# HCV for Primary Care Providers

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## Program Outline

- Overview of Chronic HCV (CHC) Infection
  - HCV epidemiology, natural history, comorbidities/extrahepatic manifestations
  - Cure is possible and has significant benefits
- Pre-treatment Assessment
  - Recommended HCV screening guidelines, populations, and process
  - Patient assessment prior to starting antiviral therapy, including liver fibrosis assessment
- Managing Patients on HCV Therapy
  - Patient monitoring on treatment
- Post-treatment Follow-up
  - Patient monitoring following antiviral therapy

# Overview of Chronic HCV Infection

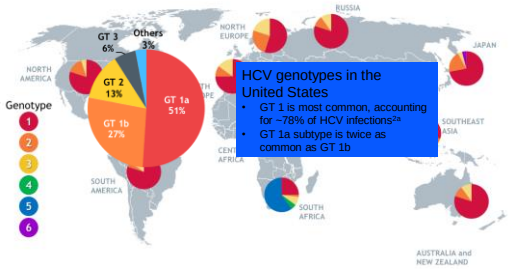
## HCV History

- An RNA virus that used to be known as non-A, non-B hepatitis until it was discovered in 1988[1]
- No vaccine available
- First therapy approved in 1991[2]
- Before 2011, HCV treatment could last as long as a year, with cure* (SVR) rates of 40%–50% for the most common genotype in the US[3]
- Since that time, scientific advances have made HCV treatment shorter and more effective
- There are better tolerated, interferon-free treatment options available that have shown cure (SVR) rates of 90% and greater in clinical studies and real world cohorts[4]

1. CDC. *MMWR Morb Mortal Wkly Rep.* 1998;47(RR-19):1-39. 2. Swartz ML. *Gastroenterol Nurs.* 1991;14(1):40-43. 3. Ghany MG *et al. Hepatology.* 2011;54(4):1433-1444. 4. AASLD, IDSA, IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Accessed January 19, 2017. 5. US Department of Health and Human Services, Center for Drug Evaluation and Research. Draft Guidance for Industry. Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment. May 2016.

*Cure, also known as sustained virologic response (SVR), is defined as no detectable HCV in the blood at 12 or more weeks after therapy is complete[4,5]

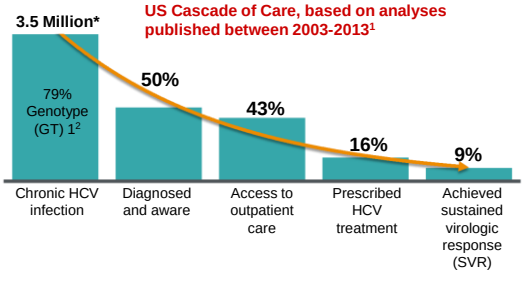
## HCV Genotypes by Geographic Region




HCV genotypes in the United States
- GT 1 is most common, accounting for ~78% of HCV infections[2a]
- GT 1a subtype is twice as common as GT 1b

GT=genotype.
*Derived from HCV RNA–positive participants in NHANES III conducted 1988 to 1994 (N=275).
1. World Gastroenterology Organisation. Diagnosis, management and prevention of hepatitis C. 2013.
2. Nainan OV, et al. *Gastroenterology.* 2006;131:478-484.

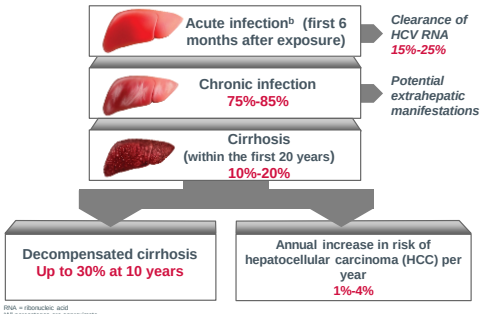
## Population Studies Show a Significant Gap in HCV Care in the United States




*Including populations excluded from NHANES (e.g., the incarcerated, homeless, institutionalized, and those living on Native American reservations) brings the total estimate to 4.6 million[3]

1 Yehia BR, et al. *PLoS One.* 2014;9:e101554
2 Zein NN, et al. *Ann Intern Med.* 1998;125:634-639
3 Edlin BR, et al. *Hepatology.* 2015;62:1353-1363.

