NC AIDS ATEC
University of North Carolina at Chapel Hill
AIDS Training and Education Center

Screening, Testing, and Diagnosis of HCV

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Disclosures

- Dr. Chastain has received research/grant support paid to his institution from Gilead Sciences Inc.:
  - Site investigator for HIV/HCV SWITCH Registry Study
  - Key faculty personnel for Gilead FOCUS HCV Screening Program through the Vanderbilt University Medical Center Emergency Department

Objectives

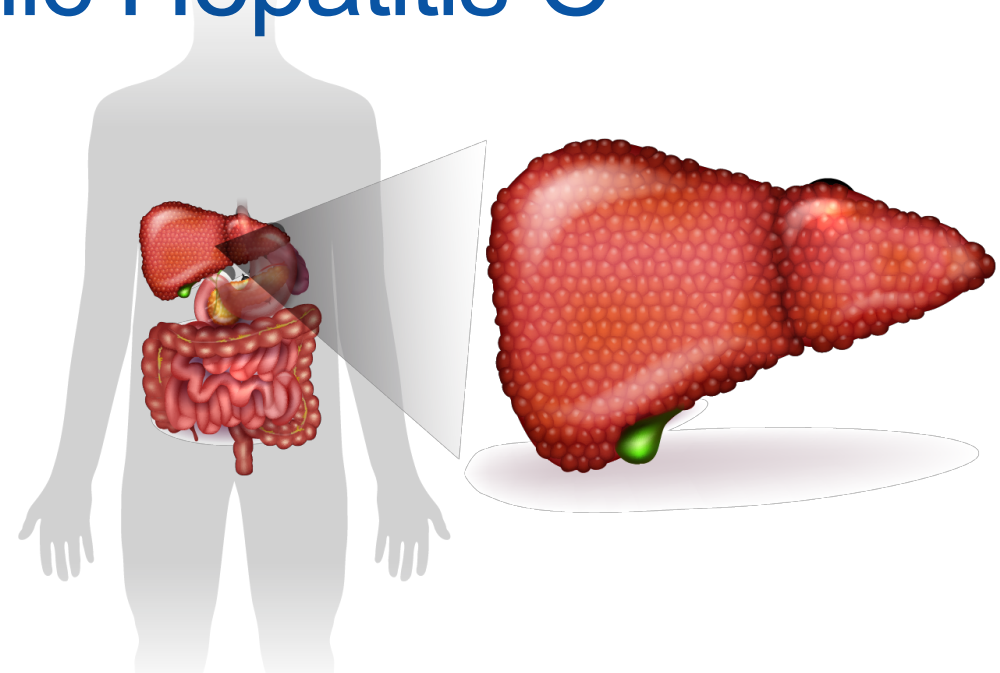
After this training, participants should be able to:

- Review the indications for screening for HCV
- Identify clinical manifestations of HCV
- Discuss the principles of and indications for treatment of HCV

HIV/HCV Co-infection:
An AETC National Curriculum

Core Competency 3: Screening, Testing, Diagnosis, and Clinical Evaluation of HCV Infection among PLWH

Lesson 1: Chronic Hepatitis C Virus Infection



July 2017

HIV/HCV Co-infection:
An AETC National Curriculum

Core Competency 3: Screening, Testing, Diagnosis, and Clinical Evaluation of HCV Infection among PLWH

Lesson 2: Acute Hepatitis C Virus Infection

July 2017

Lesson Objectives (Chronic HCV)

By the end of this lesson, the learner will be able to:

- Define chronic HCV
- Screen and diagnose chronic HCV
- Identify factors that increase morbidity and mortality associated with chronic HCV
- Recognize clinical manifestations of chronic HCV
- ~~Evaluate chronic HCV, including taking a history, performing a physical examination, and ordering laboratory and imaging studies~~

Lesson Objectives (Acute HCV)

By the end of this lesson, the learner will be able to:

- Define acute HCV
- Describe the epidemiology of acute HCV
- Understand the natural history of acute HCV
- Recognize clinical manifestations of acute HCV
- Screen and diagnose acute HCV
- ~~Evaluate acute HCV, including taking a history, performing a physical examination, and ordering laboratory and imaging studies~~
- ~~Understand considerations for treatment of acute HCV~~

Outline

- Screening and Testing
- Diagnosis (Clinical Manifestations)
- Principles and Indications for Treatment

Outline

- **Screening and Testing**
- Diagnosis (Clinical Manifestations)
- Principles and Indications for Treatment

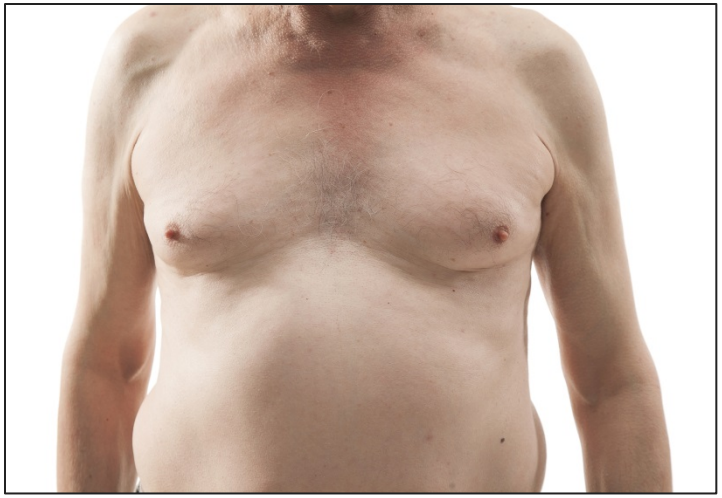
Two Cases

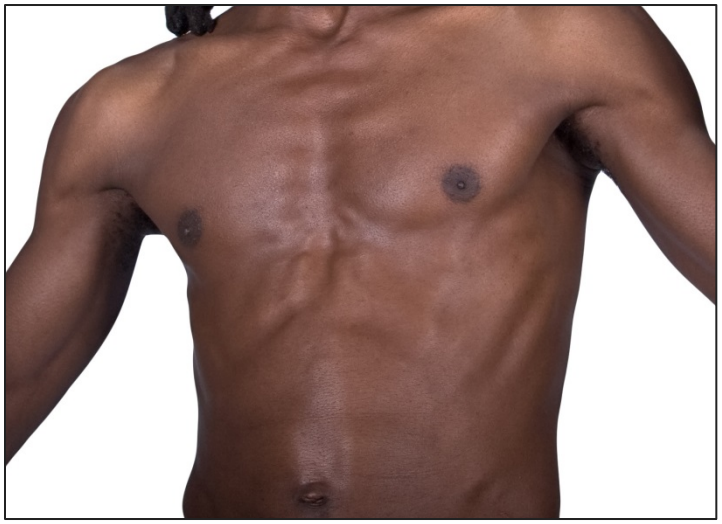
- Mr. B. Boomer is a 60-year-old man with a past medical history of diabetes and hypertension.
- He presents for an annual physical and health maintenance evaluation.
- Mr. Y. Man is a 21-year-old man who identifies as bisexual. He was recently diagnosed with HIV during an ED evaluation for an influenza-like illness.
- He has been referred to clinic for HIV evaluation and care.

Commonality?

