HEPATITIS C BREAKTHROUGHS: NEW CURES, BEST PRACTICE & HEALTH EQUITY

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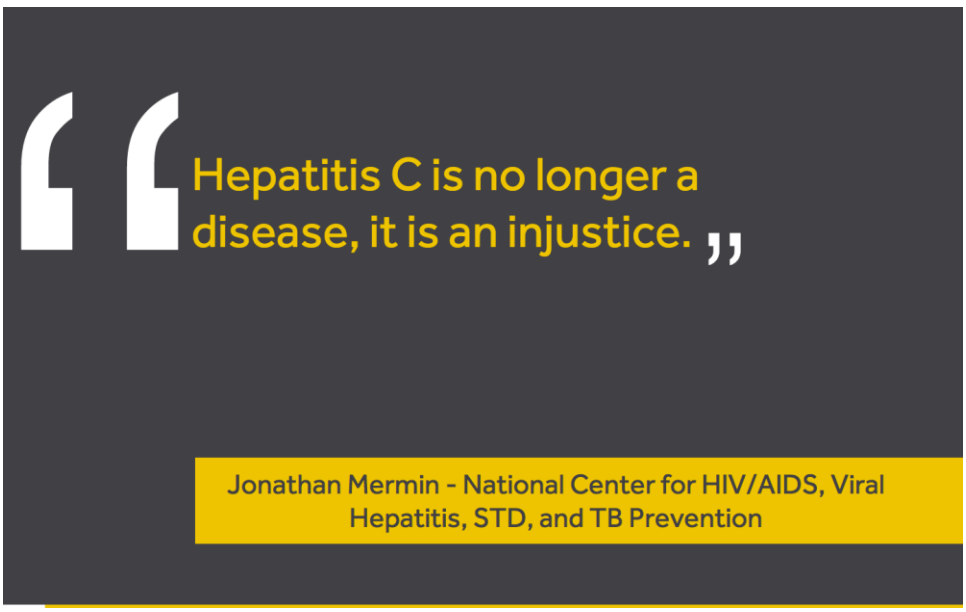


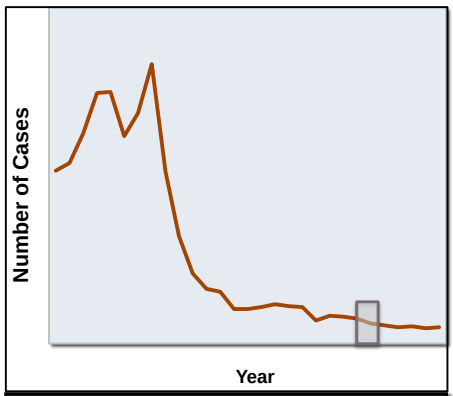
This workshop will:

- provide an update on current treatment regimens;
- review best practice for screening and risk counseling and
- provide recommendations for community and clinical action.

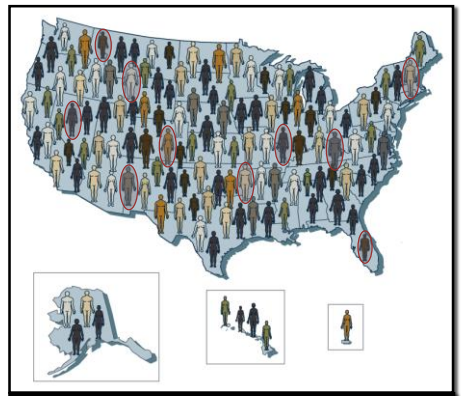
Outline

- Epidemiology
- What is Hepatitis C?
- Treatment
- Hepatitis C and Public Health Best Practice
- Moving forward recommendations

Hepatitis C Incidence and Prevalence



HCV Incidence. The number of people who become newly infected with HCV in a defined time period.



HCV Prevalence. The number of people living with HCV in a population at a point in time.

Hepatitis Web Study & the University of Washington Hepatitis C Online Course

- Source: CDC Division of Viral Hepatitis. Statistics and Surveillance.

Expanded Estimate of HCV Prevalence
Estimated Number of anti-HCV Positive Persons in U.S

- HCV Prevalence Estimate: Expansion of NHANES Survey

- Addition of Groups
  - Incarcerated
  - Homeless
  - Nursing Home Residents
  - Hospitalized Persons
  - Active Military Duty
- Recalculation of Groups
  - Healthcare Workers
  - Chronic Hemodialysis
  - Veterans

5.2 million Antibody Positive for HCV

4.1 million living with chronic HCV

Hepatitis Web Study & the University of Washington Hepatitis C Online Course

- Source: Chak E, et al. Liver Int. 2011;31:1090-101.

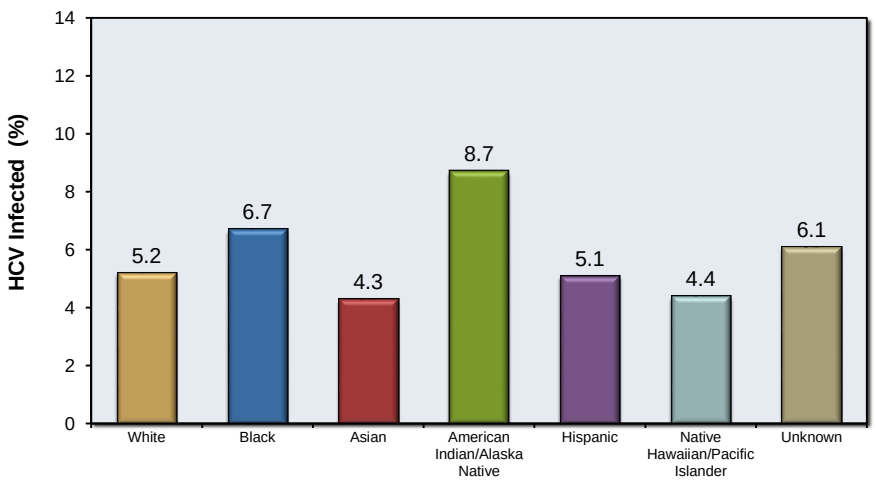
New Hepatitis C Infections in the United States

