

Viral Hepatitis in the Commonwealth

Joint Commission on Health Care
September 16, 2014 Meeting

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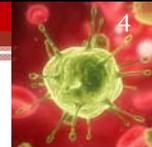
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Study Mandate

- During the 2014 General Assembly Session, House Joint Resolution 68 (Delegate Hodges and Delegate O'Bannon) directed the Joint Commission on Health Care to conduct a two year study of viral hepatitis in the Commonwealth
 - Identify resources for, and factors limiting, testing, treatment and prevention
 - Identify opportunities for integration of viral hepatitis treatment within new or existing HIV treatment programs

Background

Viral Hepatitis



- Is inflammation of the liver caused by a virus
- Between 3.2 and 5.3 million Americans are believed to be living with viral hepatitis, and *up to 75 percent do not know they are infected*
 - Hepatitis is the leading infectious cause of death among Americans, claiming 12,000-18,000 lives per year
 - In 2007, annual deaths in the U.S. due to viral hepatitis outpaced deaths due to HIV for the first time
- A, B, C, D and E refer to different viruses
 - Hepatitis A (HAV), hepatitis B (HBV) and hepatitis C (HCV) are the most common in the U.S.
 - Hepatitis B,C and D can cause chronic hepatitis which can lead to cirrhosis, liver failure and liver cancer
 - Chronic viral hepatitis is the most common cause of liver cancer and liver transplants in the U.S.

	Hepatitis A	Hepatitis B	Hepatitis C ⁵
Estimated Prevalence	17,000 new infections per year	•18,800 new infections per year •1.2 million chronic infections	•20,000 new infections per year •3.0-5.2 million chronic infections
Is there a vaccine?	Yes (FDA approval in 1995)	Yes (FDA approval in 1981)	No (In development)
Routes of Transmission	Ingestion of infected food, water or other fecal contaminated objects	When infected blood or other body fluid enters the body	When infected blood enters the body
Likelihood of Symptomatic Acute Infection (within infected population)	<ul style="list-style-type: none"> • <10% of children less than 6 years of age • 40%-50% of children 6-14 years of age • 70%-80% of persons >14 years of age 	<ul style="list-style-type: none"> • <1% infants • 5%-15% of children 1-5 years of age • 30%-50% of persons >5 years of age 	20%-30% of all newly infected persons
Can it become a chronic infection? (within infected population)	No	Yes <ul style="list-style-type: none"> • >90% of infants • 25%-50% of children aged 1-5 yrs • 6-10% of older children and adults 	Yes 75%-85% of infected

	Hepatitis A	Hepatitis B	Hepatitis C ⁶
Persons at Risk	<ul style="list-style-type: none"> •Travelers to, and immigrants from, regions of medium to high HAV infection •Household members, caregivers, and sex partners of infected persons •Persons with clotting factor disorders •Users of certain illegal drugs 	<ul style="list-style-type: none"> •Infants born to infected mothers •Household members of infected persons •Sex partners of infected persons and persons with multiple sex partners •Injection drug users •Persons with a STD •Health care and public safety workers at risk of percutaneous blood exposure •Hemodialysis patients •Residents and staff of facilities for developmentally disabled •Travelers to, and immigrants from, regions of medium to high HBV infection 	<ul style="list-style-type: none"> •Current or former injection drug users •Recipients of clotting factor concentrates before 1987 •Recipients of blood transfusions or donated organs before July 1992 •Long-term hemodialysis patients •Health care and public safety workers at risk of percutaneous blood exposure •HIV infected persons •Infants born to infected mothers

7

Viral Hepatitis B (HBV)

- Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC) vaccination recommendations:
 - All infants at birth (1st dose), 1-2 months of age (2nd dose) and 6-18 months (3rd dose)
 - All children not previously vaccinated
 - At-risk adults
 - Including adults with diabetes mellitus 19-59 years of age
 - Anyone else seeking long term protection
- Acute hepatitis, especially in older children and adults, often resolves on its own
- Severe acute HBV and chronic HBV can be treated with anti-virals which slow the replication of the virus and boost the immune system

8

Viral Hepatitis B (HBV)

- Mother-to-child transmission of HBV
 - 90 percent of HBV infected newborns will develop chronic infection and remain infected throughout their lives
 - Up to 25% of these children will die of cirrhosis, liver failure or liver cancer later in life
 - Standard of care for pregnant women now includes HBV testing during pregnancy since interventions are available to prevent transmission to the infant during birth

9

Viral Hepatitis C (HCV)

Progression of Hepatitis C

For Every 100
People Infected with the Hepatitis C Virus

75-85
Will Develop Chronic Infection

60-70
Will Develop Chronic Liver Disease

5-20
Will Develop Cirrhosis

1-5
Will Die of Cirrhosis or Liver Cancer

OVER TIME

- The CDC (August 2012) and the USPSTF (June 2013) issued the following recommendations on HCV screening in adults who have no signs or symptoms of HCV infection and who have not been diagnosed with liver disease or liver function problems
 - Adults at high risk for hepatitis C infection should be screened
 - Health care professionals should offer 1-time HCV screening to adults born between 1945 and 1965

ANYONE BORN
1945 - 1965

CDC – Centers for Disease Control and Prevention
USPSTF – U.S. Preventive Services Task Force

10

Viral Hepatitis C (HCV)

- HCV and HIV co-infection
 - People living with HIV are at a greater risk of acquiring HCV
 - 25% of individuals with HIV are also infected with HCV
 - Liver disease can progress more rapidly in individuals co-infected
- In 2011, there was a 45% increase in the number of reported cases of new HCV infection due to predominately white and young adults with a history of injection drug use and prescription opiates, mostly in rural areas

Viral Hepatitis C (HCV)

- Prior to 2013, HCV was treated with interferon-based anti-viral regimes with long treatment durations (up to one year), significant side effects, complicated dosing schedules and modest cure rates
- In 2013, Sovaldi (sofosbuvir) and Olysio (simeprevir) were approved by the FDA as part of a combination anti-viral treatment regimen for HCV infection
 - These drugs must still be taken with at least one of the traditionally used anti-virals that can cause significant side effects
 - Both Sovaldi and Olysio based treatment regimens offer significantly higher cure rates than traditional regimens; however, there is some debate regarding the accuracy and range of the cure rates