- Two individuals with different health histories and needs

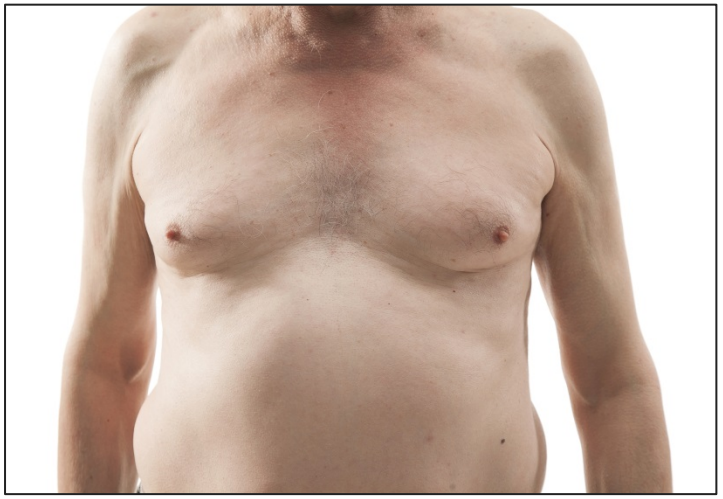
- Both warrant HCV screening

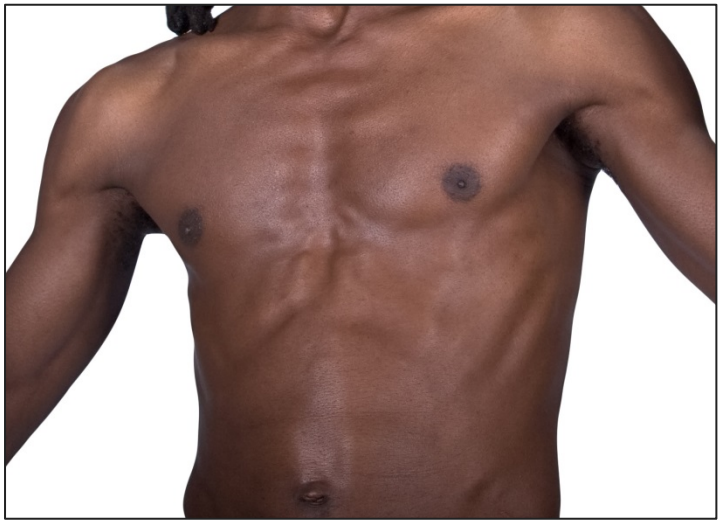




Screening Recommendations

- Mr. B. Boomer was born between 1945 and 1965.
- Mr. Y. Man is HIV infected.





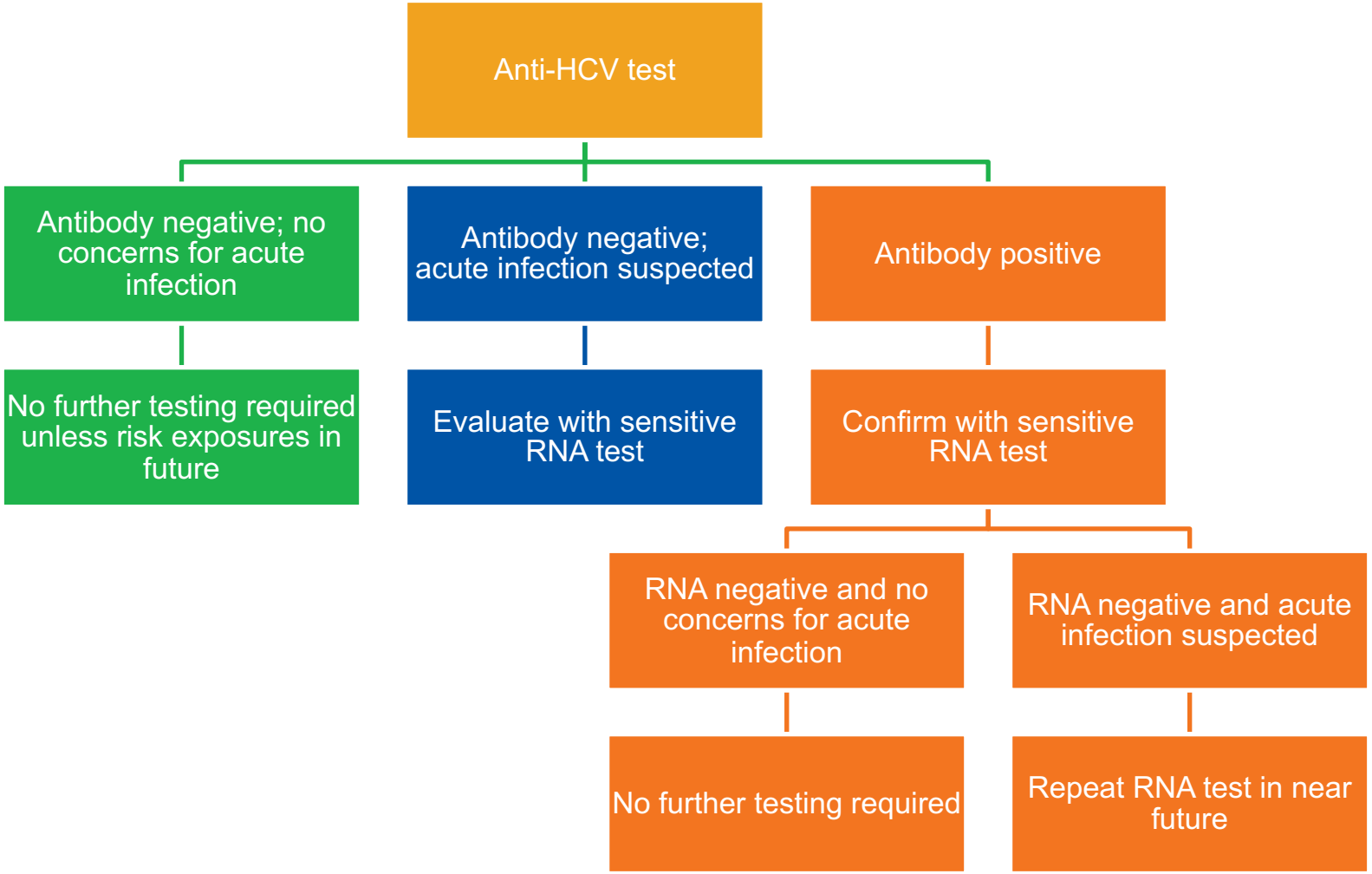
Definition of Chronic HCV[1-3]

- Infection with HCV and detectable/quantifiable HCV RNA at least 6 months after infection
- For many patients, the initial date of HCV infection cannot be identified

Definition of Acute HCV Infection[1-4]

- 6-month time frame after HCV infection
- Not defined by presence of symptoms
- Laboratory-based diagnosis
  - Positive (detectable) HCV RNA with a negative HCV antibody
  - Positive HCV antibody with a documented negative HCV antibody in the past 12 months
- Non-official clinically based diagnosis
  - Fluctuating ALT levels without another cause
  - Low HCV RNA or fluctuating HCV RNA levels
  - Subsequent spontaneous clearance of HCV

Screening and Diagnosis[1-4]



Screening and Diagnosis (of Acute HCV)[1,2,10]