Incidence of New Hepatitis C Infections									
Type of Cases	Year								
	2002	2003	2004	2005	2006	2007	2008	2009	2010
Acute Clinical Cases Reported	1,223	891	758	694	802	849	878	781	853
Estimated Number of Acute Clinical Cases	4,800	4,500	4,200	3,400	3,200	2,800	2,900	2,600	2,800
Estimated Number of New Infections	29,000	28,000	26,000	21,000	19,000	17,000	18,000	16,000	17,000

Hepatitis Web Study & the University of Washington Hepatitis C Online Course

- Source: CDC. Division of Viral Hepatitis-Statistic and Surveillance.

Private Health Care Organizations, United States, 2006-2008
HCV Infection by Race



HCV infection defined as either positive anti-HCV or HCV RNA

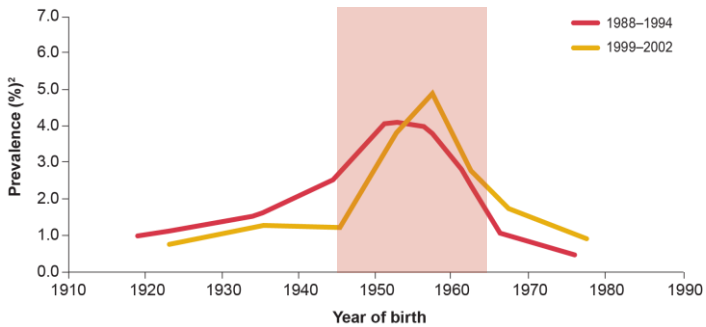
Hepatitis Web Study & the University of Washington Hepatitis C Online Course

- Source: Spradling PR, et al. Clin Infect Dis. 2012;55:1047-55.

The US Prevalence of Hepatitis C Infection Is Highest in the 1945-1965 Birth Cohort

- Based on CDC estimates, 77% of individuals infected with HCV (~2.06 million) were born between 1945 and 1965[1,2]

New screening guidelines



1. Smith BD, et al. *MMWR Recomm Rep.* 2012;61(RR-4):1-32, 2. Armstrong GL, et al. *Ann Intern Med.* 2006; 144(10):705-714.

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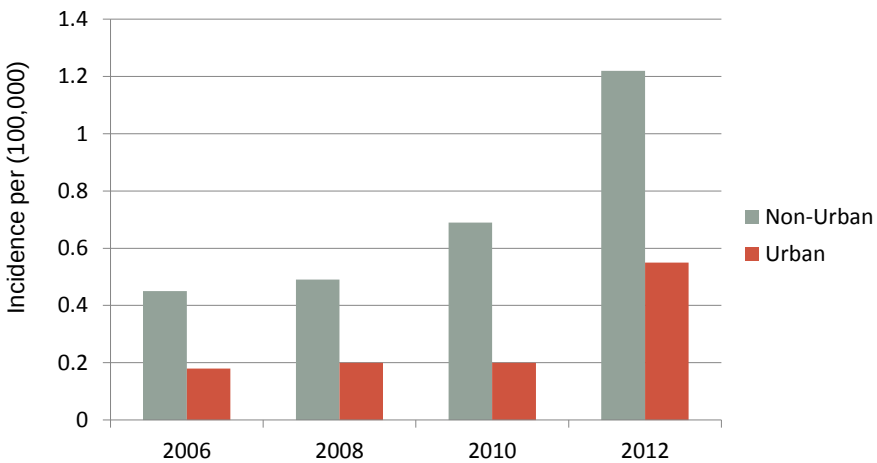
Trends in Incidence of Acute Hepatitis C Among Young Persons Reported to the CDC



Adapted from Suryaprasad AG et al. CID 2014:59 (15 November) • 1411-19

Trends in Incidence of Acute Hepatitis C Among Young Persons Reported to the CDC

- Increase in HCV infection in 2012 compared to 2006 among young PWID
- Annual increase (>2 times) in nonurban compared to urban jurisdictions.

"All available information indicates that early prescription opioid abuse and addiction, followed by initiation to IDU, is fueling increases in HCV infection among young PWID"

Suryaprasad AG et al. CID 2014:59 (15 November) • 1411-19

Epidemiology Summary

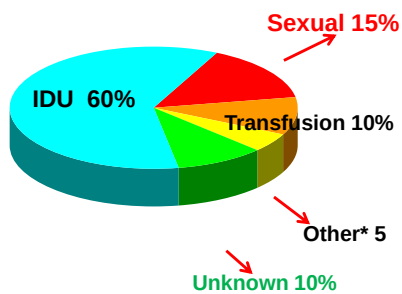
- It disproportionally affects
  - AI/AN
  - People born between 1945-1965
  - People who inject drugs (in rural settings too)

What is Hepatitis C?

- How does it act?
- What are it's characteristics?
- How are we dealing?

