

HEPATITIS C TREATMENT UPDATE



Hepatitis C: Burden of Disease in USA

- HCV is generally asymptomatic until advanced liver disease
- 4.1 million persons ever infected; 3.2 million chronic infections
 - ▣ Up to 75% unaware of status
- Major cause of liver disease
 - ▣ Leading indication for liver transplants
 - ▣ Leading cause of liver cancer (approx. 50% of liver cancer incident)
 - ▣ 37% lifetime risk of HCV-related mortality for patients with chronic HCV¹
- HCV-related deaths doubled from 1999-2007 to over 16,000/year
 - ▣ In 2007, HCV related deaths began to exceed HIV deaths
- Number of patients with morbidity and mortality from HCV is increasing²
 - ▣ Estimated cases of advanced liver disease will increase from 195,000 in 2008 to 601,000 in 2015.
 - ▣ 74% of advanced liver disease cases will be in patients who were undiagnosed in 2008

¹Rein et al. Dig Liver Dis 2011; 43:66.

²Zalesak et al PLOS ONE 2013; 8(5):e63959.

NYS Trends in HCV

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- HCV rates in NYS are estimated to be higher than national rates¹
- Total costs associated with HCV in NYS are estimated to be \$1.35 billion (2009)²
 - ▣ Direct costs for HCV-related chronic liver disease and primary liver cancer were \$300 million and \$73 million, respectively.
 - ▣ Healthcare utilization attributing to direct costs was highest among males ages 45-64 with 75% of utilization among “baby boomers”.
- HCV death rates are increasing over time in NYS and have surpassed HIV death rates in ROS²
 - ▣ Average age at diagnosis 56.3 for deceased compared to 48.1 for living
 - ▣ More deaths from baby boomer cohort than others

¹. Hart-Malloy, R., Flanigan, C., & Carrascal, A. (2011). Estimating the prevalence of Hepatitis C cases in New York State. In *139th Annual American Public Health Association*.