Viral Hepatitis C (HCV)

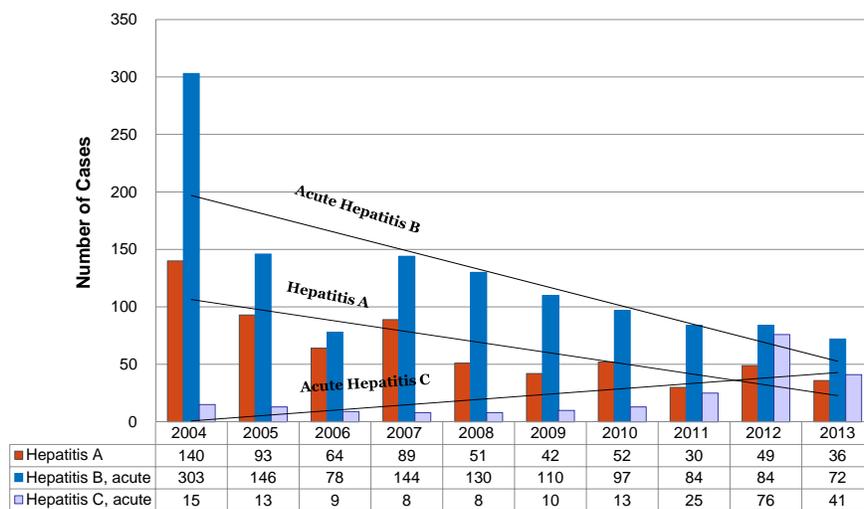
- Treatment costs with Sovaldi and Olysio
 - Sovaldi: \$84,000 for 12 week supply
 - Olysio: \$66,360 for a 12 week supply
 - Example cost of a complete 12 week treatment regimen:
 - Sovaldi + PEG interferon + ribavirin = \$116,910*
 - Example cost of a complete 24 week treatment regimen with “older generation” anti-virals:
 - telaprevir + PEG interferon + ribavirin = \$111,606*
- New HCV medications are expected within the next year that will have high cure rates and easy dosing schedules, and some will not require the use of co-medications that cause significant side effects

*Source: <http://jama.jamanetwork.com/article.aspx?articleid=1890401>

Incidence of Viral Hepatitis in the Commonwealth

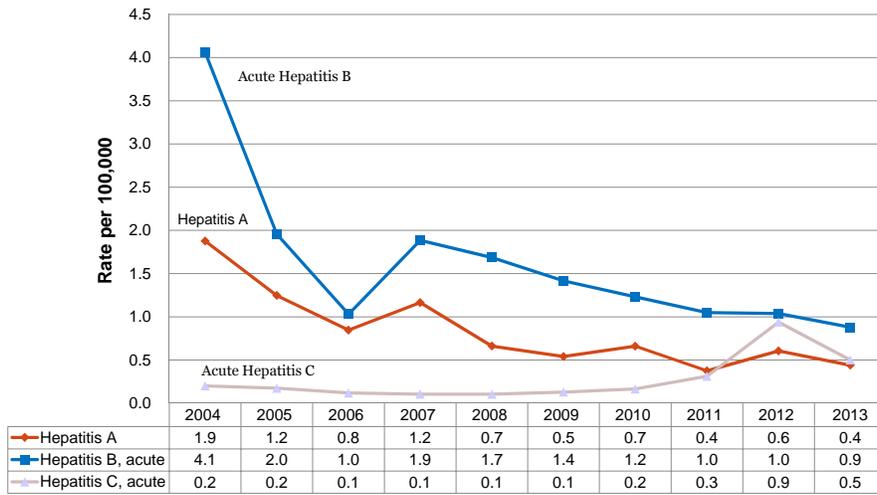
Source: Virginia Department of Health, Division of Surveillance and Investigation
 Contact Diane Woolard or Rebecca Early

Ten-Year Trend in Number of Reported Cases of Hepatitis A and Acute Hepatitis B and C, Virginia, 2004-2013



Sources: Reportable Diseases in Virginia, VDH.

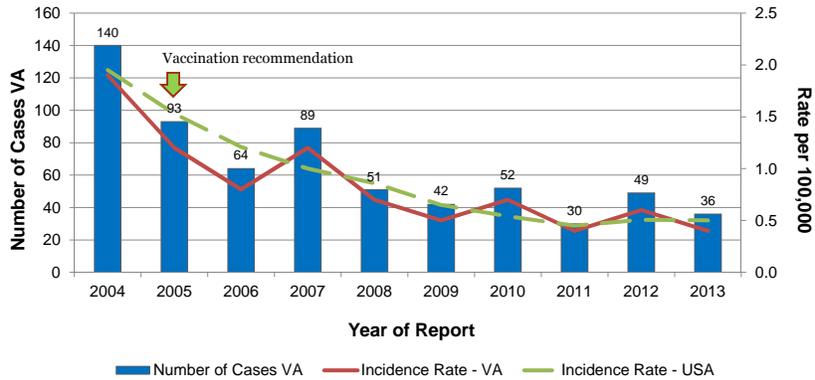
Ten-Year Trend in Incidence of Reported Cases of Hepatitis A and Acute Hepatitis B and C, Virginia, 2004-2013



Sources: Reportable Diseases in Virginia, VDH.