HCV: Transmission

- ***Blood***
  - IVDU is the leading cause in the United States
  - Blood transfusion (Before 1992)
  - Percutaneous/mucosal
    - Needle stick
    - Tattoo
    - Dentist
- ***Sexual contact***
  - Rare in heterosexual
  - More frequent in MSM
- ***Mother-to-child***
  - The rate is 1.7% - 4.3 %
  - *Increased in IVDU, HIV co-infection, VL (?)*



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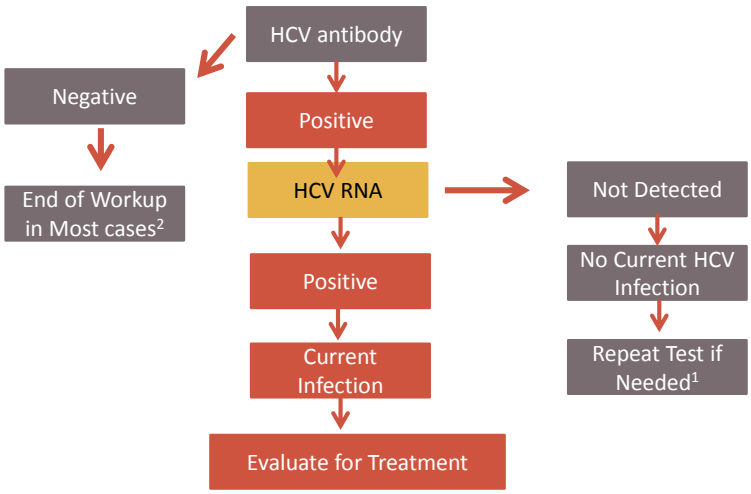
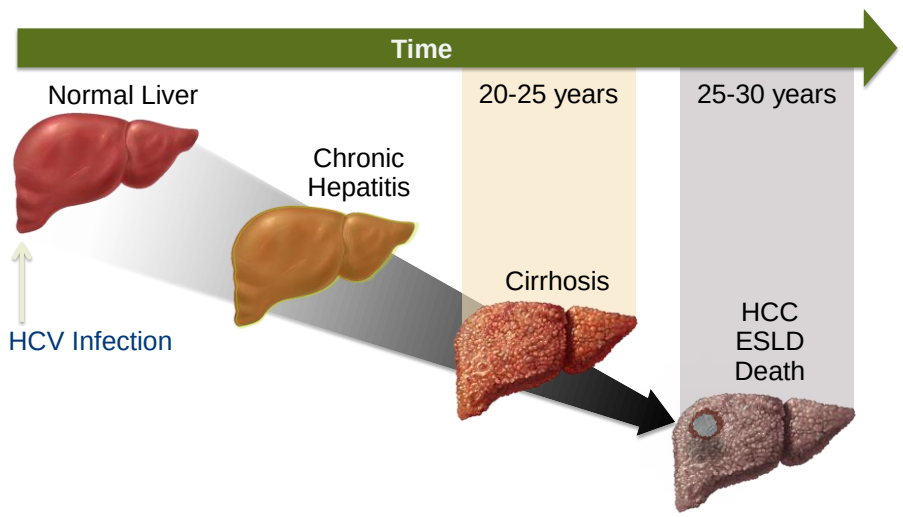
HCV: Diagnostic Algorithm



1. If exposure was within the last 6 months
   Concern in the handling of specimen
2. Immunocompromised or exposure in last 6 months

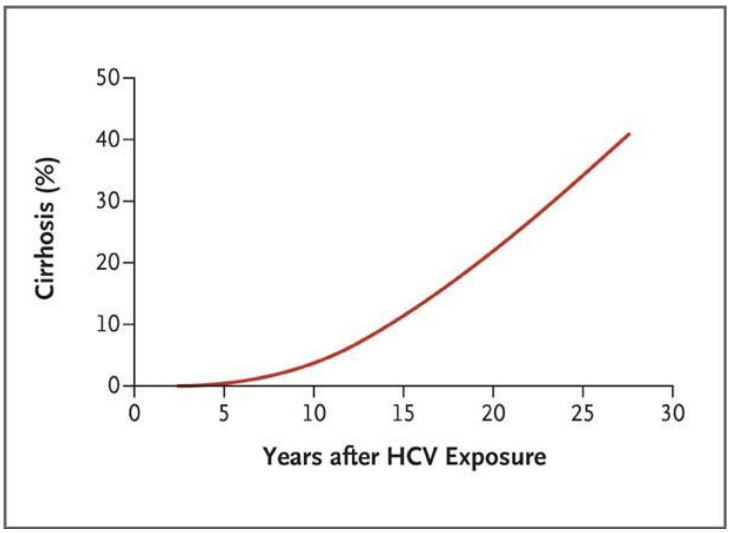
Adapted from Paneer N et.al. CID 2014:59(15) 875-82

Hepatitis C: Progression of Disease



- University of Washington, Hepatitis C

Natural History of Hepatitis C Virus (HCV) Infection



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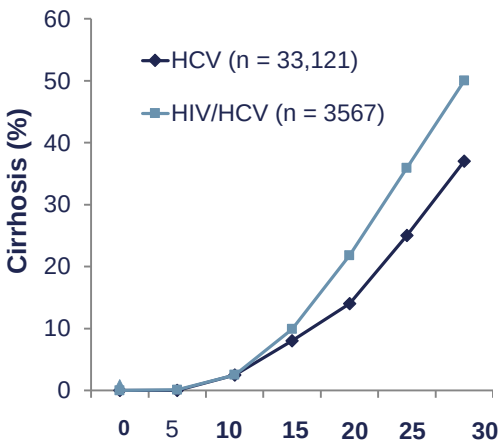
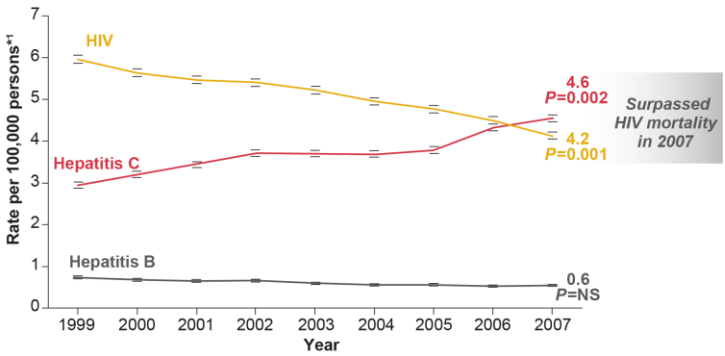
Disease Progression

- Non-linear
- Modifiable factors are
  - Weight loss
  - Diabetes control
  - Hemochromatosis
  - Alcohol and marijuana
  - Vaccination for HAV, HBV
  - HIV



Thein H-H et al. *AIDS*. 2008;22:1979-1991.
Thein H-H et al. *Hepatology*. 2008;48:418-431.

