The Chronic Hepatitis Cohort Study ('CHeCS')

A Brief Overview

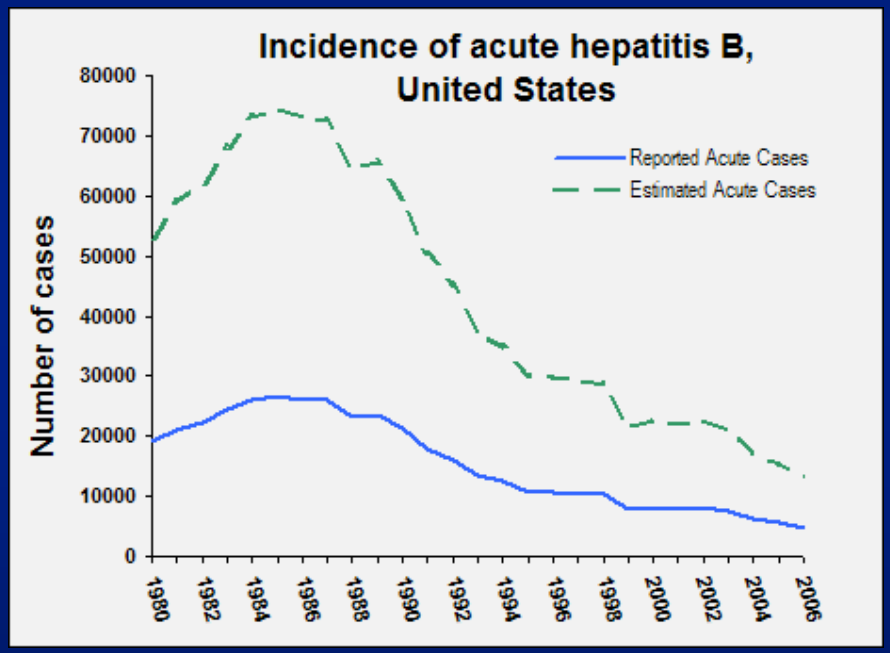
Scott D Holmberg, MD, MPH
Epidemiology and Surveillance Branch
Division of Viral Hepatitis, CDC
contact: sdh1@cdc.gov; or
Anne Moorman acm4@cdc.gov

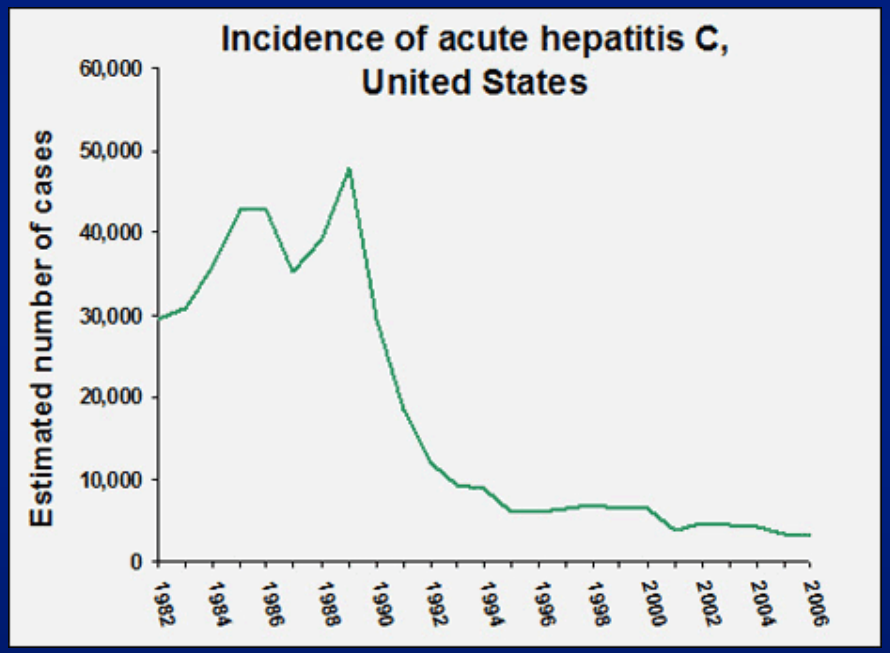
Division of Viral Hepatitis

CHeCS
Chronic Hepatitis Cohort Study

CDC

What are the major health and medical issues within the context of declining HBV and HCV incidence?