- Diagnosis may be difficult unless suspected exposure noted
- See definition of acute HCV
- Diagnosis may require both HCV antibody and RNA (often with repeated values over time)
- Screening is often contingent on risk factor assessment
- Anti-HCV test and HCV RNA test should be assessed for screening and diagnosis

Risk Factors for HCV Infection[1-3]

Risk Exposures

- Persons on long-term hemodialysis
- Persons with percutaneous/ parenteral exposures
- Occupational health exposures
- Children born to HCV-infected women
- Transfusion/organ recipient prior to July 1992
- Clotting factor concentrate recipients prior to 1987
- Persons ever incarcerated
- PLWH

Risk Behaviors

- Injection drug use (current or ever)
- Intranasal illicit drug use
- Sexually active individuals considering PrEP for HIV

Birth Cohort

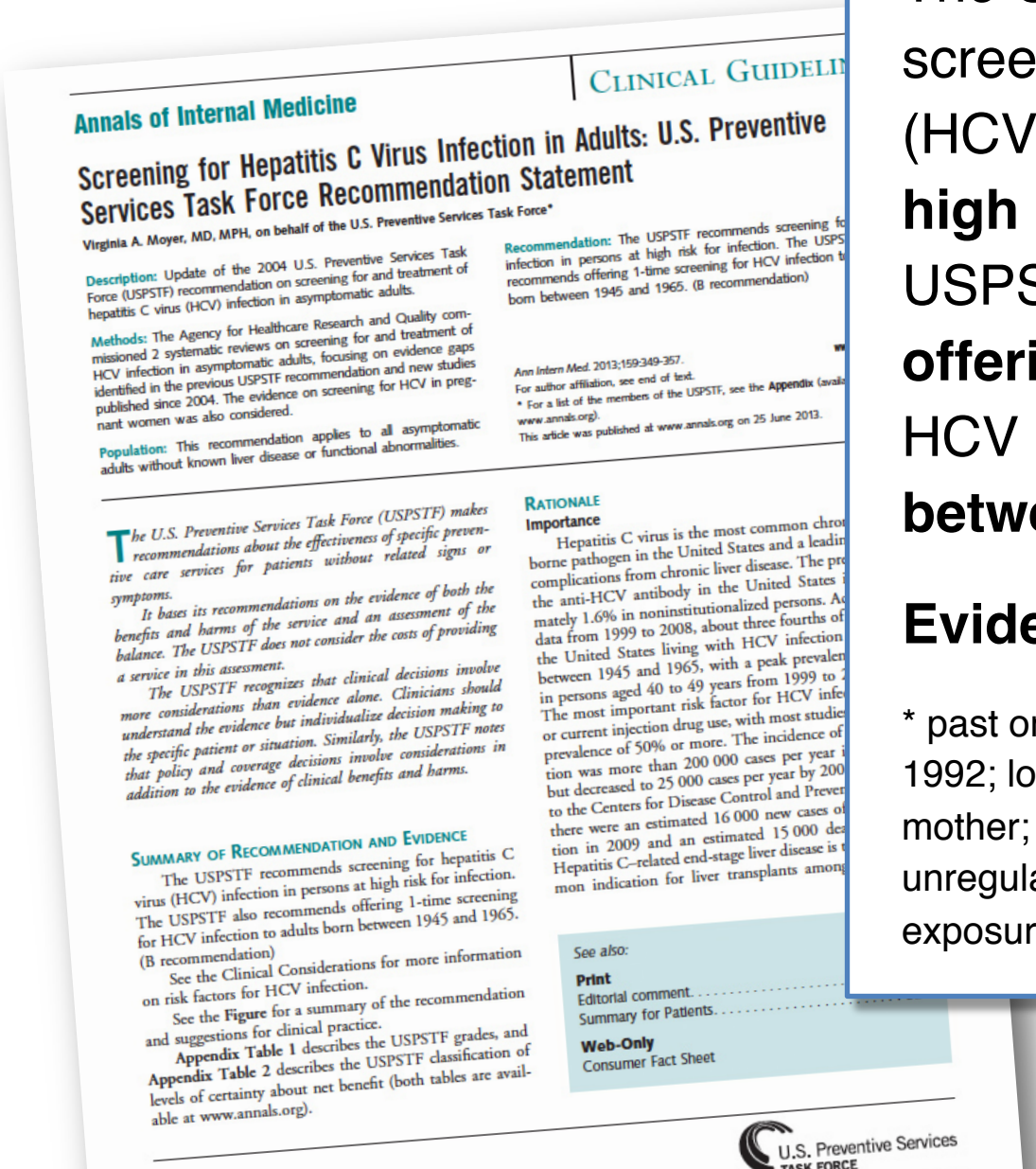
- Persons born between 1945 and 1965

Other Groups

- Unexplained chronic liver disease and/or chronic hepatitis
- Solid organ donors (deceased and living)

Slide courtesy of Dr. Christopher Hurt

2013



Annals of Internal Medicine

CLINICAL GUIDELI

Screening for Hepatitis C Virus Infection in Adults: U.S. Preventive Services Task Force Recommendation Statement

Virginia A. Moyer, MD, MPH, on behalf of the U.S. Preventive Services Task Force*

Description: Update of the 2004 U.S. Preventive Services Task Force (USPSTF) recommendation on screening for and treatment of hepatitis C virus (HCV) infection in asymptomatic adults.

Methods: The Agency for Healthcare Research and Quality commissioned 2 systematic reviews on screening for and treatment of HCV infection in asymptomatic adults, focusing on evidence gaps identified in the previous USPSTF recommendation and new studies published since 2004. The evidence on screening for HCV in pregnant women was also considered.

Population: This recommendation applies to all asymptomatic adults without known liver disease or functional abnormalities.

Recommendation: The USPSTF recommends screening fo infection in persons at high risk for infection. The USPS recommends offering 1-time screening for HCV infection t born between 1945 and 1965. (B recommendation)

Ann Intern Med. 2013;159:349-357.
For author affiliation, see end of text.
* For a list of the members of the USPSTF, see the **Appendix** (avail www.annals.org).
This article was published at www.annals.org on 25 June 2013.

The U.S. Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific preventive care services for patients without related signs or symptoms.

It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.

The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.

Summary of Recommendation and Evidence

The USPSTF recommends screening for hepatitis C virus (HCV) infection in persons at high risk for infection. The USPSTF also recommends offering 1-time screening for HCV infection to adults born between 1945 and 1965. (B recommendation)

See the Clinical Considerations for more information on risk factors for HCV infection.

See the **Figure** for a summary of the recommendation and suggestions for clinical practice.

Appendix Table 1 describes the USPSTF grades, and **Appendix Table 2** describes the USPSTF classification of levels of certainty about net benefit (both tables are available at www.annals.org).

Rationale

Importance

Hepatitis C virus is the most common chro borne pathogen in the United States and a leadi complications from chronic liver disease. The pr the anti-HCV antibody in the United States mately 1.6% in noninstitutionalized persons. A data from 1999 to 2008, about three fourths of the United States living with HCV infection between 1945 and 1965, with a peak prevalen in persons aged 40 to 49 years from 1999 to The most important risk factor for HCV infe or current injection drug use, with most studie prevalence of 50% or more. The incidence of tion was more than 200 000 cases per year but decreased to 25 000 cases per year by 200 to the Centers for Disease Control and Prever there were an estimated 16 000 new cases o tion in 2009 and an estimated 15 000 de Hepatitis C–related end-stage liver disease is mon indication for liver transplants amon

See also:

Print
Editorial comment
Summary for Patients

Web-Only
Consumer Fact Sheet

U.S. Preventive Services TASK FORCE

The USPSTF recommends screening for hepatitis C virus (HCV) infection in **persons at high risk for infection.*** The USPSTF also recommends **offering 1-time screening** for HCV infection to **adults born between 1945 and 1965**.