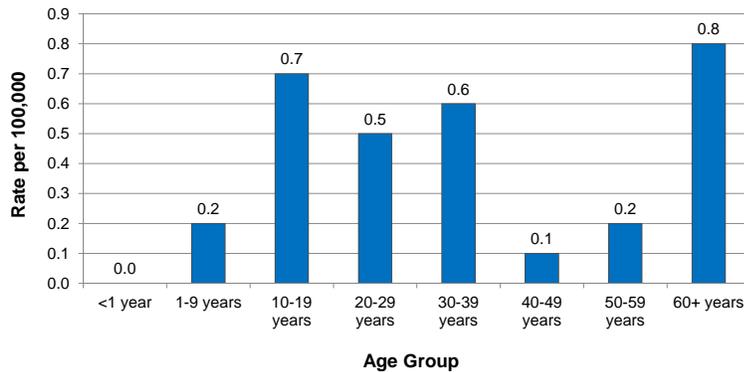
Hepatitis A

Hepatitis A: Ten-Year Trend in Number of Cases and Incidence, Virginia, 2004-2013



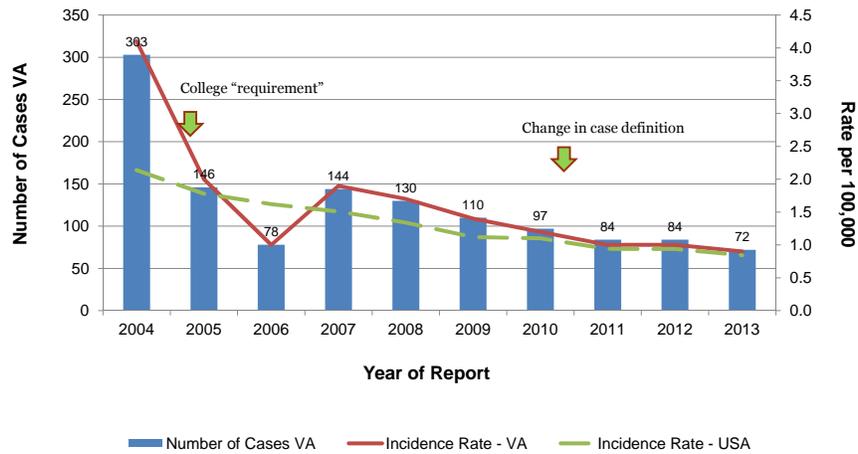
*Note: USA incidence rates for 2012 and 2013 are provisional. Sources: Tables of Selected Reportable Diseases in Virginia, VDH and MMWR Summary of Notifiable Diseases.

Hepatitis A: Incidence Rate by Age Group, Virginia, 2013



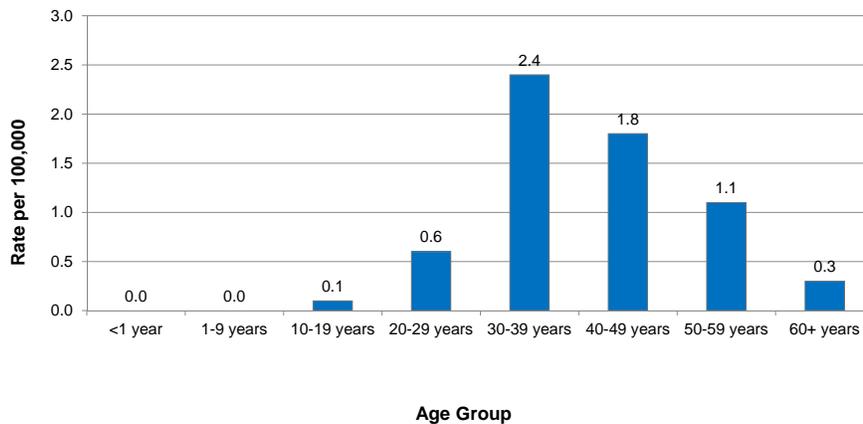
Sources: Reportable Diseases in Virginia, VDH.

Acute Hepatitis B: Ten-Year Trend in Number of Cases and Incidence Rate, Virginia, 2004-2013



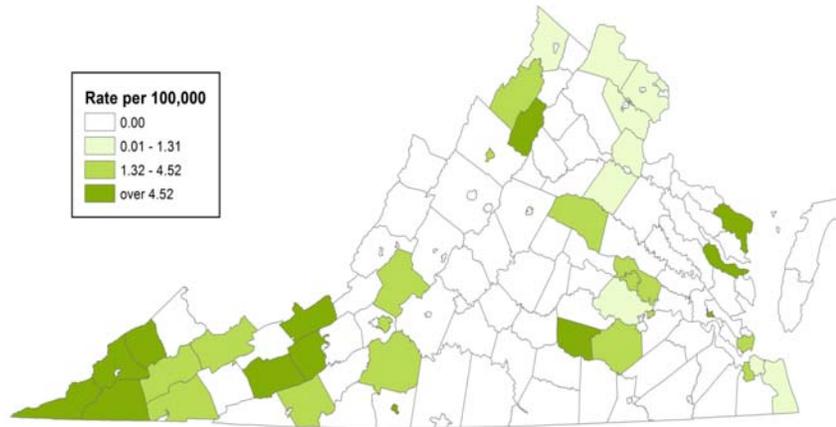
*Note: USA incidence rates for 2012 and 2013 are provisional. Sources: Tables of Selected Reportable Diseases in Virginia, VDH and MMWR Summary of Notifiable Diseases.

Acute Hepatitis B: Incidence Rate by Age Group, Virginia, 2013



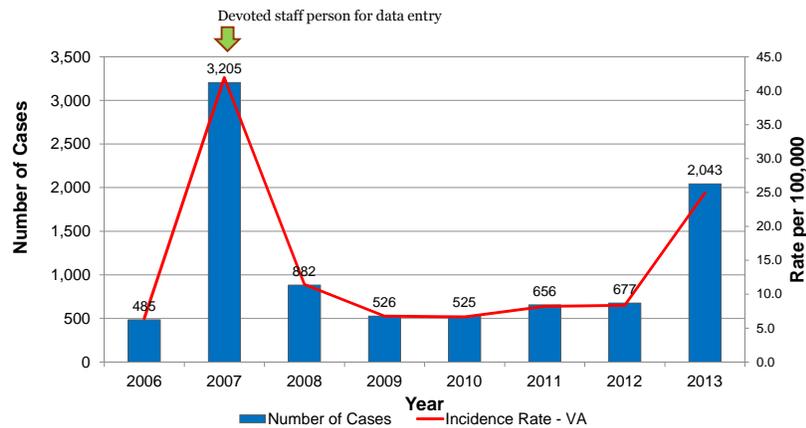
Sources: Reportable Diseases in Virginia, VDH.