Division of Viral Hepatitis

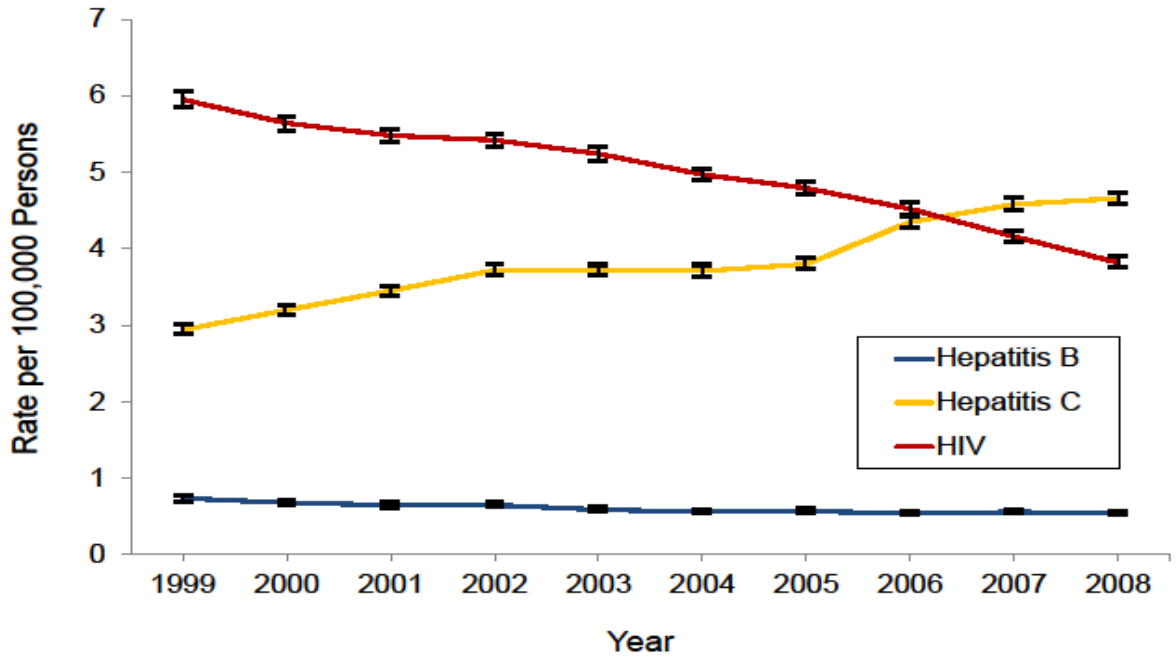
CDC

In contrast, increasing problem of chronic disease

- CDC estimates:
  - 3.2 million Americans with chronic HCV
  - ~1 million with chronic HBV
- Others estimate more.

From national mortality/death certificate data*, updated through 2008:

Figure. Annual age-adjusted rates of mortality and 95% confidence intervals of hepatitis B, hepatitis C, and HIV listed as a cause of death* in the United States, 1999 – 2008.