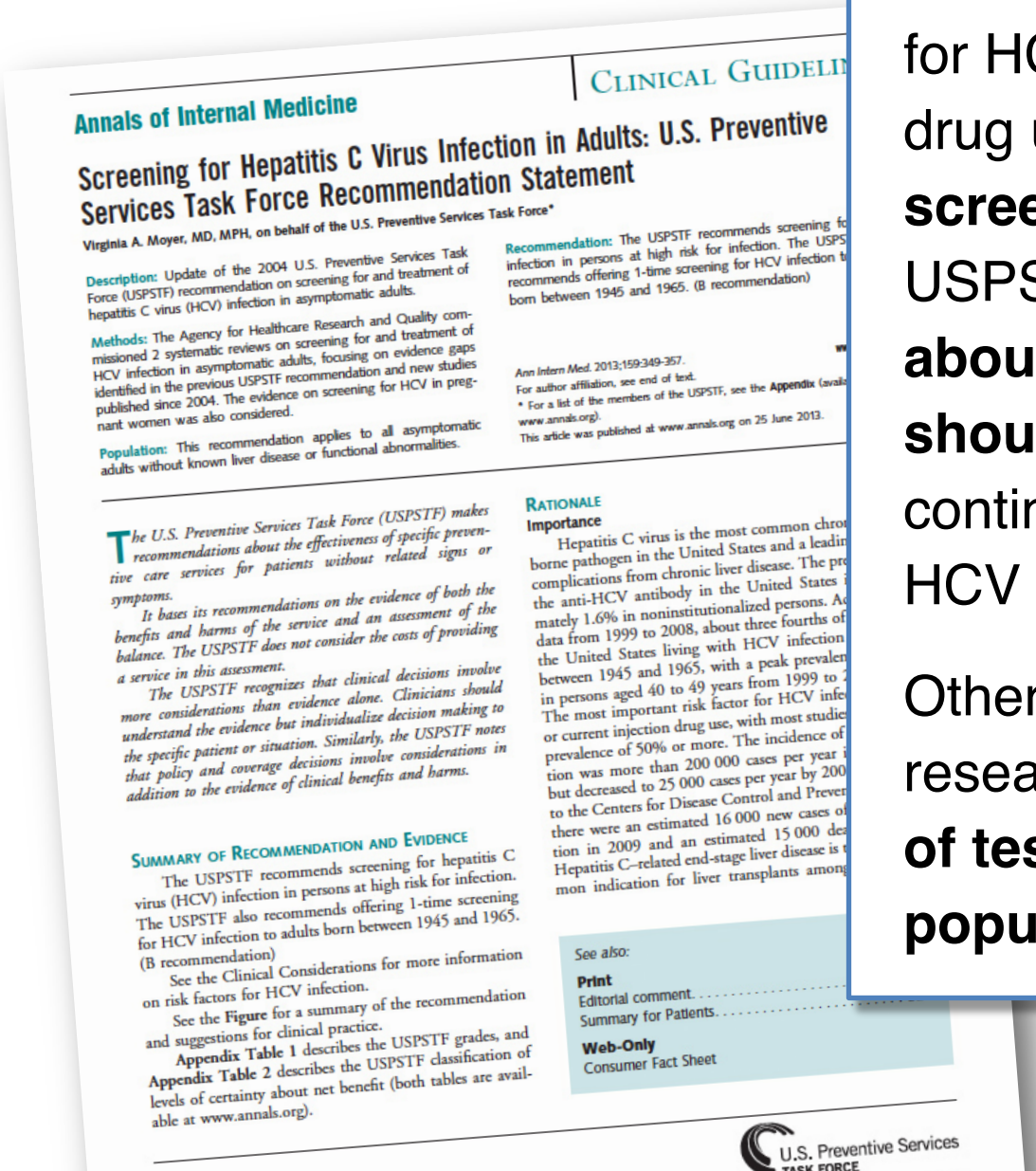
Evidence grade: B

* past or current IDU; transfusion before 1992; long-term hemodialysis; born to HCV+ mother; incarceration; intranasal drug use; unregulated tattoos; other percutaneous exposures… ± sexual exposure

https://www.ncbi.nlm.nih.gov/pubmed/23798026

Slide courtesy of Dr. Christopher Hurt

2013



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U.S. Preventive Services TASK FORCE

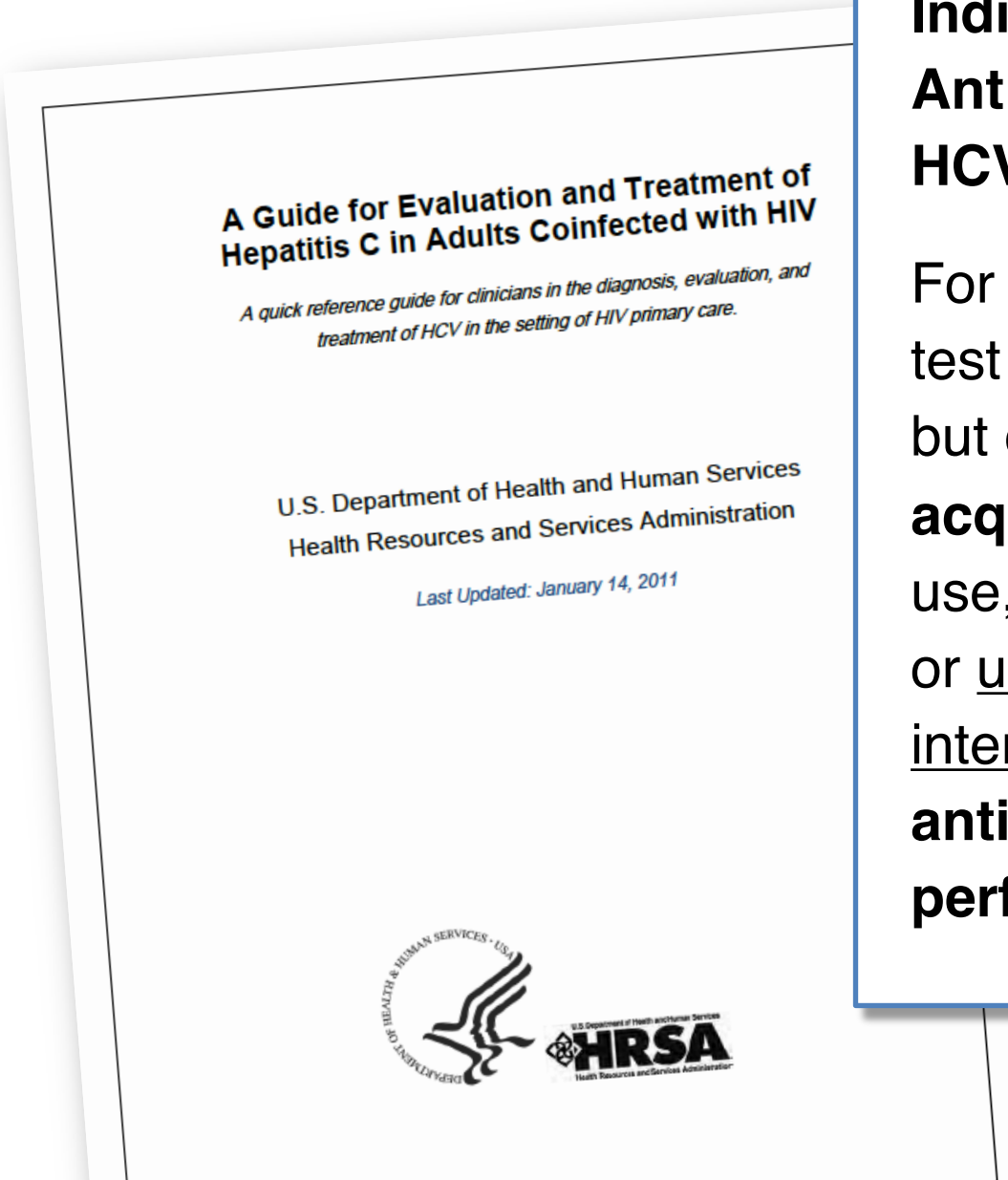
Persons with continued risk for HCV infection (injection drug users) **should be screened periodically**. The USPSTF found **no evidence about how often screening should occur** in persons who continue to be at risk for new HCV infection.