Acute Hepatitis B: Incidence Rate by Locality, Virginia, 2013



Sources: Reportable Diseases in Virginia, VDH.

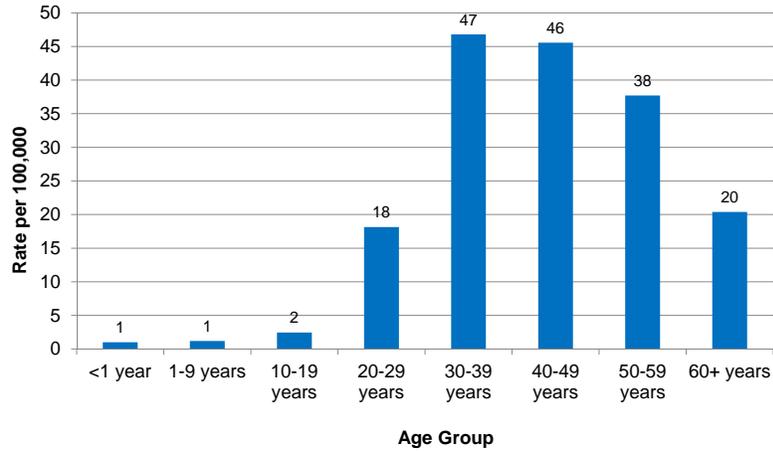
Chronic Hepatitis B (Newly-Reported to VDH or Diagnosed), Virginia, 2006-2013



*Note that data are undergoing quality review and are not representative. Please interpret with caution. 2013 data are not finalized.

Sources: Reportable Diseases in Virginia, VDH.

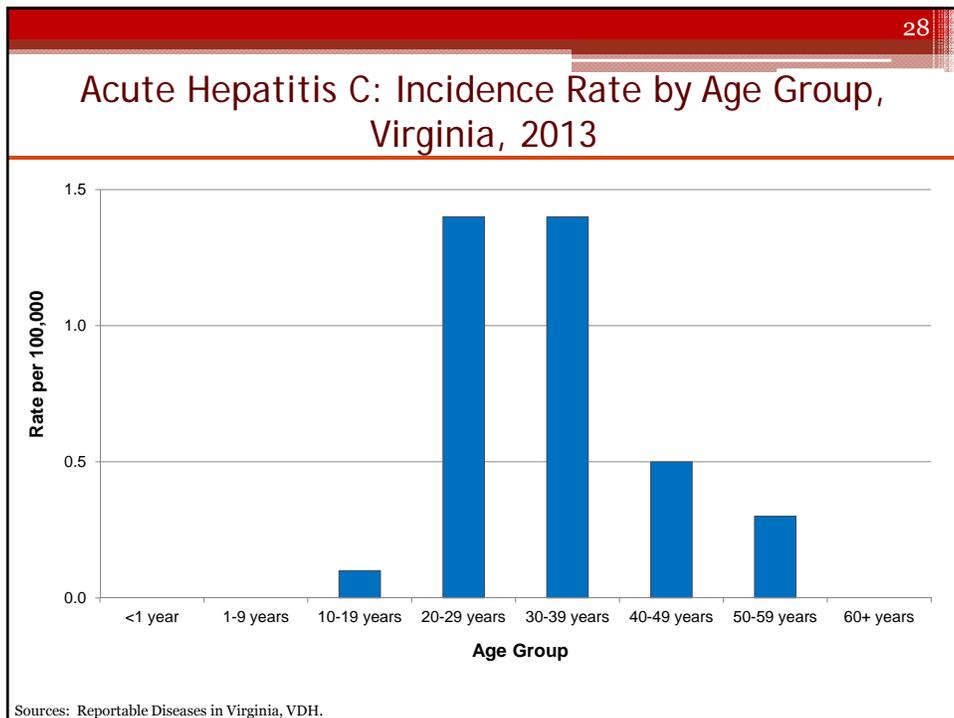
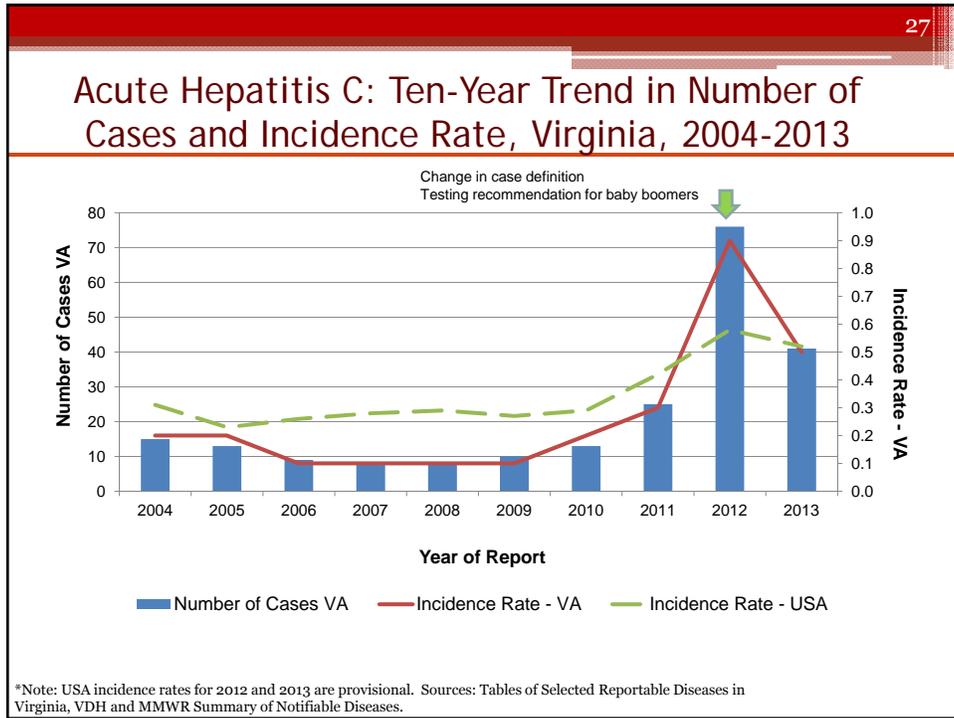
Chronic Hepatitis B: Incidence Rate by Age Group, Virginia, 2013