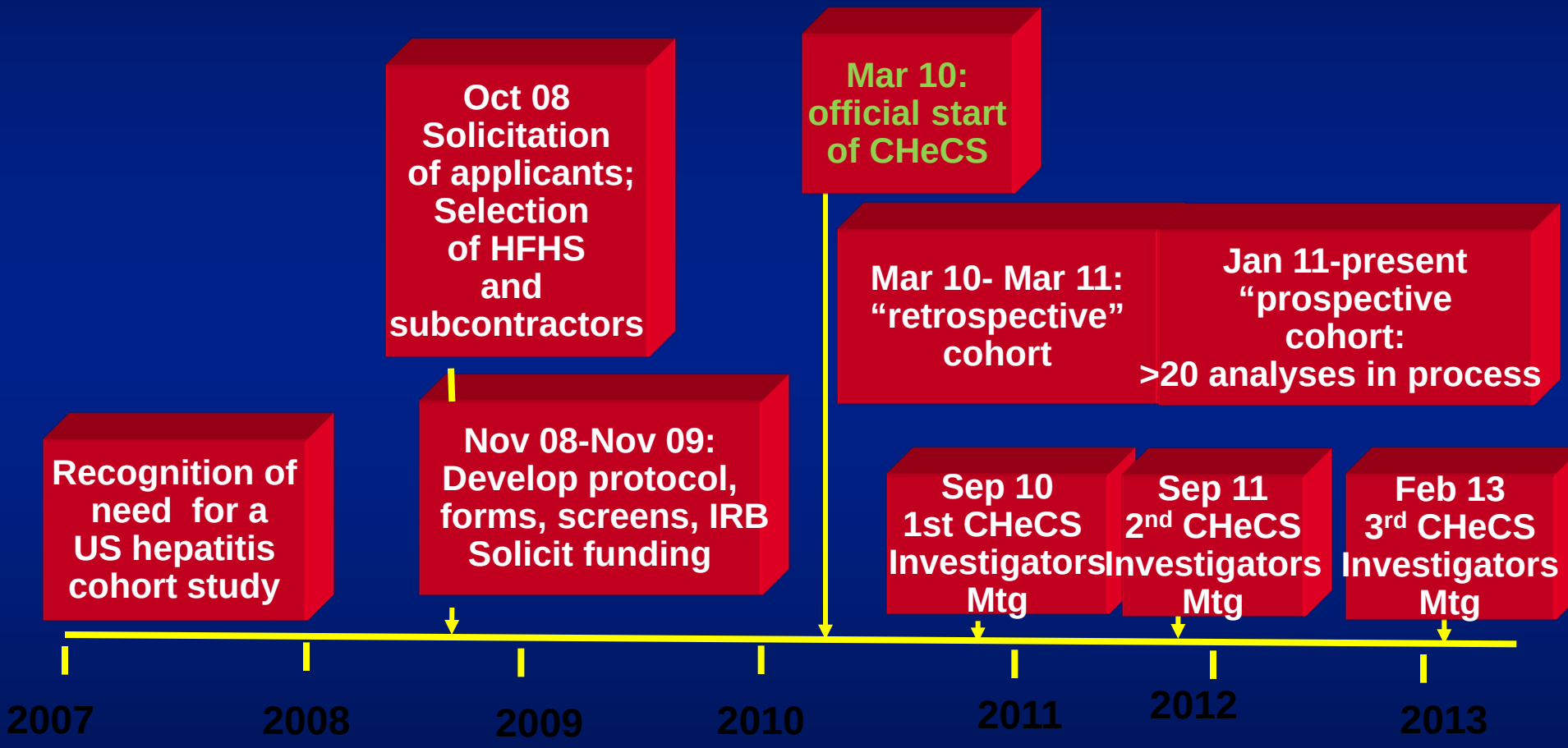
*Cause of death is defined as the underlying cause or one of the multiple causes of death.

Division of Viral Hepatitis

* Ly K et al, Ann Intern Med 2012; 156:271-8

CDC

CHeCS Evolution



Division of Viral Hepatitis

CDC

The Chronic Hepatitis Cohort Study (CHeCS):

Public health/policy/burden objectives:

- Health burden and mortality;
- Spectrum and natural history of disease;
- Characteristics of persons in care;
- Modes of transmission and ongoing risk behaviors;
- Use/effectiveness of recommended screening/care practices;
- Access to testing, care and treatment

Clinical epidemiology/treatment issues/population basis:

- Types of therapy in use, the benefits and risks/adverse effects associated with therapy, and factors influencing outcome of therapy
- Costs and potential savings of care and treatment;

CHeCS--some operational elements :

- **Each site(s) has/have data manager(s) .**
- **Data collected from integrated electronic medical systems (clinic, hospital, ERs)**
- **Some data (eg liver biopsy, interviews) manually collected and entered**
- **Survey of patient behaviors important.**
- **Study is run by an Executive Committee comprised of CDC staff and PIs (Cooperative Agreement model).**