Other areas of needed research include **frequency of testing in high-risk populations**…

https://www.ncbi.nlm.nih.gov/pubmed/23798026

Slide courtesy of Dr. Christopher Hurt

2011


A Guide for Evaluation and Treatment of Hepatitis C in Adults Coinfected with HIV

A quick reference guide for clinicians in the diagnosis, evaluation, and treatment of HCV in the setting of HIV primary care.

U.S. Department of Health and Human Services
Health Resources and Services Administration

Last Updated: January 14, 2011

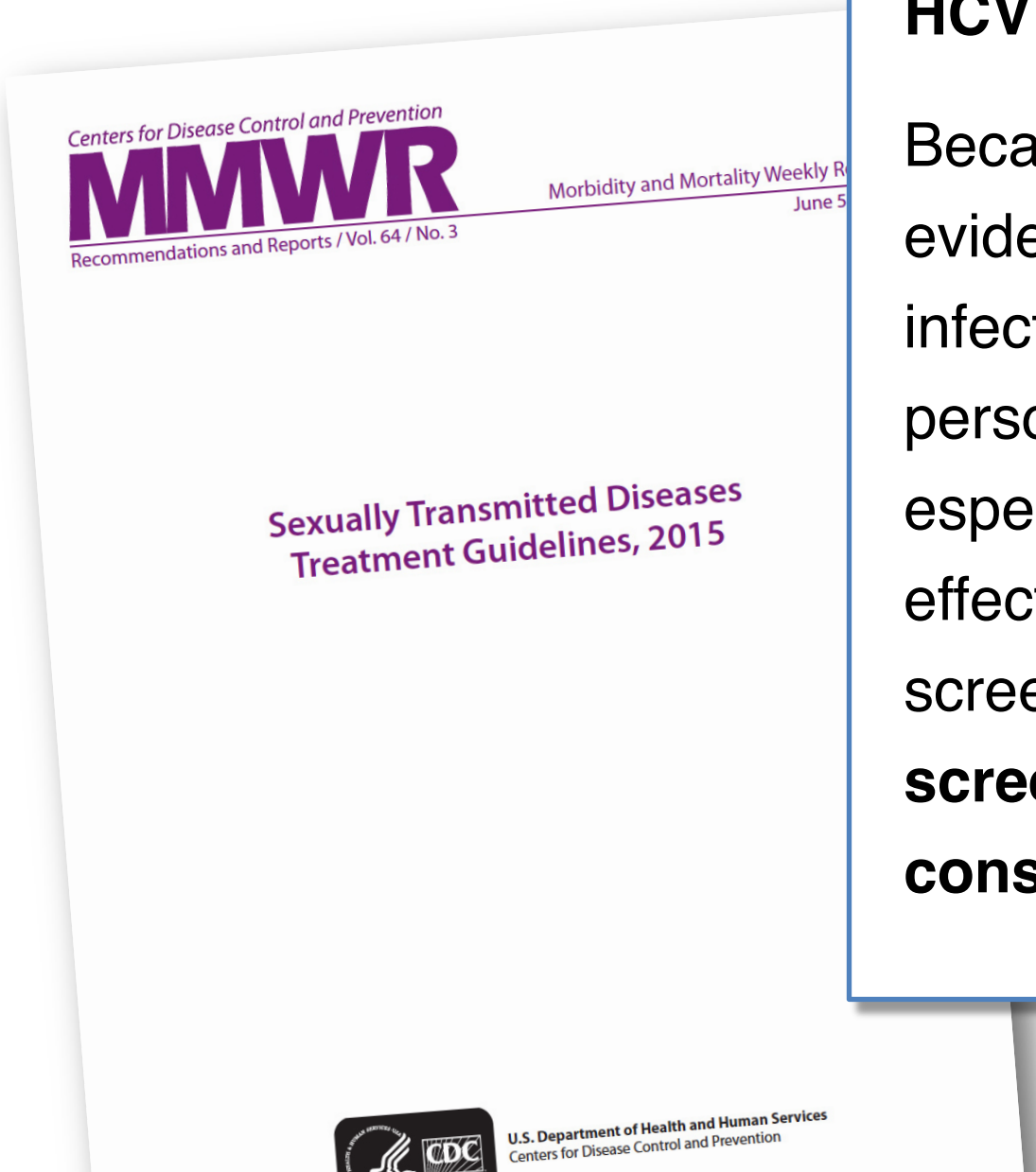
Indications for Repeat HCV Antibody Screening in HIV+ HCV-Seronegative Persons

For HIV-infected patients who test HCV antibody negative, but **continue to have risk for acquiring HCV** (injection drug use, intranasal cocaine use, or unprotected sexual intercourse), **repeat HCV antibody testing should be performed annually**.

https://hab.hrsa.gov/sites/default/files/hab/clinical-quality-management/hepccoinfectguide2011.pdf