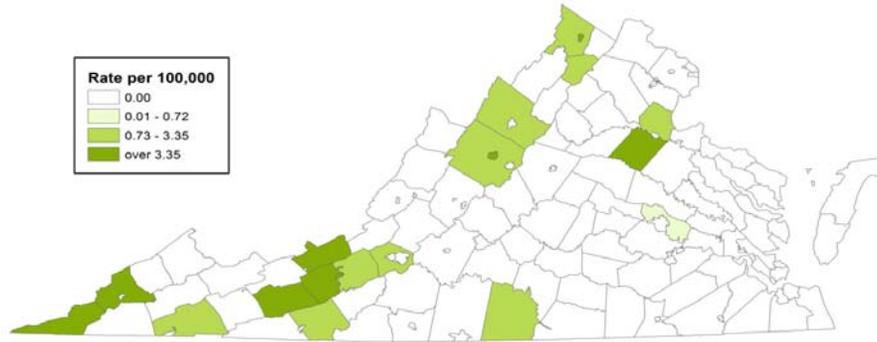
*Note that data are undergoing quality review and are not representative. Please interpret with caution. 2013 data are not finalized.

Sources: Reportable Diseases in Virginia, VDH.

Hepatitis C

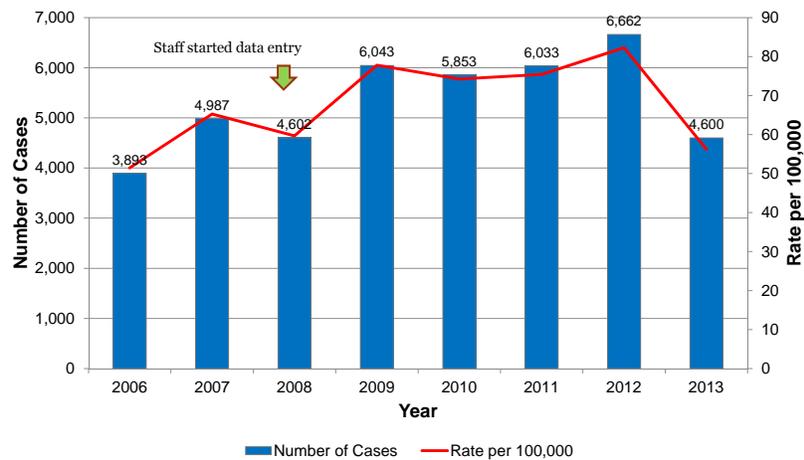


Acute Hepatitis C: Incidence Rate by Locality, Virginia, 2013



Sources: Reportable Diseases in Virginia, VDH.

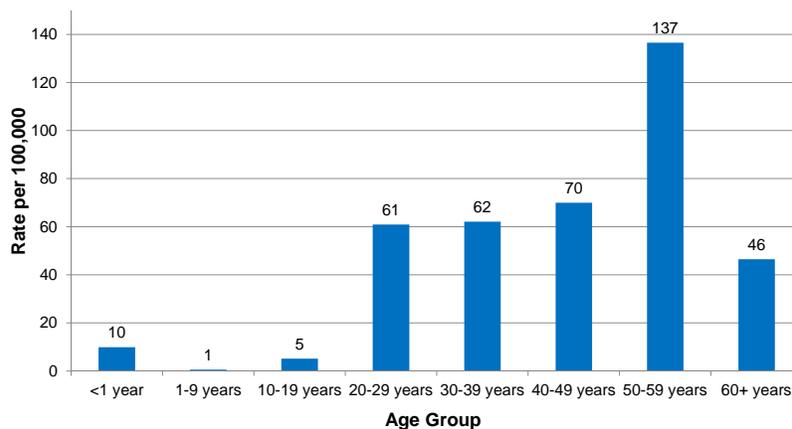
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Chronic Hepatitis C: Incidence Rate by Age Group, Virginia, 2013

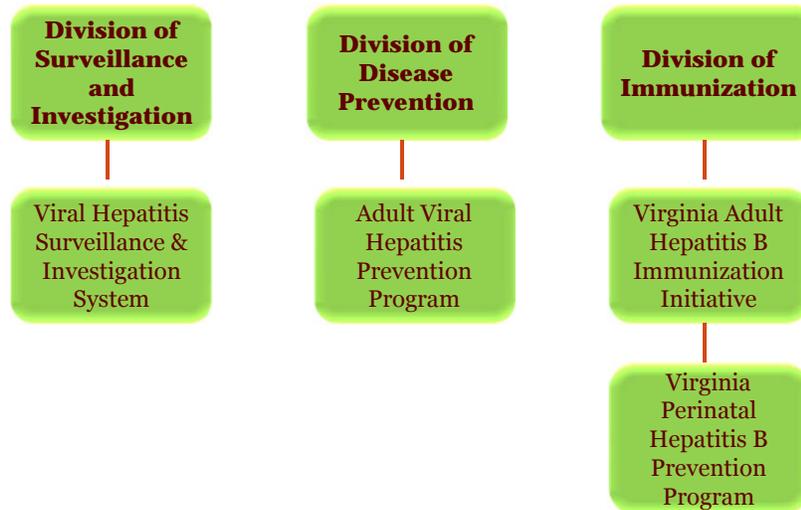


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Sources: Reportable Diseases in Virginia, VDH.