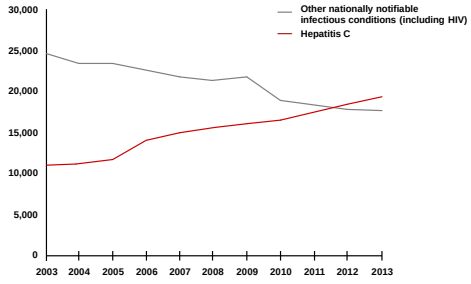
## Natural History of HCV Infection[a]




RNA = ribonucleic acid
[a]All percentages are approximate.
[b]20%-30% of individuals are symptomatic.
Adapted from Chen SL, Morgan TR. *Int J Med Sci*. 2006;3:47-52.



## Annual Deaths from HCV Surpass All Other Nationally Notifiable Infectious Conditions, Including HIV,* in the United States (2003-2013)




* 60 infectious conditions other than HCV, as reported to CDC (including HIV, Staph. aureus, HBV , TB, and pneumococcal disease)
Holmberg, S. et al ID Week 2015; 1972



## HCV IMPACTS **MORE THAN JUST THE LIVER**

**HCV may affect organs other than the liver, resulting in extrahepatic manifestations such as[1-4]:**

1. Mixed cryoglobulinemia vasculitis
2. Lymphoproliferative disorders
3. Peripheral neuropathy[a]
4. Membranoproliferative glomerulonephritis[a]
5. Insulin resistance
6. Cutaneous manifestations (eg, *lichen planus, porphyria cutanea tarda, palpable purpura*[a])

**HCV may increase the risk for other diseases and conditions, including[3,5]:**

1. Depression — 2.30x
2. Type 2 diabetes mellitus — 1.58x
3. Hypertension
4. Fatigue
5. Congestive heart failure

Relative risk in HCV patients[6]

**74%** of HCV patients have **at least one** clinical extrahepatic manifestation[7]

[a]Secondary to mixed cryoglobulinemia vasculitis.

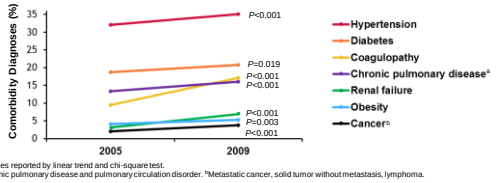
**References:** 1. Lauletta G et al. *Clin Dev Immunol*. 2012;2012:502156. 2. Khoury T et al. *World J Gastroenterol*. 2014;20(43):16197-16202. 3. Younossi ZM et al. *Aliment Pharmacol Ther*. 2013;37(6):647-652. 4. Wozniak LE et al. *J Eur Acad Dermatol Venereol*. 2017 Mar 2. doi: 10.1111/jdv.14186. [Epub ahead of print]. 5. Adinolfi LE et al. *World J Gastroenterol*. 2015;21(8):2269-2280. 6. Younossi Z et al. *Gastroenterology*. 2018;155(7):1599-1605. 7. Cacoub P et al. *Arthritis Rheum*. 1999;42(10):2204-2212.



## Common Comorbidities Diagnosed in Chronic HCV Patients: 2005-2009

- Several comorbidities, such as lymphoma, type 2 diabetes mellitus, and renal manifestations, have been shown to be associated with CHC[1]
- A cross-sectional, retrospective analysis of the US National Inpatient Sample (NIS) identified comorbidities commonly diagnosed in hospitalized CHC patients between 2005 and 2009[2]

Comorbidities as Primary or Secondary Diagnoses for Hospitalized CHC Patients[2]




P values reported by linear trend and chi-square test.
[a]Chronic pulmonary disease and pulmonary circulation disorder. [b]Metastatic cancer, solid tumor without metastasis, lymphoma.