Slide courtesy of Dr. Christopher Hurt

2015



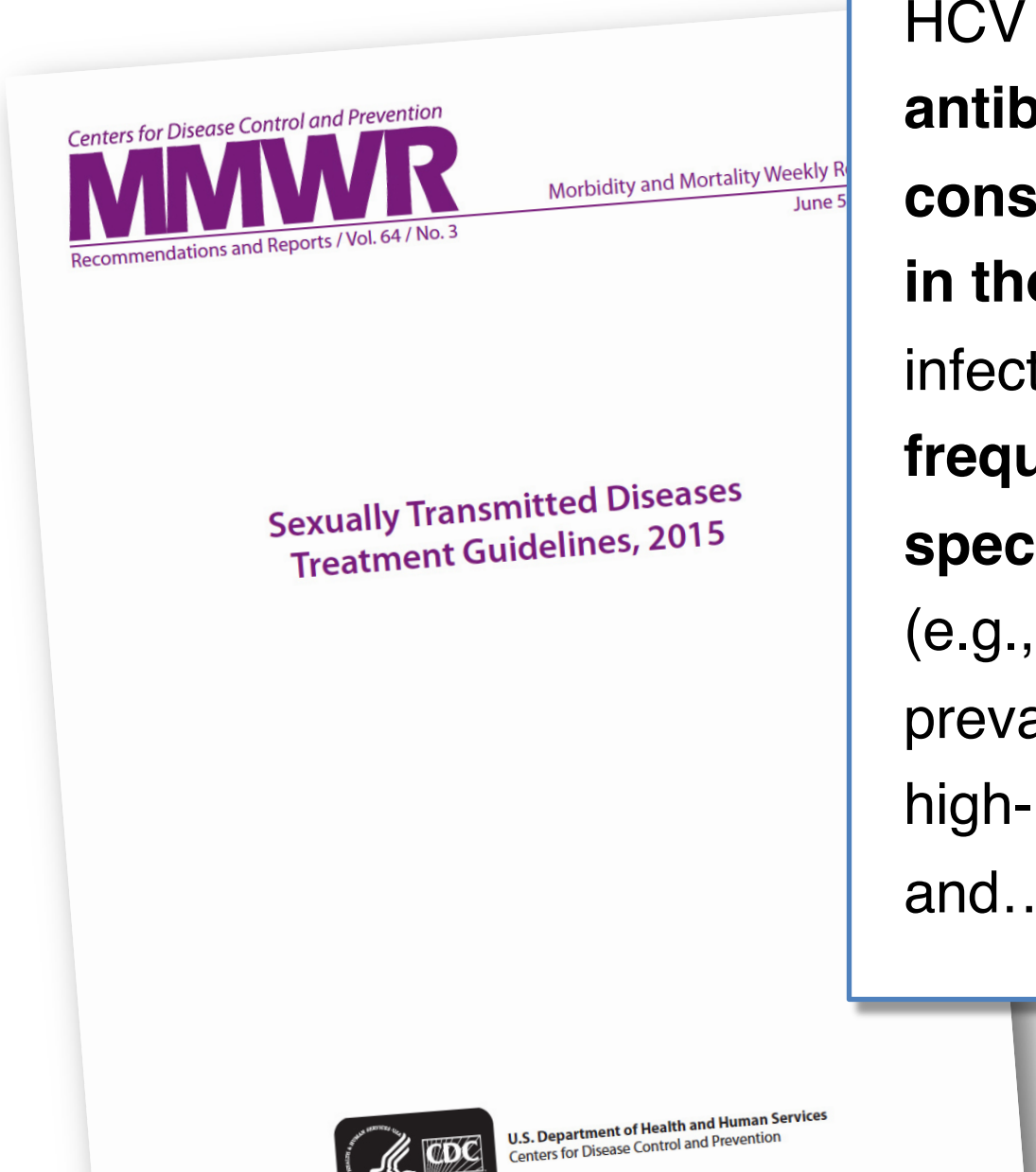
HCV rescreening of PLwH

Because of accumulating evidence of acute HCV infection acquisition in persons with HIV infection, especially MSM, and cost-effectiveness of regular screening, **periodic HCV screening should be considered**.

https://www.cdc.gov/std/tg2015/emerging.htm

Slide courtesy of Dr. Christopher Hurt

2015

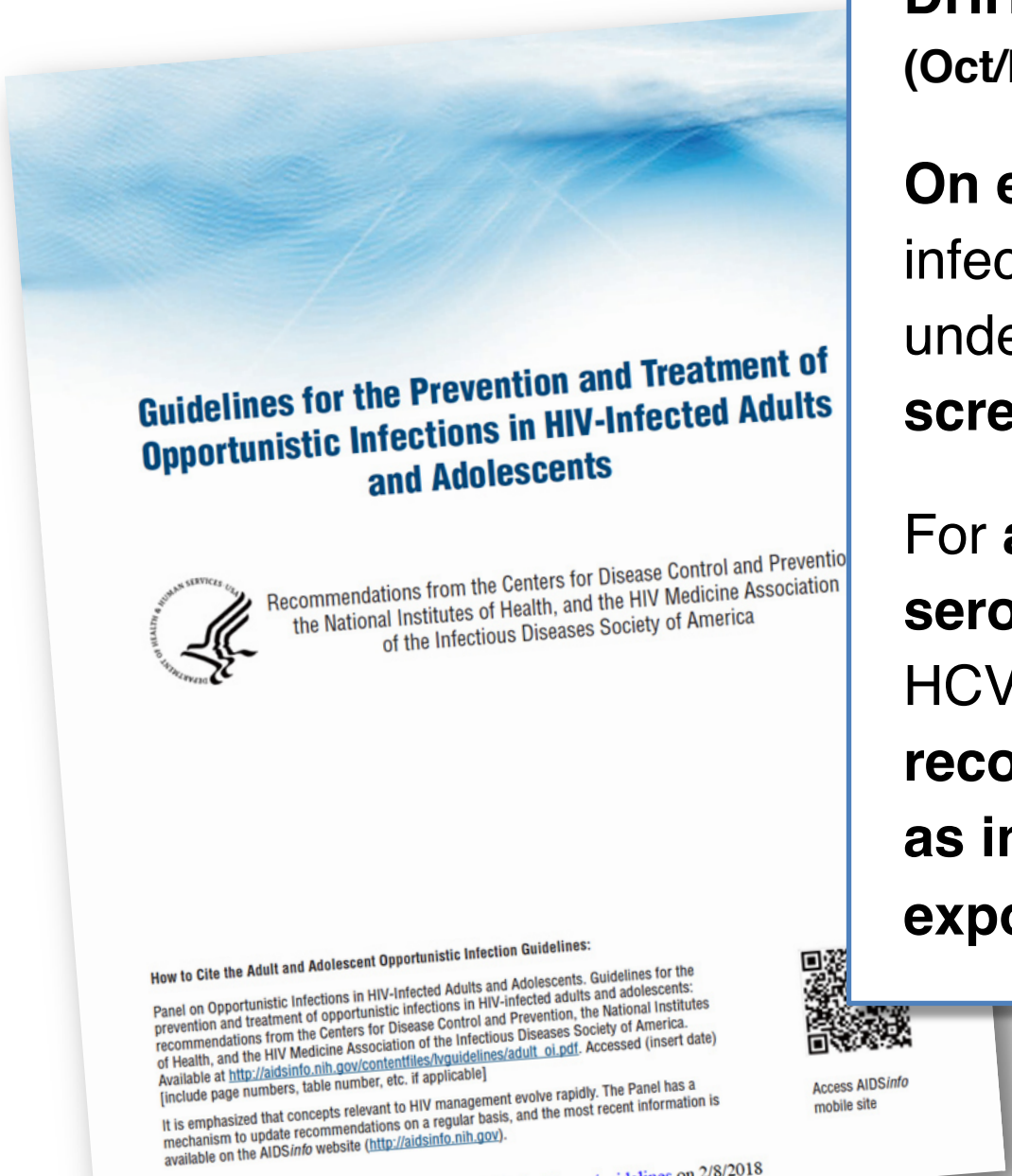


HCV **screening with** HCV **antibody** can be **considered at least yearly in those at high risk** for infection and **more frequently depending on specific circumstances** (e.g., community HCV prevalence and incidence, high-risk sexual behavior, and… ulcerative STDs…)

https://www.cdc.gov/std/tg2015/emerging.htm

Slide courtesy of Dr. Christopher Hurt

2017


Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents

Recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America

How to Cite the Adult and Adolescent Opportunistic Infection Guidelines:

Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents. Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Available at http://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf. Accessed (insert date) [include page numbers, table number, etc. if applicable]

It is emphasized that concepts relevant to HIV management evolve rapidly. The Panel has a mechanism to update recommendations on a regular basis, and the most recent information is available on the AIDS*info* website (http://aidsinfo.nih.gov).