Virginia Department of Health Viral Hepatitis Programs

VDH State Hepatitis Control Programs



Virginia Perinatal Hepatitis B Prevention Program

- The Program is a collaborative effort between the VDH, local health departments, private providers and hospitals to identify hepatitis B positive pregnant women, their household contacts, needle-sharing partners, sexual partners, and infants
- Once identified disease intervention activities are initiated to test and vaccinate the contacts and partners and to vaccinate and test the infants

35

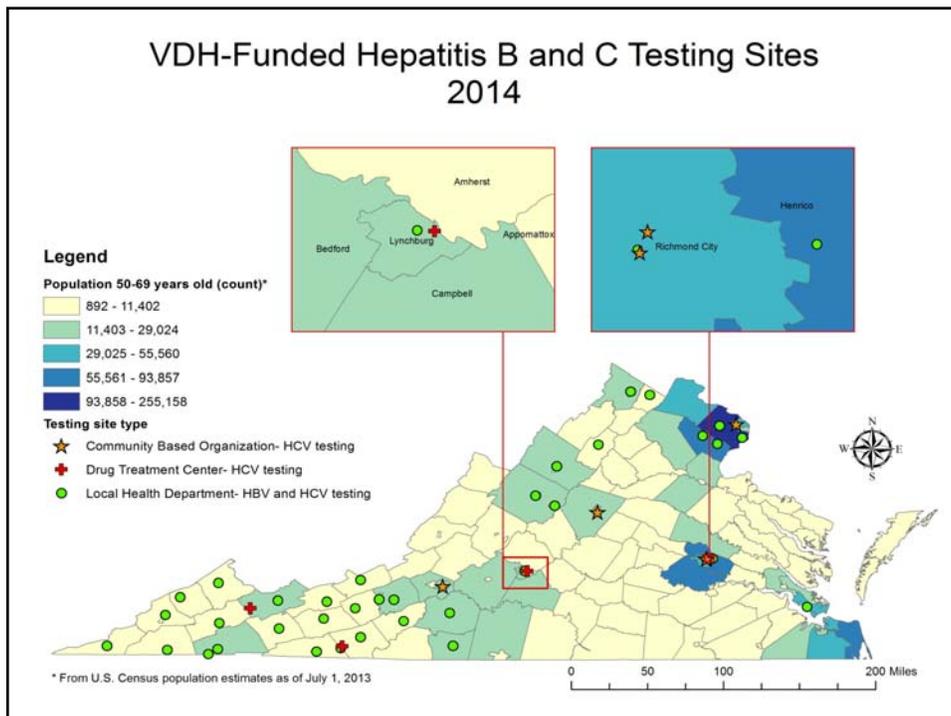
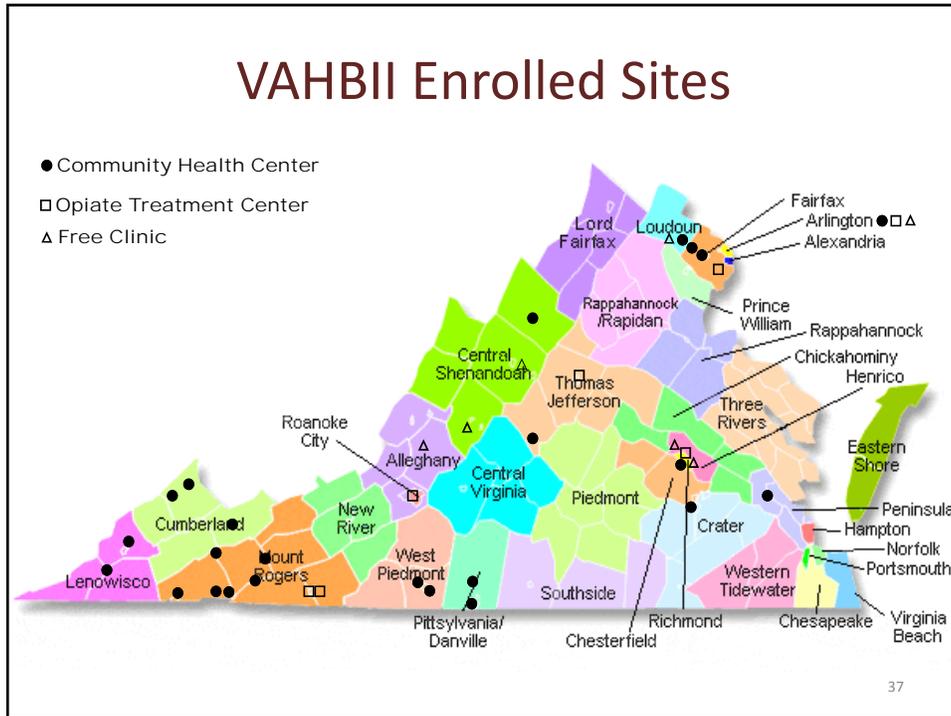
Adult Viral Hepatitis Prevention Program

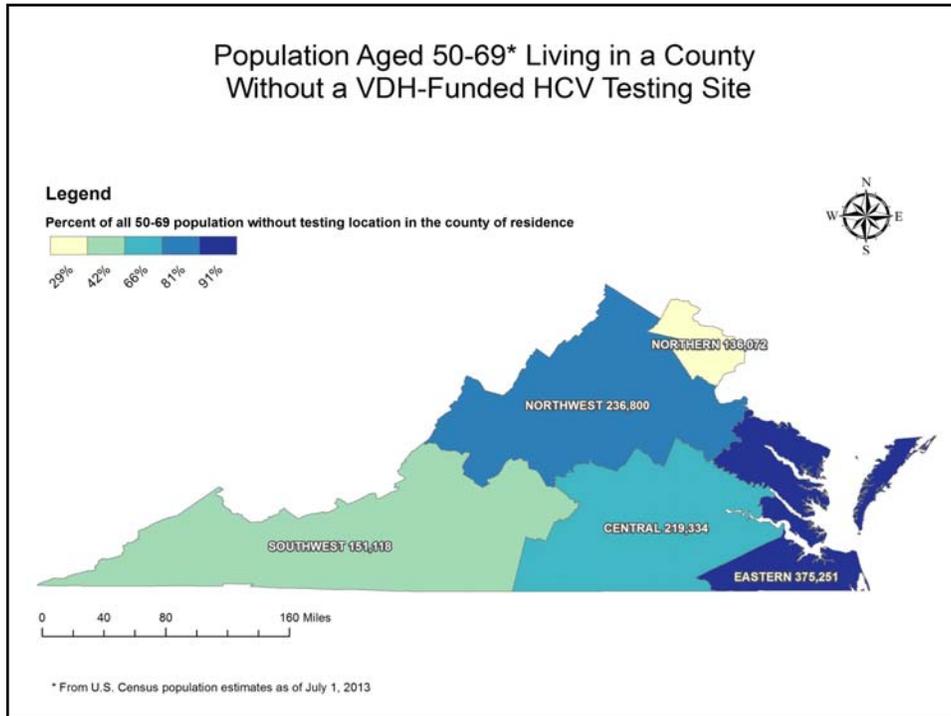
- The program provides education and prevention programs to lessen the public health burden of all types of viral hepatitis throughout the Commonwealth of Virginia
- Specifically, the program provides:
 - HBV vaccines in all VDH STD clinic sites for at risk persons
 - HCV testing program in limited and designated STD clinic sites for at risk persons
 - Answers to the public regarding all types of viral hepatitis
 - Technical support to state and local health agencies, and assistance to researchers and grant writers
 - Viral hepatitis trainings to physicians and nurses in public or private practice throughout Virginia
 - Collaboration with state and federal agencies