- Convincing evidence suggests that HCV may directly promote cardiovascular disease. In particular, a correlation between the severity of liver necro-inflammation caused by HCV infection and cardio-vascular morbidity has been shown[3]

1. Zignego AL, et al. *Intern Emerg Med*. 2012;7:S201-S208.
2. Younossi ZM, et al. *J Viral Hepat*. 2015;22:137-145.
3. Nahon P, et al. *Gastroenterology*. 2016 Sep 15. pii: S0016-5085(16)35070-3.doi

## **SCIENTIFIC ADVANCES** HAVE LED TO ALL-ORAL, FIXED-DOSE DAILY REGIMENS, WHICH ARE SHORTER AND MORE EFFECTIVE[1-3]

Treatments average **12 weeks in duration**[3]

**HIGH CURE RATES WITH INTERFERON-FREE OPTIONS**[3,4]

40%–50% → ~95%

Before 2011[2] Present[3,4]

Cure, also known as sustained virologic response (SVR), is defined as no detectable HCV in the blood 12 weeks after completion of therapy[3,4]

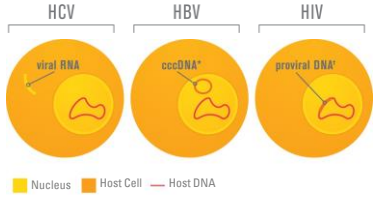
[a]For the most common genotype in the United States

**References:** 1. Rockstroh JK. *J Virus Erad*. 2015;1:55-59. 2. Ghany MG et al. *Hepatology*. 2011;54(4):1433-1444. 3. AASLD, IDSA, IAS-USA. http://www.hcvguidelines.org. Accessed September 21, 2017. 4. US Department of Health and Human Services, Center for Drug Evaluation and Research. Draft Guidance for Industry. Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment. May 2016.



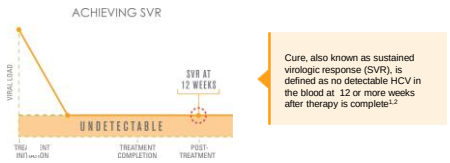
## Why Is Cure Possible?

- HCV does not integrate into the nuclei of infected cells, while HBV and HIV DNA are incorporated into the nucleus of the cell[1]




*HBV cccDNA (covalently closed circular DNA): accumulates in hepatocyte nuclei, acting as a template for viral messenger RNA transcription.
†HIV proviral DNA: integrates into the chromatin of infected cells, acting as the template for the transcription of viral genes.
1. Soriano V et al. *J Antimicrob Chemother*. 2008;62(1):1-4.

## What Defines HCV Cure?




Cure, also known as sustained virologic response (SVR), is defined as no detectable HCV in the blood at 12 or more weeks after therapy is complete[1,2]

- In some instances, HCV treatment does not result in cure, or SVR, because the virus does not reach undetectable levels or because it does not stay undetectable after therapy completion
- In one study, of those patients who reached SVR, 99% had undetectable levels of HCV RNA more than 4 years after treatment end[3]
- These patients do not experience viral recurrence and may be considered to be cured[3]

1. US Department of Health and Human Services, Center for Drug Evaluation and Research. Draft Guidance for Industry. Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment. October 2013.
2. AASLD, IDSA, IAS-USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Accessed January 19, 2017