Access AIDS*info* mobile site

DHHS OI Guidelines
(Oct/Nov 2017 edition)

On entry to HIV care, all HIV-infected patients should undergo **routine HCV screening**.

For **at risk HCV-seronegative individuals**, HCV antibody testing is **recommended annually or as indicated by risk exposure**.

https://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf

KNOW MORE HEPATITIS™

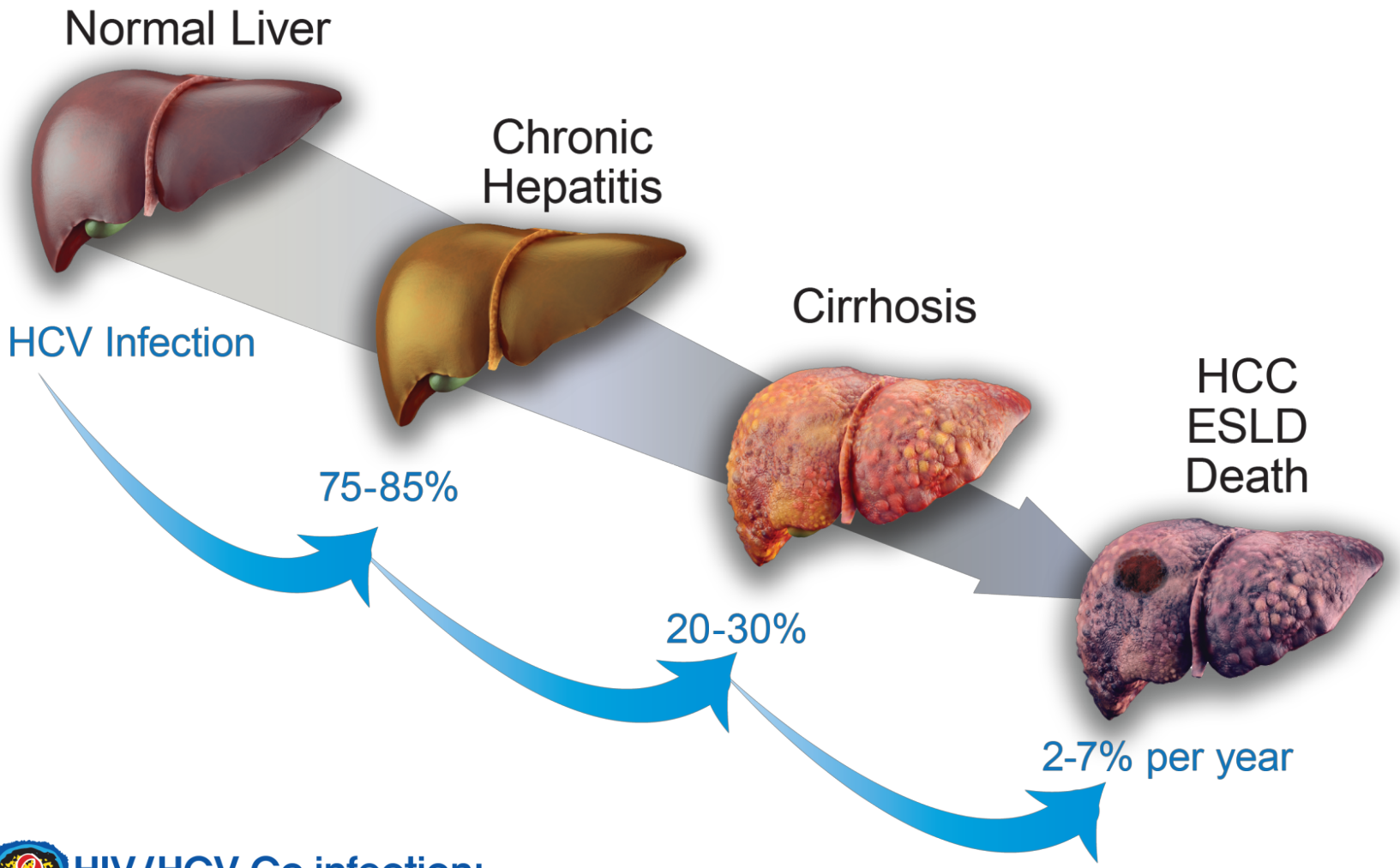
Take-home messages

- Screening at entry-to-care is universally recommended (for people living with HIV)
- Risk-based rescreening requires routine **discussion** of **sensitive topics**
- HRSA[2011] and DHHS[OI 2017] support generalized, annual testing… *but depends on how strictly "at risk" defined*

Outline

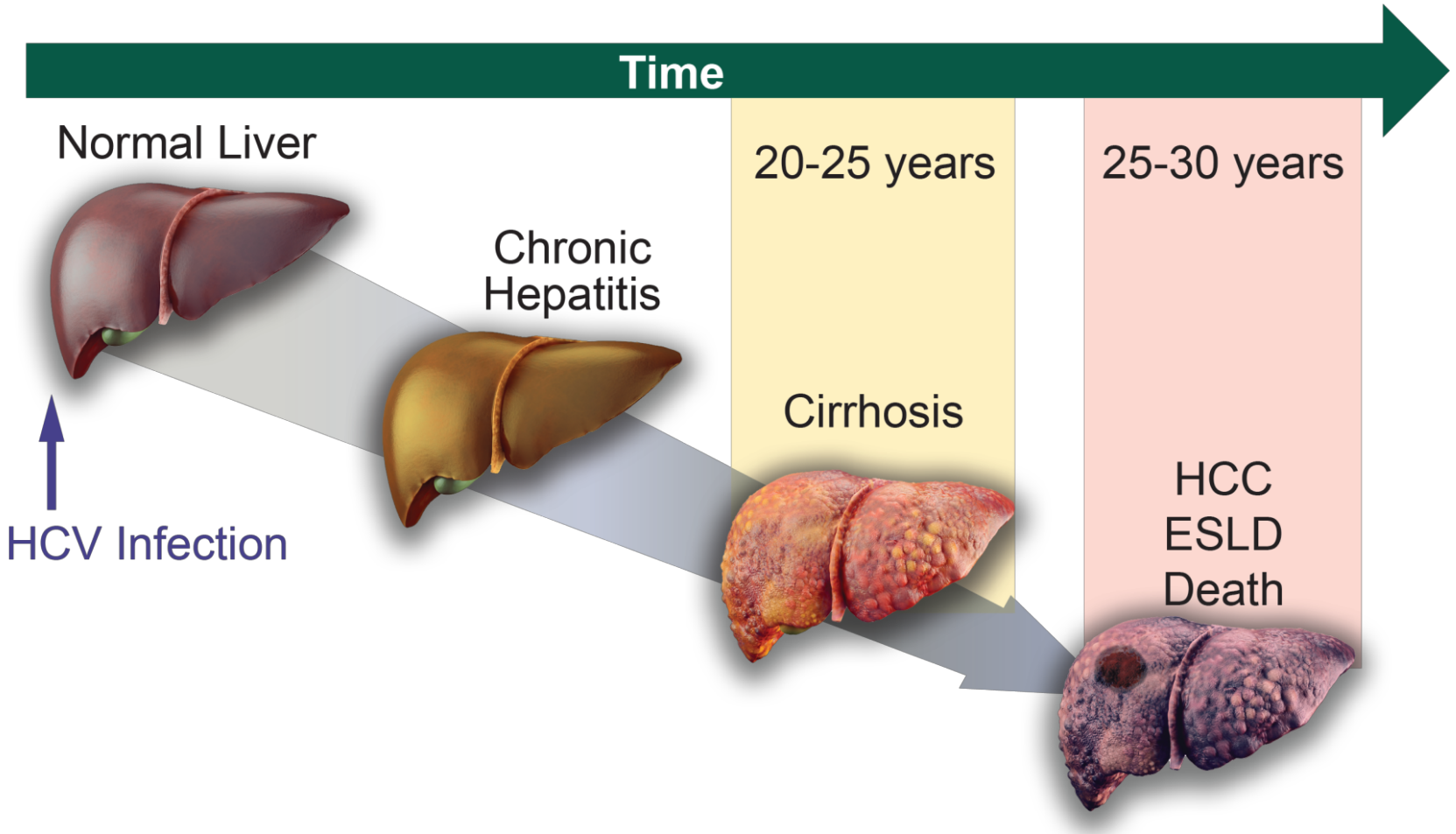
- Screening and Testing
- **Diagnosis (Clinical Manifestations)**
- Principles and Indications for Treatment