50% Increase in HCV-Associated US Deaths From 1999 to 2007



- In 2007, 73% of HCV-related deaths occurred in persons aged 45 to 64 years[1,2]
  - Median age of death was 57 years, 20 fewer years than the average lifespan[2]

Ly KN, et al. *Ann Intern Med*. 2012;156(4):271-278. 2. Smith BD, et al. *MMWR Recomm Rep*. 2012;61(RR-4):1-32.

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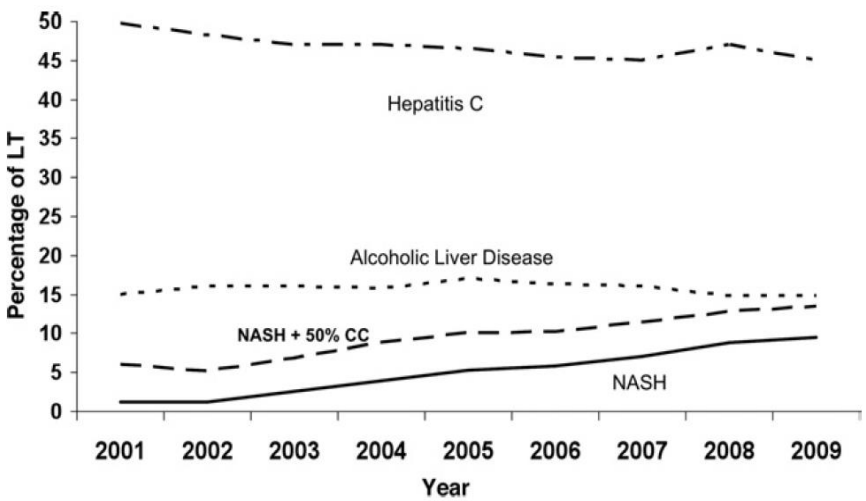
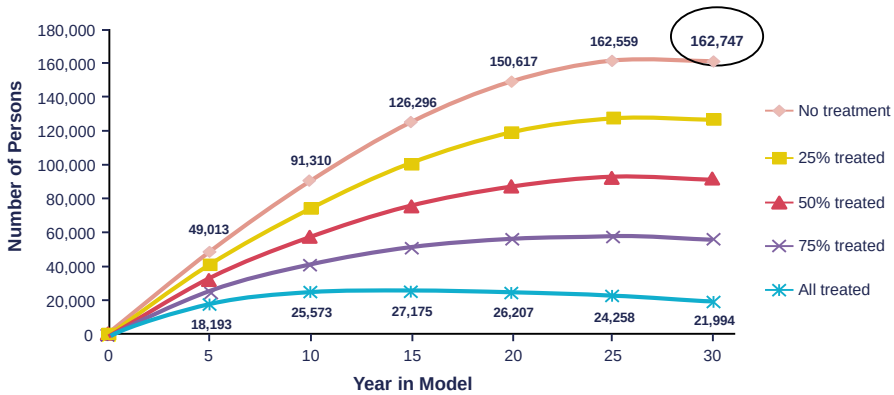
Indications For Liver Transplantation in the US



Gastroenterology 2011;141:1249-1253

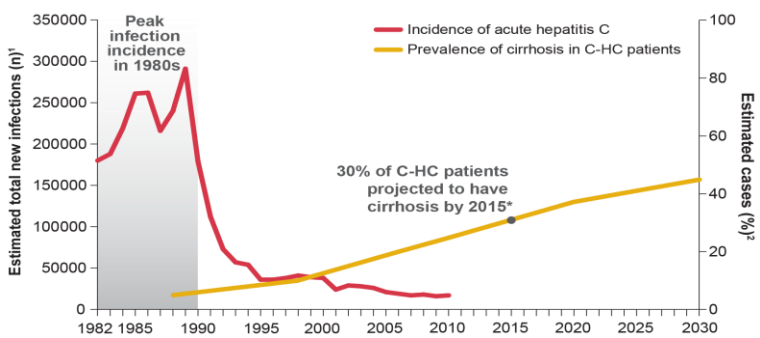
Liver Transplant Projection From 2013 to 2043

Potential Transplant Need: Treatment of all candidates and SVR of 90% will still require ≈22,000 transplants/year in 2033



Desai et al. AASLD 2013. Abstract 1427

Cirrhosis Is Projected to Increase in Patients Infected With HCV



- Individuals infected during the 1980s have already been living with HCV for ~25 to 30 years[1]
  - As a result, the increase in HCV-related cirrhosis is projected to continue[2]

1. Centers for Disease Control and Prevention. http://www.cdc.gov/hepatitis/HCV/StatisticsHCV.htm. Updated September 13, 2011. Accessed January 29, 2013. 2. Davis GL, et al. *Gastroenterology*. 2010;138(2):513-521.