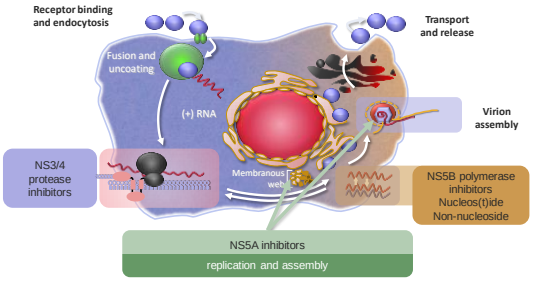
## Improvements in HCV Therapy: Overall SVR Rates in the Pre-DAA and DAA Eras

| Era | Standard of Care | Overall SVR[a] Rates |
|---|---|---|
| Pre-2011 (Pre-DAA) | Peg-IFN + RBV | 47%-54%[1,2] *SVR=24-week follow-up |
| 2011-2013 (Early DAA) | DAA + Peg-IFN + RBV | 67%-75%[3,4] *SVR=24-week follow-up |
| 2013-present (all-oral DAA regimens) | DAA regimen ± RBV | ≥90%[5-9] *SVR=12-week follow-up |

- Recent data suggests that patients with traditionally negative predictors of response, such as African Americans, achieve similar rates of SVR12 as the overall population[10,11]
- The IFN-containing regimens were associated with higher rates of serious adverse events (eg, anemia and rash), longer treatment duration in some cases, high pill burden, numerous drug-drug interactions, more frequent dosing, and higher intensity of monitoring for safety or treatment response.[12]

1. Manns MP, et al. *Lancet*. 2001;358:958-965.
2. Fried MW, et al. *N Engl J Med*. 2002;347:975-982.
3. Poordad F, et al. *N Engl J Med*. 2011;364:1195-1206.
4. Jacobson IM, et al. *N Engl J Med*. 2011;364:2405-2416.
5. Lawitz E, et al. *N Engl J Med*. 2013;368:1878-1887.
6. Ferenci P, et al. *N Engl J Med*. 2014;370:1983-1992.
7. Afdhal N, et al. *N Engl J Med*. 2014;370:1889-1898.
8. Feld JJ, et al. *N Engl J Med*. 2015;373:2599-2607.
9. Foster GR, et al. *N Engl J Med*. 2015;373:2608-2617.
10. Afdhal, EASL 2016, LBP519.
11. Wilder M, et al. *Hepatology*. 2016 Feb;63(2):437-44.
12. Adapted from AASLD/IDSA. Not Recommend Regimens in HCV Treatment. http://hcvguidelines.org. Accessed January 19, 2017

## HCV Life Cycle and Targets for Direct-Acting Antivirals (DAAs)




Adapted from Manns MP, et al. *Nat Rev Drug Discov*. 2007;6:991-1000.

## Examples of commonly used DAA's

| Branded drug | NS3/4A Protease Inhibitors (PIs) | NS5B Polymerase Inhibitors | NS5A Inhibitors |
|---|---|---|---|
| **Epclusa** | ---------- | Sofosbuvir | Velpatasvir |
| **Harvoni** | ---------- | Sofosbuvir | Ledipasvir |
| **Mavyret** | Glecaprevir | ---------- | Pibrentasvir |
| **Vosevi** | Voxilaprevir | Sofosbuvir | Velpatasvir |
| **Zepatier** | Grazoprevir | ---------- | Elbasvir |



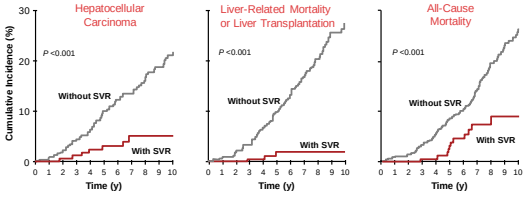
## Potential Benefits of SVR (Virologic Cure)

- Achieving SVR is associated with:
  - Reduced medical costs when compared with patients who do not achieve SVR[1,a]
  - Reductions in HCC, liver-related mortality or transplantation, and all-cause mortality[2,a]
  - Lowering the incidence of HCV-related comorbidities[3-6,a]
  - Improving relevant aspects of attentional and neurocognitive performance[7,a]
  - Certain improved quality-of-life measurements in a real-world cross-sectional study[8,a]
  - Regression of cirrhosis and fibrosis are frequently observed in patients with cirrhosis who achieve long-term SVR (median period of 61 months)[9]

[a]SVR was defined as lack of detection of HCV RNA at 24 weeks after the cessation of treatment.