36

Virginia Adult Hepatitis B Immunization Initiative (VAHBII)

- The program is a collaborative effort between VDH, local health departments and community partners to identify high-risk adults and provide free HBV vaccines





40

Factors Limiting the Prevention & Care of Viral Hepatitis in Virginia

41

Limitations of Surveillance System

- VDH surveillance data is used to track the incidence of infection and guide development and evaluation of programs and policies designed to prevent infection and minimize the public health impact of viral hepatitis
- However, VDH receives no federal or State funding for viral hepatitis surveillance and investigation activities
- As a result, there is insufficient surveillance at the local and State levels
 - Many cases of hepatitis go undiagnosed and many go unreported, leading to an underestimate of the true burden of disease

42

Limitations of Surveillance System

- The agency has limited resources for investigation of reports, for data entry and for quality assurance on entered reports/cases
 - Many reports received by the agency lack information on linkage to care, risk data, and demographic information
 - Inability to investigate and document reports results in undercounting of cases and, in general, poor data quality
 - Due to a lack of funding for data entry for all viral hepatitis reports, HIV hotline staff do the data entry between calls

Lack of Dedicated Funding Streams for Hepatitis C Testing

- VDH's strongest defined role in the prevention of viral hepatitis is in testing; however, the agency does not have a stable source of funding for HCV testing
 - State departments receive no categorical federal funding to support HCV testing
 - VDH, like most state health departments, do not have enough funding to adequately respond to HCV testing needs
 - Much of the leveraged funding is not available from year to year and is pulled from other program areas
 - Approximately \$86,000 of HIV prevention funds are used for HCV testing
 - The only HCV testing-specific funds are from a limited grant of \$240,000 for testing and care linkage for injection drug users which ends March 31, 2015
 - This funding cannot be used for HCV testing of persons in other populations

Virginia Response to New National Screening and Treatment Guidelines for Hepatitis C

New National Screening Guidelines for HCV

- As mentioned previously, the CDC and the USPSTF issued the recommendation that adults at high risk for hepatitis C infection should be screened and health care professionals should offer 1-time HCV screening to adults born between 1945 and 1965

New National Treatment Guidelines for HCV

- The American Association for the Study of Liver Disease (AASLD) and the Infectious Disease Society of America (IDSA) HCV treatment recommendations:
 - Treatment is assigned the highest priority for those patients with advanced fibrosis (Metavir F3), those with compensated cirrhosis (Metavir F4), liver transplant recipients, and patients with severe extrahepatic hepatitis C
 - Most providers are following these recommendations and advising patients that do not have advanced fibrosis to continue monitoring and postpone treatment
 - Due to the side effects of current medications and the expectation of improved treatment options in the near future

Medicaid

HCV Screening

- The ACA incentivizes state Medicaid programs to cover all USPSTF A and B graded services (including HCV screening for at-risk persons and baby-boomers) by offering a 1 percent increase in federal matching payments for coverage of these preventive services
 - At this time, DMAS has chosen not to apply for the increased match due to the additional cost of providing all USPSTF A and B preventive services
 - However, it is believed that most health plans are encouraging providers to follow the HCV screening guidelines, but there is insufficient data regarding how well these recommendations are being followed
- Over the past 10 years, 67,525 recipients have been screened for HCV
 - 27,207 (40.3%) tested positive for HCV
 - 1,488 (5.7%) of those diagnosed received treatment

Medicaid

HCV Screening

- Over the last 10 years, 352,024 Medicaid recipients were identified as at-risk (pregnant women, persons with multiple sex partners, receivers of blood transfusion or donated organs, and organ donors)
 - 36,248 (10.3%) received HCV screening
- In 2013, the cost per HCV test was \$30, and 4,532 recipients were screened

HCV Treatment

- Sovaldi and Olysio are “non-preferred” drugs that require pre-authorization
 - A patient must be determined to have serious fibrosis or cirrhosis of the liver (Metavir score of F3 or greater) in order for their treatment to be covered by Medicaid

Treatment of HCV Within the Virginia Medicaid Population Since November, 2013*

	Number of Recipients	Percent of Recipients	Amount Per Recipient	Amount Paid**
Total Diagnosed 1,379				
Treated With Olysio	13	1%	\$10,244	\$132,918
Treated With Sovaldi	108	8%	\$10,796	\$1,165,918
Other Treatment ***	143	10%	\$628	\$89,851
Total Amount Paid	****	****	****	\$1,388,687

*DMAS approved the use of Sovaldi and Olysio in November, 2013

** Payment refers to direct costs (i.e., fee-for-service) only; managed care costs are not included

*** 'Other Treatment' includes attendant drugs taken with either Sovaldi, Olysio or both

****Number of Recipients', 'Percent of Population' and 'Amount Per Recipient' columns should not be totaled

Source: Virginia Department of Medical Assistance Services (DMAS)