Hepatitis C Summary

- Highest transmission rates:
  - Injection Drug Use
  - Sexual Contact
- Long disease process
- Modifiable characteristics
- There will be a drastic increase in cirrhosis in the next 40 years due to Hepatitis C

HCV treatment

Then:

Now:

Complexity of Treatment

- Shorter
- Oral only
- Fewer side effects
- 90-99% cure rate

AASLD/IDSA Treatment Recommendations

HCV Genotype	Recommended Treatment
HCV 1	**SOF/LDV (Harvoni) 8 -24 weeks** **OBV/PTV/r and DSV (Viekira) + RBV x 12-24 weeks** SOF + SMV ±RBV x 12 weeks
HCV 2	**SOF + RBV x 12-16 weeks**
HCV 3	**SOF + RBV x 24 weeks** SOF + PEG+ RBV x 12 weeks

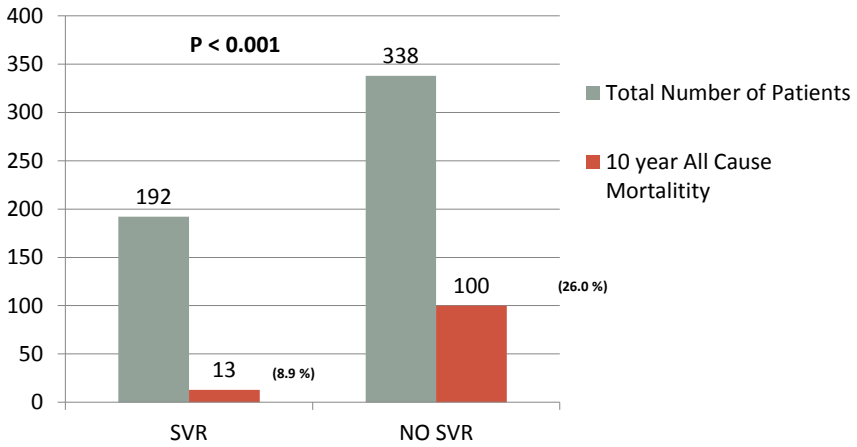
Initial therapy and duration likely to vary depending on presence of cirrhosis and if patient is treatment naïve or treatment experienced

Hepatitis C Antiviral Treatment

- **Sofosbuvir/ledipasvir**
  - Side Effects
    - Headache, myalgias, fatigue, insomnia, irritability
  - Medication Interactions
    - Seizure medication /Anti retroviral / St Johns wort etc.
- **Ribavirin**
    - Anemia, teratogenic, rash

Both treatments contraindicated with GFR < 30 ml/min

Association Between Sustained Virological Response and All-Cause Mortality Among Patients With Chromic Hepatitis C and Advanced Hepatic Fibrosis



Van der Meer, AJ JAMA. 2012;308(24):2584-2593

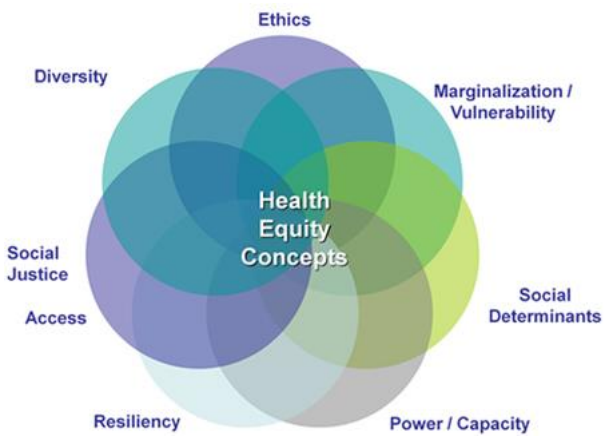
Cost of Drugs

Newest Drug - $94,000 for treatment or over $1000 a pill.

Treatment Summary

- New drugs are highly successful in curing Hepatitis C
- New drugs are incredibly expensive

Health Equity



Intersect of Hepatitis C and Public Health

- Health is a fundamental right of every human being.
- Public health must emphasize prevention and embrace collective, multifaceted action to respond to emerging challenges…; it must investigate disease determinants and risks, improve health care quality and delivery, and influence policy.

Core Functions of Public Health: "Public Health in America"

- **Core Functions of Public Health**
  - Assessment
  - Policy development
  - Assurance
- **Purpose of Public Health**
  - Prevent epidemics and spread of disease
  - Protect against environmental hazards
  - Prevent injuries
  - Promote and encourage healthy behaviors
  - Respond to disasters and assist communities in recovery
  - Assure the quality and accessibility of services

http://iom.edu/Reports/1988/The-Future-of-Public-Health.aspx
http://www.health.gov/phfunctions/public.htm

How do we respond?

- Monitor
- Find
- Educate
- Partner
- Policy development
- Link to Care
- TA
- Evaluate
- Research

PHCC - Monitoring Health to Identify and Solve Community Health Problems

- **Accurate, periodic assessment of the community's health status related to Hepatitis C**
  - Identification of health risks – Boomer, IDU, occupational risks
  - Attention to vital statistics and disparities
  - Identification of assets and resources – How can the state, Area and HQ assist?
- **Maintenance of population health registries**
  - State reporting for Hepatitis C
  - Local registries for Hepatitis C population management

Current Recommendations for HCV Screening

CDC recommends one-time HCV testing for all adults born during 1945-1965[1]

- All Vietnam Veterans (service between 1964 and 1975) should also be screened due to high HCV infection prevalence[2]

Routine HCV Testing Is Recommended for the Following Groups[1]				
HIV positive*	Ever injected illicit drugs, including just once/a few times many years ago	Select medical conditions: hemophilia with receipt of clotting factor concentrates before 1987, current or history of hemodialysis, persistently abnormal ALT	Received transfusion/organ transplant before July 1992 or received blood from a donor who later tested HCV-positive	Recognized exposure: health care workers exposed after needle-sticks, sharps or mucosal exposures to HCV-positive blood, children born to HCV-positive mothers

1. Smith BD, et al. *MMWR Recomm Rep*. 2012;61(RR-4):1-32.
2. 2. US Department of Veterans Affairs. http://www.hepatitis.va.gov/provider/guidelines/testing-prevention-counseling.asp. 2001. Updated January 2013. Accessed February 12, 2013.