1. Manos MM, et al. *J Managed Care Pharmacy*. 2013;19:438-447.
2. van der Meer AJ, et al. *JAMA*. 2012;308:2584-2593.
3. Arase Y, et al. *Hepatology*. 2009;49:739-744.
4. Arase Y, et al. *J Med Virol*. 2014;86:169-175.
5. Arcaini L, et al. *Ann Oncol*. 2014;25:1404-1410.
6. Hsu YC, et al. *Hepatology*. 2014;59:1293-1302.
7. Kraus MR, et al. *Hepatology*. 2013;58:497-504.
8. John-Baptiste AJ, et al. *Am J Gastroenterol*. 2009;104:2439-2448.
9. D'Ambrosio R, et al. *Hepatology*. 2012;56:532-543.

## SVR Associated With a Reduction in HCC, Liver-Related Mortality, Transplantation, and All-Cause Mortality




- This was an international, multicenter, long-term follow-up study of 530 consecutive CHC patients with advanced hepatic fibrosis or cirrhosis (Ishak score 4-6), who started an IFN-based treatment regimen between 1990 and 2003, from 5 large tertiary care hospitals in Europe and Canada. Complete follow-up occurred between January 2010 and October 2011. Median follow-up duration was 8.4 years
- This study showed significant reduction of 10-year cumulative incidence of HCC, liver-related mortality or transplantation, and all-cause mortality in patients who achieved SVR
- SVR was defined as lack of detection of HCV RNA at 24 weeks after the cessation of treatment

van der Meer AJ, et al. *JAMA*. 2012;308:2584-2593.

## Pre-treatment Assessment

## Limited Success With Risk-Based Screening

- Since 1998, the CDC has recommended screening individuals largely based on behavioral risk factors (eg, IV drug use, tattoos from unregulated environments)[1]
- Risk-based screening has had limited success, as shown by the large number of undiagnosed individuals[1]
- HCV is much more prevalent among baby boomers, persons born between 1945–1965, than other age cohorts[1]
- HCV screening guidelines include both risk-based and age-based factors[1, 3, 4]

1. Smith BD et al. *MMWR Recomm Rep.* 2012;61(RR-4):1-32.
2. CDC. http://www.cdc.gov/nchhstp/newsroom/docs/HCV-TestingFactSheetNoEmbargo508.pdf. Accessed January 19, 2017
3. USPSTF. http://www.uspreventiveservicestaskforce.org/uspstf12/hepc/hepcfinalrs.htm. Accessed October 12, 2016.
4. AASLD, IDSA, IAS-USA. Recommendations for testing, managing, and treating hepatitis C http://www.hcvguidelines.org. Accessed January 19, 2017

## WHO TO SCREEN?

The CDC, USPSTF, and AASLD recommend **screening all high-risk populations**, including a one-time screening of all baby boomers[1-3]

- Baby boomers (born 1945–1965)
- Persons who ever injected illegal drugs
- HIV-infected patients
- Persons who have received tattoos from unlicensed or unregulated environments
- Those with certain medical conditions, including:
  - Persons who received clotting factor concentrates produced before 1987
  - Persons who were ever on long-term hemodialysis
  - Persons with persistently abnormal alanine aminotransferase levels
- Prior recipients of transfusions or organ transplants, including:
  - Persons who were notified that they received blood from a donor who later tested positive for HCV infection
  - Persons who received a blood transfusion, blood components, or an organ transplant before July 1992
- Healthcare, emergency medical, and public safety workers after needlesticks, sharps, or mucosal exposures to HCV-positive blood
- Children born to an HCV-positive mother

**References: 1.** Smith BD et al. *MMWR Recomm Rep.* 2012;61(RR-4):1-32. **2.** USPSTF. https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/hepatitis-c-screening. Accessed December 14, 2016. **3.** AASLD, IDSA, IAS-USA. http://www.hcvguidelines.org. Accessed September 21, 2017.