Division of Viral Hepatitis

CDC

CHeCS Cohorts: Patients retrospectively/prospectively identified*

Site	2006-present HBV	HCV
Henry Ford Health System (Detroit MI)†	1 135	5 422
Geisinger Health (Danville PA)	267	2 092
Kaiser- HI (Honolulu HI)	952	1 309
Kaiser -Northwest (Portland OR)	1 090	3 447
Total	3 444	12 270

* Only patients meeting inclusion criteria
† Main site
‡ "Includes "retrospective cohort" (2006-2008) and "prospective cohort" (2008-present)

Division of Viral Hepatitis

CDC

In addition, we continue to fund an independent ongoing CDC-Alaska collaboration

	HBV	*HCV*
Alaska Native Tribal Health Consortium (ANTHC) Hepatitis B and C Registries	**~ 1 500**	**~1 100**

- In future analyses, we hope to integrate this special cohort with data from the 4 CHeCS sites

Division of Viral Hepatitis

CDC

Baseline Characteristics of CHeCS Patients

	HBV	HCV
Total	2 202	8 810
Received antiviral therapy (2010)	15%	8%
Underwent liver biopsy, 2001-2010	22%	7%
Most recent HBV DNA levels undetectable > 2,000	 47% 34%	 — -
HCV RNA levels > 100,000 IU/µl	—	67%
Hospitalized, 2001-2010	38%	44%
Died, 2006-2010	9%	14%

Division of Viral Hepatitis

CDC

CHeCS: some recent findings

- Only 2/3 of predicted HBV and 1/2 HCV tested/identified in this population.
- Only half of those with ≥2 abnormal ALT got HBV/HCV testing
- About 35-40% of those with HCV Ab+ had NAT testing (indicative of follow-up)
- Asians (API) most likely HBV-infected; 40-69 yos were most likely HCV-infected
- Very high hospitalization and mortality rates for both HBV and HCV, even in those who are relatively young (aged 45-65)
- Antiviral therapy (lamuvidine, tenofovir) in HBV patients prevents hepatocellular carcinoma
- Serum/blood assays (ALT, AST, platelet count) and age can be calculated to reduce the need for doing liver biopsy

Some current plans:

- > 20 analyses in progress or planned
- Factors preventing HCV patients from getting antiviral therapy
- Major cost: effectiveness analysis of different treatment strategies and timing (Leidner, CDC Prevention Effectiveness Fellow); some initial studies first:
  - Using FIB-4 scores to ‘stage’ HCV disease progression to stratify patients in analyses
  - Excess mortality analysis (Mahajan et al)
  - Excess hospitalizations (morbidity) (Gerbi et al)

We have spent a lot of time just starting and getting CHecS up to speed, but

- We are having difficulty doing “hot” analyses quickly/timely given overload of data abstractors, data managers and analysts

DISCUSSION AND PLANS

- CHeCS, a ‘dynamic ‘observational cohort study, has recruited about 3,500 chronic HBV and 12,000 chronic HCV patients drawn from a pool of > 1.6 M adults at four integrated health systems
- Ongoing data collected from CHeCS will permit longitudinal assessments of HBV and HCV infection co-morbidities, access to care, and treatment adherence and outcome
- Barrier now: ability to analyze the large database, especially the most recent information

Division of Viral Hepatitis

CDC

CHeCS Executive Committee

- **CDC**:
  - Scott Holmberg, MD
  - Anne Moorman, MPH
  - Phil Spradling, MD
  - Eyasu Teshale, MD

- **Henry Ford Hosp/Detroit**
  - Stuart Gordon, MD
  - David Nerenz, PhD
  - Lora Rupp, MPH
  - Mei Lu, PhD

- **Kaiser/ Hawaii**
  - Vinutha Vijayadeva, PhD
- **Geisinger/ central Penn**
  - Joe Boscarino, PhD
- **Kaiser NW/Portland, OR**
  - Mark Schmidt, PhD
- **Alaska Native Tribal Health/ Anchorage (ancillary site)**
  - Brian McMahon, MD

Division of Viral Hepatitis

CHeCS Chronic Hepatitis Cohort Study

CDC