

# The Chronic Hepatitis Cohort Study (‘CHeCS’)

Overview of a model of cooperation  
between external partners, CDC  
Foundation, and CDC researchers

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# HIV Outpatient Study (HOPS)

Started in 1994, thirteen years into the HIV epidemic. By 1997, could observe clear trends in outcomes of therapy on a population basis

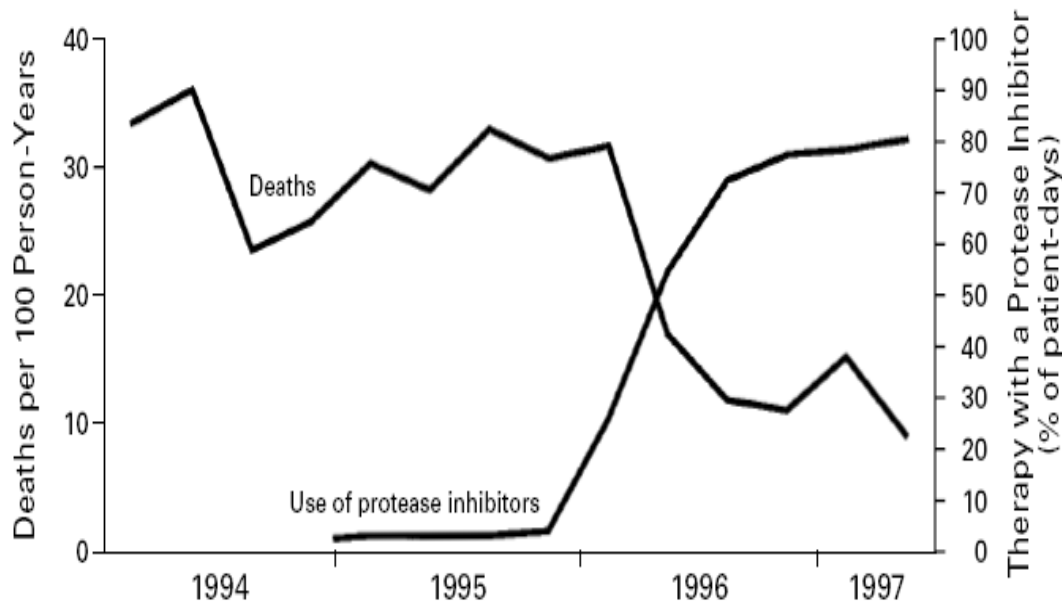


Figure 1. Mortality and Frequency of Use of Combination Antiretroviral Therapy Including a Protease Inhibitor among HIV-Infected Patients with Fewer Than 100 CD4+ Cells per Cubic Millimeter, According to Calendar Quarter, from January 1994 through June 1997.

# Burden of CVH in the US

- CDC estimates
  - 3.2 million Americans with chronic HCV
  - ~1 million with chronic HBV
  
- Other studies estimate more

# Why do we need a cohort study of chronic hepatitis? (or, why aren't all studies controlled, blinded trials?)

- Questions about a disease spectrum require study of many patients over a long period
- Effects of drugs, good and bad, can often not be discerned in 24-, 48- or even 96- weeks
- Questions of public health, policy and epidemiology require population-based study
- Many questions cannot be answered by clinical trials methods because they would be too expensive, impossible, and/or unethical

# Funding

- CHeCS has been generously funded by a CDC Foundation Grant:
  - Vertex Pharmaceuticals
  - Johnson & Johnson/Tibotec
  - Abbott
  - Genentech/Roche
- The CDC Foundation acts as a “firewall” to avoid both reality or appearance of commercial bias to CHeCS findings

# CHeCS: solicited letters of intent

- Applicants were evaluated based on:
  - Number and geographic/demographic diversity of patients, quality of data, ability to capture non-clinic (hospital/other) data
  - Proven or anticipated ability to enroll, follow, and collect information on patients
  - Previous track record in science and collaboration with CDC or NIH
- Decision to fund a consortium of sites co-ordinated by Henry Ford Health System (Detroit)

# Current CHeCS Population

## *Fulfilling Inclusion Criteria, 2006-8*

<i>CHeCS sites</i>	<i>HBV</i>	<i>HCV</i>
• <b>Henry Ford Health System (Detroit MI) *</b>	<b>712</b>	<b>3 903</b>
• Geisinger Health System (Danville PA)	240	2 145
• Kaiser- Hawaii (Honolulu HI)	738	1 193
• Kaiser- Northwest (Portland OR)	846	3 469
<b>Totals</b>	<b>2 536</b>	<b>10 710</b>

\* Main site

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

	<i>HBV</i>	<i>HCV</i>
<i>Alaska Native Tribal Health Consortium (ANTHC) Hepatitis B and C Registries</i>	~ 1 500	~1 100

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



# Preliminary Analysis of Testing and Linkage to Care among Health Plan Members in CHeCS, 2006 – 2008

	# Adults $\geq 1$ visit	% Tested*	% Positive†	% Tested after $\uparrow$ ALT	% Positive after $\uparrow$ ALT	% Positive seen by specialist	Mean/median days to specialty visit
HBV	875 511	18	1.5	32	1.5	59	599/132
HCV	870 894	13	5.1	34	7.1	70	423/93

\* Tested = Ever tested for HBsAg or HBV DNA; ever tested for anti-HCV or HCV RNA

† Positive = Ever positive for HBsAg or measurable HBV DNA; ever positive for anti-HCV or measurable HCV RNA

# DISCUSSION AND PLANS

- CHeCS, a 'dynamic 'observational cohort study, has recruited over 2,500 chronic HBV and 10,000 chronic HCV patients drawn from a pool of > 1.6 M adults at four integrated health systems
- CHeCS is representative of mainly urban HBV- and HCV-infected patients receiving ongoing outpatient specialty care. There is broad demographic and socioeconomic representation in the patient base.
- Ongoing data collected from CHeCS will permit longitudinal assessments of HBV and HCV infection co-morbidities, access to care, and treatment adherence and outcome

# 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**

- Cynthia Nakasato, MD

- **Geisinger/ central Penn**

- Joe Boscarino, PhD

- **Kaiser NW/Portland, OR**

- Emily Henkle, PhD

- **Alaska Native Tribal Health**

- Brian McMahon, MD

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  - Dacia LaDonis
  - Leah-Lane Lowe
- CDC:
  - John Ward
  - Dale Hu
  - Jian (“Jim”) Xing

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