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'ers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Re
nmendations and Reports / Vol. 61 / No. 4
August 17, 2

Rationale

May 2012
(Baby boomer screening)

- 45%-85% of infected persons are undiagnosed
- Limitations of current risk-based strategies
- 75% of chronic infections are in persons born from 1945-196

May 2013 (RNA testing)

- The objective of screening is to confirm chronic infection, engage in care and treat

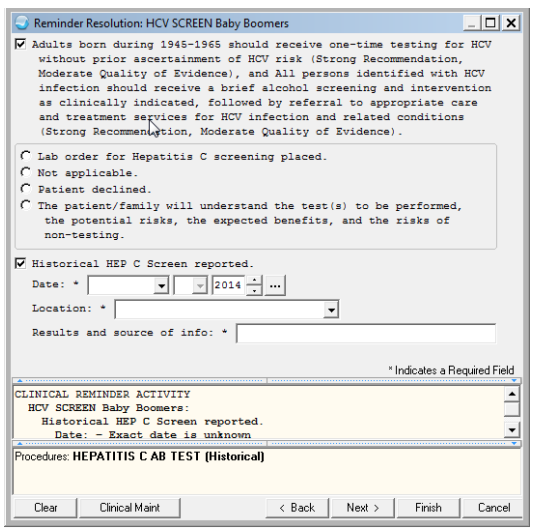
Recommendations for the Identification of Chronic Hepatitis C Virus Infection Among Persons Born During 1945–1965

PHCC - Diagnosing and Investigating Health Problems and Hazards in the Community

- **Timely identification and investigation of health threats**
- **Availability of diagnostic services, including laboratory capacity**
  - **What labs need to be ordered?**
  - **How are you staging liver fibrosis?**
- **Response plans to address major health threats**
  - **What is your clinic's response? Do you have policies and guidelines in place?**

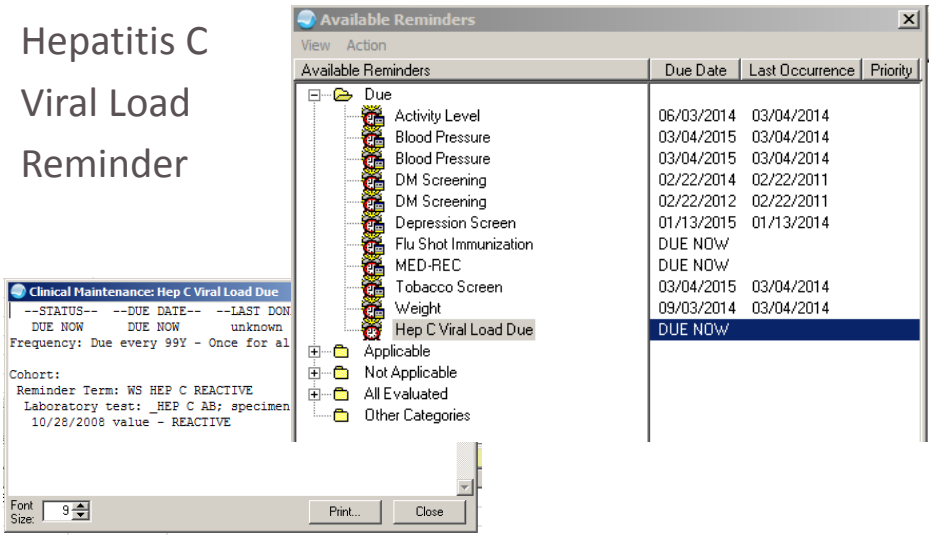
Screening and Test to Diagnose

- Utilize EHR and reminders



Confirm

Hepatitis C Viral Load Reminder



PHCC - Informing, Educating, and Empowering People About Health Issues

- **Initiatives using health education and communication sciences to**
  - Build knowledge and shape attitudes around screening and treatment for Hepatitis C
  - Inform decision-making choices for living with Hepatitis C or staying Hepatitis C negative
  - Develop skills and behaviors for healthy living with Hepatitis C
- **Media advocacy and social marketing**

PSA for Screening

Why should baby boomers get tested for Hepatitis C?

While anyone can get Hepatitis C, more than 75% of adults infected are baby boomers, people born from 1945 through 1965. Hepatitis C can be in your body for many years with no symptoms. Most people with Hepatitis C do not know they are infected.

- Baby boomers are five times more likely to have Hepatitis C.
- The longer people live with Hepatitis C, the more likely they are to develop serious, life-threatening liver disease.
- Getting tested can help people learn if they are infected and get them into lifesaving care and treatment.

It is recommended that anyone born from 1945 through 1965 get tested for Hepatitis C.

Why do baby boomers have such high rates of Hepatitis C?

The reason baby boomers have high rates of Hepatitis C is not completely understood. It is believed most boomers became infected in the 1970s and 1980s when rates of Hepatitis C were very high. Since people with Hepatitis C can live for decades without symptoms, many baby boomers are living with an infection they got many years ago.

Hepatitis C is mostly spread through contact with blood from an infected person. Many baby boomers could have been infected from contaminated blood and blood products before widespread screening of the blood supply began in 1992. Others may have become infected from injecting drugs, even if only once in the past. Still, many baby boomers with Hepatitis C do not know how or when they were infected.

What should baby boomers know about Hepatitis C?

Hepatitis C is a serious liver disease that results from infection with the Hepatitis C virus. Some people who get infected with Hepatitis C are able to get rid of the virus, but most people who get infected develop a lifelong infection. Over time, chronic Hepatitis C can cause serious health problems including liver damage, cirrhosis, liver cancer and even death. In fact, Hepatitis C is a leading cause of liver cancer and the leading cause of liver transplants.

People with Hepatitis C:
- Often have no symptoms
- Can live with an infection for decades without feeling sick
- Can usually be successfully treated with medications

How would someone know they have Hepatitis C?

The only way to know if someone has Hepatitis C is to get tested. Doctors use a blood test to find out if a person has ever been infected with Hepatitis C.

