients to an Experienced Treater

- Patients diagnosed with chronic HCV infection should be referred to a clinician experienced in treating HCV<sup>4,5</sup>
- Consult with the specialist about what can be done for the patient prior to the appointment (eg, labs, management)

### **FIGURE 2.** Preparing Patients with HCV for Treatment [5]

1. Centers for Disease Control and Prevention. http://www.regulations.gov/#!documentDetail,D=CDC-2012-0005-0002; Accessed May 22, 2012; 2. Centers for Disease Control and Prevention. http://www.cdc.gov/hepatitis/c/cfaq.htm#cFAQ08. Accessed May 9, 2012; 3. Ghany MG et al. *Hepatology*. 2009;49:1335-1374; 4. Centers for Disease Control and Prevention. http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm. Accessed May 8, 2012; 5. Volk ML. *J Antibicrob Chemother*. 2010;65:1327-1329.

### Hepatitis C Resources from PDPH

PDPH has developed an educational brochure that may help answer your patient's questions: <u>Hepatitis C: A Roadmap for the Newly Diagnosed</u> is available on our "Hep C" page at: <a href="http://www.phila.gov/health/DiseaseControl/hepatitisC.html">http://www.phila.gov/health/DiseaseControl/hepatitisC.html</a>.

To help primary care practices better understand the role they play in identifying HCV positive individuals and linking them to care, HepCAP, Philadelphia's hepatitis C coalition, has developed a peer-to-peer clinician education model called **C Change.** If you are interested in having a local clinician with expertise in HCV management and treatment come to YOUR practice for a Q&A session, contact Alex Shirreffs, Viral Hepatitis Prevention Coordinator at <a href="mailto:Alexandra.shirreffs@phila.gov">Alexandra.shirreffs@phila.gov</a> or 215-685-6462.

Finally, remember to report ALL hepatitis C cases (chronic and acute) to PDPH! PDPH now also investigates chronic cases to help ensure that a larger proportion of these individuals are receiving appropriate medical care, referral for treatment, and education regarding their illness.

#### References:

- 1. Holmberg, S. et al. Hepatitis C in the United States. NEJM, 368; 20. May 16 2013.
- 2. CDC. Recommendations for the identification of chronic hepatitis C virus infection among persons born during 1945-1965. MMWR 2012;61(No. RR-4).
- 3. CDC. <u>Testing for HCV Infection: An Update of Guidance for Clinicians and Laboratorians</u>. *MMWR* 2013;62(18);362-365 http://www.cdc.gov/mmwr/preview/mmwrhtml/mm62e0507a2.htms\_cid=mm62e0507a2\_e.
- 4. 2012 Case Definitions: Nationally Notifiable Conditions Infectious and Non-Infectious Case. (2012) Atlanta, GA: Centers for Disease Control and Prevention http://wwwn.cdc.gov/nndss/document/2012\_Case% 20Definitions.pdf#InfectiousConditions http://content.gov-delivery.com/bulletins/gd/USCDC-7a2d1e.
- $5.\ Personal\ communication\ with\ Alex\ Shirreffs,\ Philadelphia\ Department\ of\ Public\ Health,\ July\ 11,\ 2013.$

# The A.C.D. Quarterly

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REPORTING REQUIREMENTS AND FORMS ARE POSTED ONLINE AT <u>hip.phila.gov</u>.