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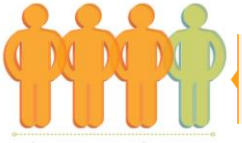
## CDC, USPSTF, and AASLD HCV Screening Recommendations in Baby Boomers

Screen all baby boomers (born between 1945 and 1965) regardless of the presence of risk factors[1, 2, 3]



Baby boomers account for 73% of HCV-related mortality and are at greatest risk for liver cancer and other liver-related complications[1]

AN ESTIMATED **75%** OF ALL HCV PATIENTS ARE BABY BOOMERS[4]

1. Smith BD et al. *MMWR Recomm Rep.* 2012;61(RR-4):1-32.
2. USPSTF. http://www.uspreventiveservicestaskforce.org/uspstf12/hepc/hepcfinalrs.htm. Accessed October 12, 2016.
3. AASLD, IDSA, IAS-USA. Recommendations for testing, managing, and treating hepatitis C http://www.hcvguidelines.org. Accessed January 19, 2017
4. CDC. http://www.cdc.gov/nchhstp/newsroom/docs/HCV-TestingFactSheetNoEmbargo508.pdf. Accessed October 12, 2016.

## This is a standard preventive benefit for Medicare and high risk patients

Medicare Preventive Services

**Hepatitis C Virus (HCV) Screening**

**HCPCS/CPT Codes**

**G0472** – Hepatitis C antibody screening, for individual at high risk and other covered indication(s)

**ICD-10 Codes**

Z72.89 and F19.20

**Who Is Covered**

Certain adult Medicare beneficiaries who fall into at least one of the following categories:

- High risk for HCV infection
- Born between 1945 and 1965

**Frequency**

- Annually only for high risk Medicare beneficiaries with continued illicit injection drug use since the prior negative screening test
- Once in a lifetime for Medicare beneficiaries born between 1945 and 1965 who are not considered high risk

**Medicare Beneficiary Pays**

- Copayment/coinsurance waived
- Deductible waived

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## SCREEN AT-RISK INDIVIDUALS REGARDLESS OF LIVER ENZYME LEVELS AND SYMPTOMS[1,2]

- Liver damage is possible in the presence of low viral loads and normal ALT or AST levels[1]
- **Approximately 30%** of patients with chronic HCV infection have persistently normal ALT levels[3]

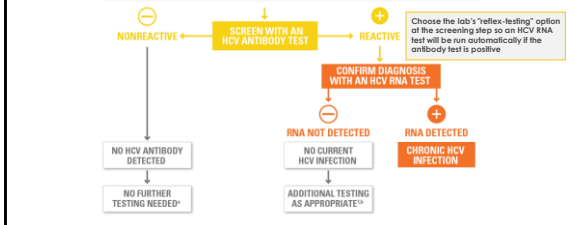
ALT = alanine transaminase AST = aspartate aminotransferase

**References: 1.** Smith BD et al. *MMWR Recomm Rep.* 2012;61(RR-4):1-32. **2.** USPSTF. https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/hepatitis-c-screening. Accessed December 14, 2016. **3.** Pusti C et al. *J Viral Hepat.* 2012;19(4):229-235.