PHHC - Mobilizing Community Partnerships to Identify and Solve Health Problems

- Identification of system partners and stakeholders for referral or support services
- Coalition development
- Formal and informal partnerships to promote health improvement

PHCC - Developing Policies and Plans That Support Individual and Community Health Efforts

- **Policy development to protect health and guide public health practice**
- **Alignment of resources to assure successful planning**

IHS Best Practice: HCV program Step One

- Identify existing cohort of HCV+ patients
- Follow up with confirmation, genotyping, etc.
- Prioritize patients that cannot wait for treatment (e.g. cirrhosis)

IHS Best Practice: HCV Program Step 2

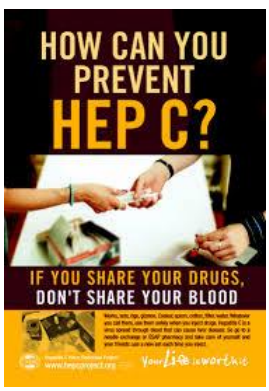
- Screen as per National Recommendations

IHS Best Practice: HCV program Step 3

- Case management, treatment
  - Navigating PAPs
  - Prioritize patients with cirrhosis, many being told to wait until the newest drug regimens approved

PHCC - Enforcing Laws and Regulations That Protect Health and Ensure Safety

- **Review, evaluation, and revision of legal authority, laws, and regulations**
- **Advocating for regulations needed to protect and promote health**
- **Support of compliance efforts and enforcement as needed**



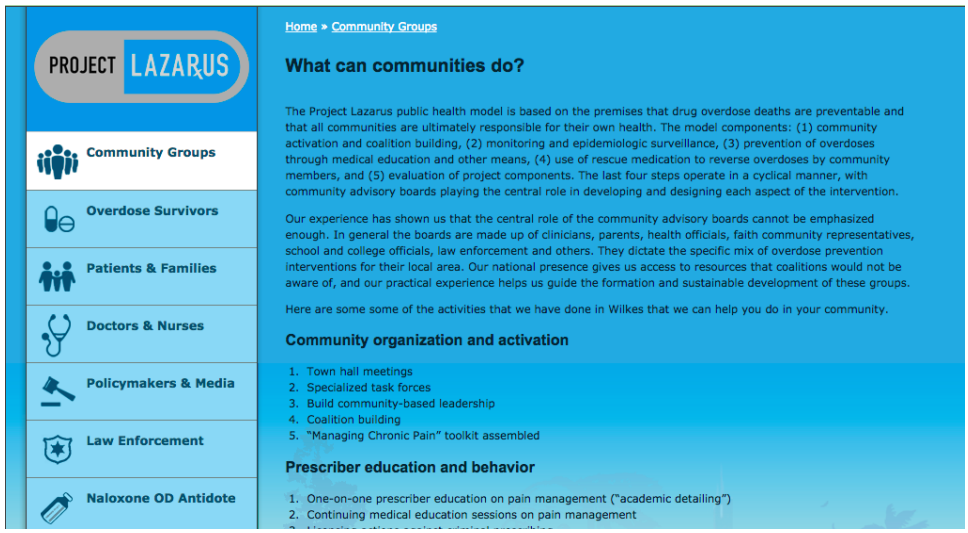
Harm Reduction

- For IDU use it may use the following steps
  - do not use illicit drugs
  - if you cannot stop using illicit drugs, do not inject
  - if cannot stop injecting, do not share equipment
  - if you cannot stop sharing equipment, clean/bleach between users
- Each of these steps requires giving education to target groups on how to fulfill each step, be it bleaching needles between use to continue to inject safely, all the way to where to find and enroll in rehab/recovery programs to quit drug use altogether

Holland Example

- drug abuse education/prevention campaign
- offered methadone programs
- offered information to IDUs how to smoke rather than inject heroin
- offered needle exchange
- offered bleach kits and education
- educated medical staff and law enforcement on harm reduction theory and outcomes such as reduced deaths from overdose, reduced transmission of disease

- Also offered 'welcome environment' e.g. drug users would access system without fear for dental issues, abscesses/infections. During medical visit, IDU might be engaged on risk behavior. Medical staff aware and supportive of treating IDU related morbidities. Law enforcement on board and supportive of programs (e.g. not watching who used the needle exchange program)



PHCC - Linking People to Needed Personal Health Services and Assuring the Provision of Health Care When Otherwise Unavailable

- Identification of populations with barriers to care – Elders without transportation, incarcerated individuals and PWID
- Effective entry into a coordinated system of clinical care
- Ongoing care management – how do you manage Hepatitis C positive patients?
- Culturally appropriate and targeted health information for at risk population groups
- Transportation and other enabling services

PHCC - Assuring a Competent Public and Personal Healthcare Workforce

- **Assessing the public health and personal health workforce**
  - Do staff know best practices for HCV treatment?
- **Continuing education and life-long learning**
  - Leadership development
  - Cultural competence