Natural History of HCV Mono-infection[5]



Adapted from www.hepatitisc.uw.edu

Natural History of HCV Mono-infection[5]
(Continued)



Adapted from www.hepatitisc.uw.edu

Natural History (of Acute HCV)[2-4,8,9]

- Estimated 20-40% clear HCV spontaneously, though reports range from 10-60%
- Rates of spontaneous clearance among PLWH appear to be lower (~10% in recent reports)[9]
- Median time to clearance is about 16 weeks
- Approximately 90% of those that clear do so by 6 months
- After 6 months, disease state is considered chronic

Natural History of HIV/HCV Co-infection[6-10]

- Increased likelihood of developing advanced fibrosis, cirrhosis, and end-stage liver disease
- Faster progression to fibrosis

Immune-Related Extrahepatic Manifestations of HCV[11,12]

- Mixed cryoglobulinemia
- Cryoglobulinemic vasculitis
- B-cell non-Hodgkin lymphoma
- Sicca syndrome
- Arthralgia/myalgia
- Polyarteritis nodosa
- Autoantibody production (i.e., cryoglobulins, rheumatoid factor, and antinuclear, anticardiolipin, antithyroid and anti-smooth muscle antibodies)
- Monoclonal gammopathies
- Immune thrombocytopenia

Inflammation-Related Extrahepatic Manifestations of HCV[11,12]

- Diabetes mellitus type 2
- Insulin resistance
- Glomerulonephritis
- Renal insufficiency
- Fatigue
- Cognitive impairment
- Depression
- Impaired quality of life
- Polyarthritis/fibromyalgia
- Cardiovascular disorders (i.e., stroke, ischemic heart disease)

Clinical Manifestations of HCV[4,14]

- Most persons with acute HCV are asymptomatic
  - See Lesson 3.2
- Many persons with chronic HCV (>6 months of infection) are asymptomatic before end-organ dysfunction occurs
- Nonspecific symptoms:
  - Fatigue
  - Joint pain
  - Abdominal pain
  - Depression

Clinical Manifestations (of Acute HCV)[2-4,8]

- Most persons with acute HCV infection are asymptomatic
- Approximately 15-30% develop symptoms, usually within 4-12 weeks after exposure
- Symptoms may include jaundice, flu-like symptoms, dark urine, light-colored stool, nausea, and/or abdominal pain
- <1% develop acute liver failure

HCV and the Physical Exam

- *May be normal without evidence of disease!*
- Focus on stigmata of chronic liver disease:
  - Palmar erythema
  - Spider nevi
  - Gynecomastia
  - Jaundice
  - Ascites
  - Asterixis
  - Encephalopathy
- Evaluate for stigmata of injection drug use
  - Track marks
  - Thrombophlebitis
  - Skin scarring

Brau N. *Clin Infect Dis* 2013.

Clinical Evaluation for HCV

- History
- Physical Exam
- Laboratory Assessment
- Staging

Outline

- Screening and Testing
- Diagnosis (Clinical Manifestations)
- **Principles and Indications for Treatment**

Who and When to Treat: Considerations[13,19]

Patient Factors

- Readiness
- Risk of reinfection

System Factors

- Access
- Affordability
- Payer coverage
- Future alternatives

Hepatic Factors

- Disease stage
- Anticipated progression
- Urgency of therapy

Other Medical Factors

- Age
- Limited life expectancy
- Comorbid conditions

Highest Priority for Treatment Owing to Highest Risk for Severe Complications

Advanced fibrosis (Metavir F3) or compensated cirrhosis (Metavir F4)

Rating: Class I, Level A

Organ transplant

Rating: Class I, Level B

Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (eg, vasculitis)

Rating: Class I, Level B

Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis

Rating: Class IIa, Level B

High Priority for Treatment Owing to High Risk for Complications

Fibrosis (Metavir F2)

Rating: Class I, level B

HIV-1 coinfection

Rating: Class I, Level B

Hepatitis B virus (HBV) coinfection

Rating: Class IIa, Level C

Other coexistent liver disease (eg, [NASH])

Rating: Class IIa, Level C

Debilitating fatigue

Rating: Class IIa, Level B

Type 2 Diabetes mellitus (insulin resistant)

Rating: Class IIa, Level B

Porphyria cutanea tarda

Rating: Class IIb, Level C

High Priority for Treatment Owing to High Risk for Complications

Fibrosis (Metavir F2)

Rating: Class I, level B

HIV-1 coinfection

Rating: Class I, l

Hepatitis B virus

Rating: Class IIa, Level

Other coexistent liver disease

Rating: Class IIa, Level C

Debilitating fatigue

Rating: Class

Type 2 Diabetes m **esistant)**

Rating: Class IIa, Level

Porphyria cutanea tarda

Rating: Class IIb, Level C

Recommendations for When and in Whom to Initiate Treatment

- **Treatment is recommended for all patients with chronic HCV infection, except those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy. Patients with short life expectancies owing to liver disease should be managed in consultation with an expert.**

  Rating: Class I, Level A

Conclusions

- HCV care at an individual and population level is dependent on screening, testing, and diagnosis.
- Work to integrate standard of care into your clinical practice.
- Ask your state or regional AETC for help!

References – Chronic HCV 1

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Resources

- AASLD and IDSA. HCV Guidance: Recommendations for Testing, Managing, and Treating HCV.
  - http://hcvguidelines.org
- Hepatitis C Online. Online training modules and resource library cover topics including screening, diagnosis, evaluation, staging, treatment, complications and comorbidities. From the CDC and University of Washington. Free CME and CEUs.
  - http://www.hepatitis.uw.edu

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Questions?

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