YOUR ROLE IN HCV 24

## HOW TO SCREEN & DIAGNOSE

If patient falls within baby boomer age cohort (born 1945–1965) or risk factor is identified:

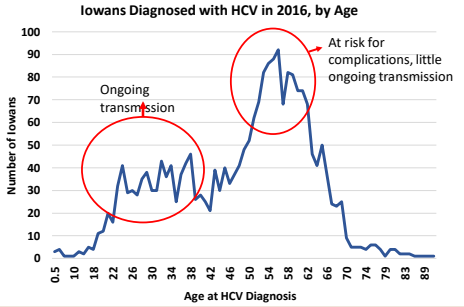



*For persons who might have been exposed to HCV within the past 6 months, consider retesting for HCV antibodies or ordering an HCV RNA test. For persons who are immunocompromised, testing for HCV RNA can be considered.
†Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease.‡

Reference: 1. CDC. *MMWR Morb Mortal Wkly Rep.* 2013;62(18):362-365.

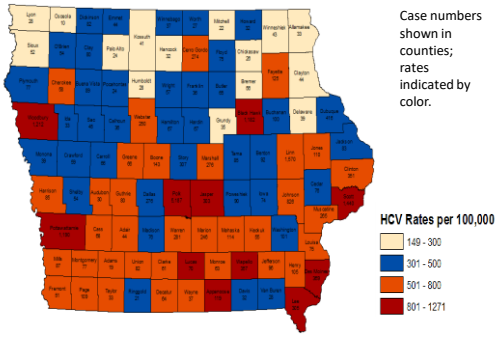
YOUR ROLE IN HCV 25

## Iowans Diagnosed with HCV in 2016, by Age



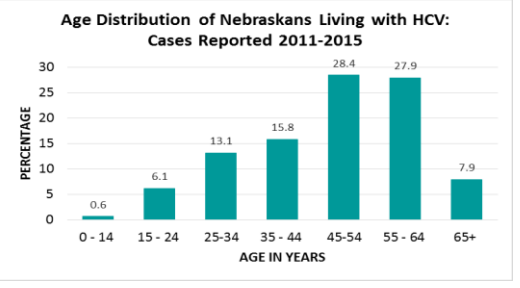

Bureau of HIV, STD, and

## Distribution of HCV in Iowa




Case numbers shown in counties; rates indicated by color.

From 2011-2015, 5,223 cases of HCV were reported to Nebraska Department of Health and Human Services.




## Managing Patients on HCV Therapy

## HCV Disease Progression: Metavir Staging System for Fibrosis


Razavi H, et al. *Hepatology.* 57(6):2164-2170

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## Baseline Fibrosis Assessment Is Important for Developing a Chronic HCV Treatment Plan

- Accurate assessment of fibrosis is recommended for all patients with CHC to determine appropriate treatment strategy and follow-up[1]
  - Patients with severe fibrosis require surveillance monitoring for liver cancer, esophageal varices, and hepatic function
- Although liver biopsy is the diagnostic standard, the most efficient approach is to combine direct biomarkers and vibration-controlled transient liver elastography[1]
  - A biopsy should be considered for any patient with discordant results between the 2 methods that would affect clinical decision making
- If direct biomarkers or elastography are not available, APRI or FIB-4 tests can help, although neither test is sensitive enough to rule out substantial fibrosis[1]
- Thrombocytopenia can be a marker of advanced liver fibrosis and portal hypertension
- Individuals with clinically evident cirrhosis do not require additional staging[1]

APRI=AST-to-platelet ratio index; FIB-4=fibrosis 4.
AASLD/IDSA. When and in whom to initiate HCV therapy. http://hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy. Accessed March 3, 2016.
Gordon S, et al. *Am J Gastroenterol*. 2015;110:1169-1177.
Sheikh MY, Raoufi R, Atia PR, et al. Prevalence of cirrhosis in patients with thrombocytopenia who receive bone marrow biopsy. *Saudi J Gastroenterol*. 2012;18(4):257–262.
Afdhal N. Thrombocytopenia associated with chronic liver disease. *J Hep* 2008;48:1000–1007