Original Article

Outcomes of Treatment for Hepatitis C Virus Infection by Primary Care Providers

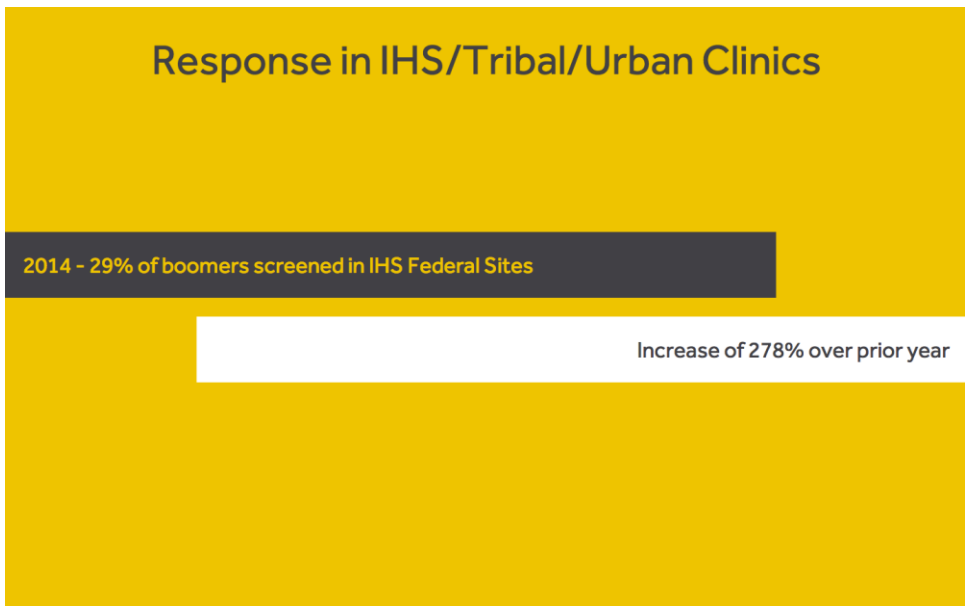
Sanjeev Arora, M.D., Karla Thornton, M.D., Glen Murata, M.D., Paulina Deming, Pharm.D., Summers Kalishman, Ph.D., Denise Dion, Ph.D., Brooke Parish, M.D., Thomas Burke, B.S., Wesley Pak, M.B.A., Jeffrey Dunkelberg, M.D., Martin Kistin, M.D., John Brown, M.A., Steven Jenkusky, M.D., Miriam Komaromy, M.D., and Clifford Qualls, Ph.D.

N Engl J Med
Volume 364(23):2199-2207
June 9, 2011

The NEW ENGLAND JOURNAL of MEDICINE

PHCC - Evaluating Effectiveness, Accessibility, and Quality of Personal and Population-Based Health Services

- **Evaluation must be ongoing and should examine:**
  - Personal health services
  - Population based services
  - The public health system
- **Quality Improvement**
- **Performance Management**



PHCC - Researching for New Insights and Innovative Solutions to Health Problems

- Identification and monitoring of innovative solutions and research to advance public health
- Linkages between public health practice and academic/research settings
- Epidemiological studies, health policy analyses and public health systems research

Who Should You Target for Treatment?

- If your goal is to prevent or mitigate the burden of liver disease and extra hepatic manifestations ***you should target the baby boomers***
- If your goal is to control or eliminate HCV ***you should target the young PWID*** *(HCV Treatment as Prevention)*

Can antiviral therapy for hepatitis C reduce the prevalence of HCV among injecting drug user populations?

Number Needed to treat per 1000 PWID every year	% Reduction in prevalence in 10 years
5	15
10	31
20	62
40	72

Considering a baseline HCV prevalence of 20 %

Martin NK et al. J Hepatol 2011; 54:1137–44.

Modelling Indicates If Elimination May Be Feasible

Parameter	Edinburgh	Melbourne	Vancouver
HCV chronic prevalence PWID	25%	50%	65%
PWID population size	4.240	25,000	13,500
Baseline treatment rate per 1000 PWID	8	1	3
Prevalence Reduction if treatment is scaled up to 40 PWID per year	95 %	54 %	22 %

Gore: CROI 2015
Martin N et al Hepatology 2013:581598-1609

HCV Target Populations for Screening as Prevention

- People who inject drugs
  - People on opioid substitution treatment
  - People in rehab centers
  - People in needle exchange programs
- Prisoners
- HIV-infected men who have sex with men
- Antenatal

Adapted from Gore: CROI 2015598-1609

Summary

- HCV is a major cause of morbidity in the USA
  - It is the main cause of liver transplantation
- The principal mode of transmission is IDU
- Although the HCV has been declining since the 1990's there appears to be an increase in the last few years
- An estimated 5.2 million persons are seropositive
  - Of these 4.1 million have a chronic liver Infection
  - 75 % were born between 1945-1965
  - Around 50 % do not know they are infected.
- Screening, engagement and care and treatment is needed
- There are mulitple best practices to learn from
- A public health response is necessary

Recommended Action

1. **Monitor health status** Based on epidemiology, HCV and IDU is an issue of importance in Indian Country. We need to ensure proper reporting.
2. **Diagnose and investigate** We need to screen and manage patients with HCV and at risk for HCV.
3. **Inform, educate, and empower** Develop a communication plan for Hepatitis C at the community level.
4. **Mobilize community partnerships** How can we partner with local and national organizations?
5. **Develop policies and plans** Are there local policies on Hepatitis C screening and treatment? Are there plans on how to ensure access to treatment?

The 10 Essential Public Health Services- include HCV examples below

1. **Enforce laws and regulations** Needle exchange for prevention? Access to medications?
2. **Link people to needed personal health services** Is everyone with Hepatitis C being managed? If it is impossible locally, are they being referred?
3. **Assure a competent workforce** What trainings are needed?
4. **Evaluate** You can access your own data to monitor!
5. **Research** for new insights and innovative solutions to health problems regarding Hepatitis C. What about treating PWID as prevention?

> Human rights and health equity are not simply vague principles – they are guiding operational definitions for healthcare institutions, businesses and governments to build a system of equity.

Thank you

For More Information in Public Health Services from CDC

- 10 Essential Public Health Services and the Public Health in America Statement
  www.health.gov/phfunctions/public.htm
- Mobilizing for Action through Planning and Partnerships
  www.naccho.org/topics/infrastructure/mapp/index.cfm
- National Public Health Performance Standards
  www.cdc.gov/nphpsp
- Public Health Accreditation Board
  www.phaboard.org

Important Resources

- http://www.hcvguidelines.org/
- http://www.hep-druginteractions.org/
- http://www.hepatitisc.uw.edu/
  - On-line curriculum on liver disease and HCV, includes clinical studies, clinical calculators, slide lectures