Safety Net Facilities

- HCV screening is offered in most, if not all, community health centers
 - Centers are screening persons in high risk categories
 - Uninsured persons who test positive are referred to VCU or UVA
 - Can take several weeks or months to get an appointment
 - Many patients live hours away and have transportation challenges
- Sovaldi and Olysio are included on The Pharmacy Connection (TPC) drug list
 - If ordered through the TPC, these medications can be received at no cost to the patient or clinic
 - Received through the pharmaceutical company's patient assistance program
 - To date, only one request (for Sovaldi) has been received from a community health center
 - No free clinics have requested these medications

Veterans in Virginia

- For the past 15 years, the VA has been screening veterans born between 1945-1965
- Any veteran testing positive for HCV can request treatment, including treatment regimen's with Sovaldi or Olysio
 - However, due to the potential side effects of treatment and the expectation that better HCV medications will soon be available, many patients are counseled to choose "watchful waiting"
- In 2013, 24 percent of VA hospital patients* with HCV received treatment

*Defined as veterans with at least one outpatient visit to a facility in 2013

Number and Percent of VA Hospital Patients* in 2013 Ever Screened for HCV by Cohort

Facility	# Born Before 1945	% (#) Ever Screened	# Born 1945-1965	% (#) Ever Screened	# Born After 1965	% (#) Ever Screened
Hampton	7,099	71.2% (5,058)	22,044	82% (18,071)	14,005	60.6% (8,491)
Richmond	12,863	57.1% (7,348)	25,395	75.4% (19,153)	9,559	66.3% (6,336)
Salem	13,140	48.3% (6,348)	17,282	71.2% (12,298)	5,263	73.1% (3,848)
Virginia	33,102	56.7% (18,754)	64,721	76.5% (49,522)	28,827	64.8% (18,675)

*Defined as veterans with at least one outpatient visit to a facility in 2013

If 100 percent of veterans in the 1945-1965 cohort are screened, approximately 699 additional cases of HCV would be found (based on an estimated prevalence rate of 4.6 percent)

Source: Veterans Administration's National Hepatitis C Clinical Case Registry

HCV Prevalence Among VA Hospital Patients* That Have Been Screened by Cohort, 2012

Facility	# Born Before 1945 with HCV Infection	Rate of HCV Infection	# Born 1945-1965 with HCV Infection	Rate of HCV Infection	# Born After 1965 with HCV Infection	Rate of HCV Infection
Nation	14,043	1.7%	160,534	9.9%	5,973	1.1%
Hampton	81	1.5%	1,613	9.7%	47	0.6%
Richmond	87	1.2%	1,923	10.7%	45	0.8%
Salem	37	0.6%	781	7.1%	67	2.1%
Virginia	205	1.1%	4,317	9.2%	159	1.2%

*Defined as veterans with at least one outpatient visit to a facility in 2013

Total number of veterans, with at least one outpatient visit to a Virginia facility in 2012, known to have HCV infection = 4,681

Source: Veterans Administration's National Hepatitis C Clinical Case Registry

Virginia Department of Corrections (DOC)

- There are no incidence or prevalence statistics for hepatitis A, B or C in Virginia's correctional population
 - Anecdotally, DOC physicians see more infections for hepatitis C than hepatitis A or B
- Currently the DOC does not screen offenders for HCV upon entry, but does plan to begin a policy of conducting a liver enzymes test for all new offenders
- In February of this year, DOC suspended treatment of hepatitis C while awaiting new HCV treatment guidelines from the Federal Bureau of Prisons
 - Guidelines were released in May, and DOC plans to resume treatment for hepatitis C, utilizing Sovaldi and Olysio, for offenders with serious fibrosis or cirrhosis of the liver

55

Virginia Department of Corrections

- For the last 10 years, DOC has been treating HCV infections within each institution's medical department
- However, the DOC currently is working on a MOA with VCU to provide HCV treatment to offenders via telemedicine
 - Offenders with serious side effects and/or complications would be transported to VCU
 - Estimated cost to treat 50 offenders per year would be \$3.2 million (\$64,000 per treatment)
 - Cost includes all medications in the regime, plus a VCU service fee

56

Private Health Plans

- The ACA requires individual and small group health plans to cover HCV screening for at-risk individuals and anyone born 1945-65, with no cost-sharing
- There is insufficient data on provider compliance with HCV screening recommendations
- Most plans are requiring pre-approval for HCV treatment with Sovaldi or Olysio
 - Patient must be determined to have serious fibrosis or cirrhosis of the liver (Metavir score of F3 or greater) in order for their treatment to be covered

Policy Options

Option 1: Take no action.

Option 2: Introduce a budget amendment (language and funding) for \$615,000 GFs for VDH to undertake viral hepatitis surveillance.

Option 3: Introduce a budget amendment (language and funding) for \$660,000 GFs for VDH to undertake strategic viral hepatitis interventions

- HCV testing of 11,000 people per year
- Public and clinician education to increase awareness of the importance of HCV testing among high-risk populations and baby-boomers
- Assistance with linkage to care for persons with HCV.

Policy Options

Option 4: Introduce a budget amendment (language and funding) for \$65,000 for VDH to increase funding for the Virginia HIV/AIDS Resource and Consultation Centers to provide information and training to HIV providers on HIV/HCV co-infection, including the addition of a consulting hepatologist.

Policy Options

Option 5: Request by letter of the JCHC Chair, that the Medical Society of Virginia encourage physicians to complete an online continuing medical education course on viral hepatitis such as the course offered by the Centers for Disease Control and Prevention.

- Free CME resources are available at:
<http://www.cdc.gov/hepatitis/Resources/Professionals/TrainingResources.htm>

Public Comments

- Written public comments on the proposed options may be submitted to JCHC by close of business on September 30, 2014. Comments may be submitted via:
 - E-mail: sreid@jhc.virginia.gov
 - Facsimile: 804-786-5538 or
 - Mail to: Joint Commission on Health Care
 P.O. Box 1322
 Richmond, Virginia 23218
- Comments will be summarized and presented during the JCHC meeting on October 8th

Internet Address

Visit the Joint Commission on Health Care
website:
<http://jchc.virginia.gov>



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