## Comparing Invasive and Noninvasive Fibrosis Tests

| | APRI or FIB-4 | FibroSure™FibroTest™ | Transient Elastography | Liver Biopsy |
|---|---|---|---|---|
| **Methodology** | Measures direct and indirect serum markers of fibrosis | Age, gender and six biochemical markers of fibrosis | Measures liver stiffness by detection of ultrasound-propagated shear waves | Direct observation |
| **Accuracy for detecting cirrhosis** | Moderate | High | High | High |
| **Accuracy for detecting intermediate fibrosis** | Low | Moderate | Moderate to high | High |
| **Risk of complications** | Minimal | Minimal | Minimal | Risk of pain/bleeding |
| **Contraindications** | Minimal | Minimal | Accuracy lessened with obesity and/or narrow rib spaces | Coagulopathy |
| **Limitations** | False-positives with hemolysis, inflammation, Gilbert's syndrome | Not good for detecting intermediate fibrosis | False-positives with inflammation, congestion | Sampling error Observer variation |
| **Cost** | Low per-test cost | Moderate | High initial equipment cost | Highest per-test cost |

ELF=enhanced liver fibrosis; MRE=magnetic resonance elastography, MRI=magnetic resonance imaging.
Nguyen D, Talwalkar JA. *Hepatology*. 2011;53:2107-2110.

## Post-treatment Follow-up

## Post-treatment Monitoring Following SVR

**Recommended follow-up for patients who achieve an SVR**

For patients without advanced fibrosis (METAVIR stage F0-F2), recommended follow-up is the same as if they were never infected with HCV

For patients with advanced fibrosis or cirrhosis (METAVIR stage F3 or F4), lifelong surveillance for HCC with twice-yearly ultrasound is recommended

- If cirrhosis is present, a baseline endoscopy is recommended to screen for varices

Among patients with ongoing risk for HCV infection or in whom otherwise unexplained hepatic dysfunction develops, assessment for HCV recurrence or reinfection is recommended

- Because antibody to HCV remains positive in most patients following an SVR, testing for reinfection should be performed with a quantitative HCV RNA assay rather than an anti-HCV serology test
- Continue to engage in harm reduction

If patients develop persistently elevated abnormal liver function tests after achieving an SVR, assess for other causes of liver disease such as alcohol consumption or fatty liver disease

AASLD/IDSA. Recommendations for testing, managing, and treating hepatitis C. http://hcvguidelines.org. Accessed January 19, 2017

## Post-treatment Monitoring for Patients Who Fail to Achieve SVR

**Recommended follow-up for patients who do not achieve an SVR**

Patients who do not achieve an SVR have ongoing HCV infection and risk continued liver injury and also represent an ongoing risk for transmission to others. They benefit from ongoing harm reduction and continued patient education around HCV transmission risk and exposure.

They should be monitored for disease progression every 6 to 12 months

- Hepatic function panel, CBC, INR

For patients with cirrhosis, screening for esophageal varices is recommended

For patients with advanced fibrosis/cirrhosis (METAVIR stage F3 or F4), lifelong screening for HCC via ultrasound every 6 months is recommended

AASLD/IDSA. Recommendations for testing, managing, and treating hepatitis C. http://hcvguidelines.org. Accessed January 19, 2017

## Summary

- At least 3.5 million people in the United States are chronically infected with HCV
  - It is estimated that only half of those infected are diagnosed
- Recommendations for managing patients with CHC include:
  - Baseline screening for all patients initiating antiviral treatment, including fibrosis assessment and assessment for comorbidities and other factors that may affect treatment response
  - Monitoring while on treatment to assess virologic and other laboratory/clinical effects of treatment
  - Post-treatment monitoring according to whether patients achieve an SVR (virologic cure) or not
- The approval of DAAs for the treatment of HCV has resulted in substantial improvements in the overall rates of SVR (virologic cure)
- The ASCEND Trial showed that successful community-based treatment of chronic HCV is possible
- Long-term, achieving an SVR may be associated with numerous clinical and quality-of-life benefits
- High rates of cure can be achieved in patients who use recreational drugs
- Harm reduction is important both for patients who do and do not achieve SVR to prevent reinfection/transmission.