². Unpublished Data. NYSDOH, AIDS Institute

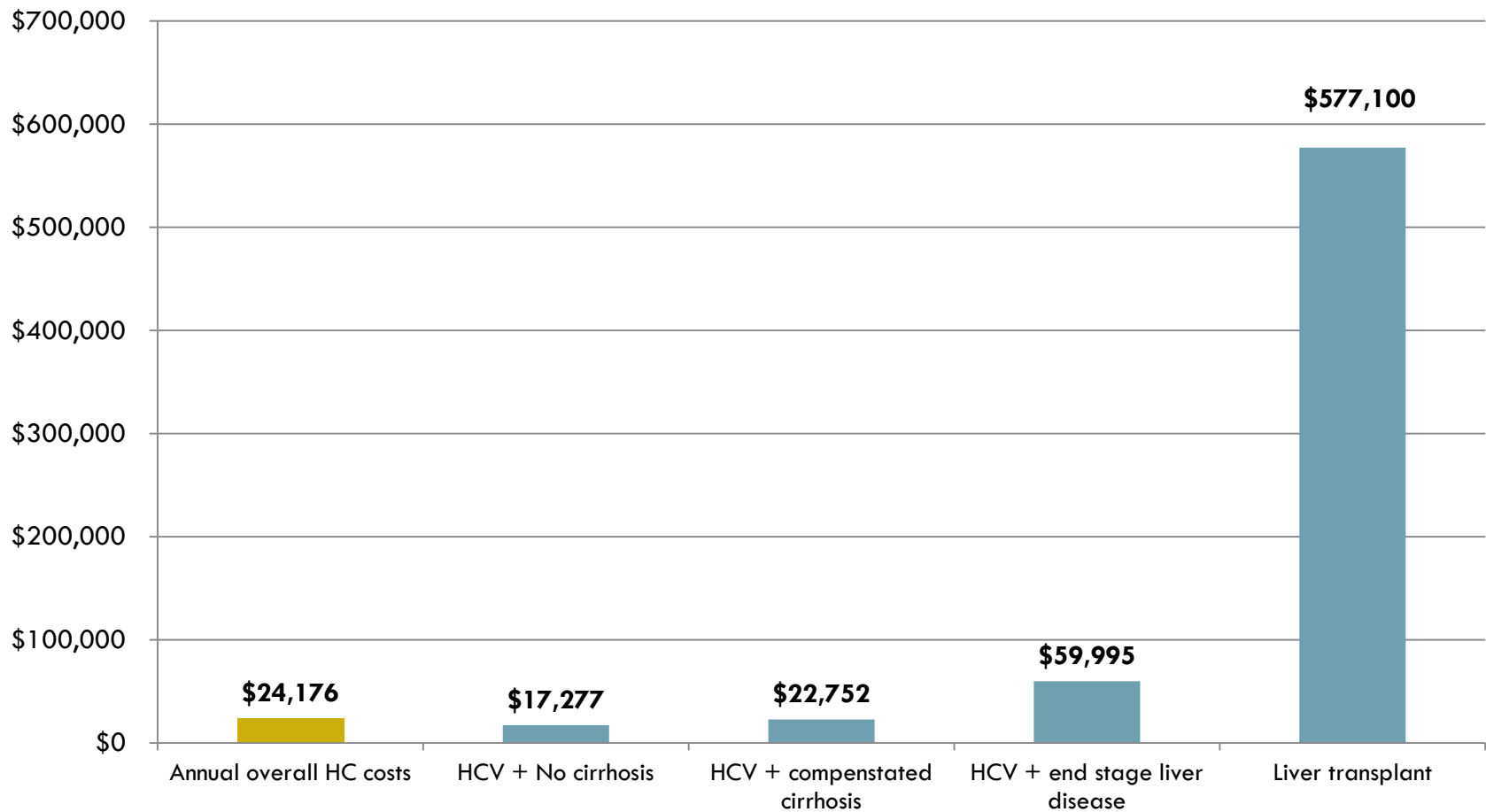
NYS Hepatitis C Testing Law

- Effective January 1, 2014
 - ▣ A hepatitis C screening test be offered to every individual born between 1945 and 1965
 - Inpatient of a hospital or
 - Receiving primary care services in the outpatient department of a hospital or
 - In a freestanding diagnostic and treatment center or
 - From a physician, physician assistant, or nurse practitioner providing primary care regardless of setting type.
 - ▣ If the test is reactive, follow-up health care including a HCV RNA test must be offered onsite or by referral

Health and Cost Impact of HCV Testing of Persons Born 1945-1965

Outcome	Birth Cohort Testing with Therapy	
	PegIFN-Riba (PR)	PegIFN-Riba + TVR
Additional Identified Cases	809,000	809,000
Cirrhosis cases averted	138,000	203,000
Decompensated cirrhosis cases averted	50,000	74,000
Hepatocellular carcinoma cases averted	32,000	47,000
Transplants averted	11,000	15,000
Deaths from hepatitis C virus averted	82,000	121,000
Medical costs averted	\$1.5b	\$2.5b
Cost/QALY gained (Societal)	\$15,700	\$35,700

HCV related costs by disease stage¹



¹Gordon SC, Pockros PJ, Terrault NA et al, Disease burden in patients with chronic hepatitis C virus (HCV) infection in a United States (US) private health insurance claims database analysis from 2003 to 2010, AASLD Nov 5-9 2011 San Francisco

Treatment Costs in the era of Directing Acting Anti-virals (DAAs)

Treatment	Costs of treatment	SVR/Cure	Duration of treatment
Traditional interferon	<\$20,000	6%	48 weeks
Pegylated interferon + Ribavirin	\$30,000	40-60%	48 weeks
Boceprevir + P/R	\$48,400+\$30,000=\$78,400	75%	48 weeks
Telaprevir + P/R	\$49,200+30,000=\$79,200	75%	12 weeks
Olysio	\$66,360	80%	12 weeks
Sovaldi	\$84,000	90%	12 weeks

Impact of HCV Sustained Virologic Response (SVR)

- SVR = Cure
 - ▣ Less than 1% chance of late relapse
- Associated with
 - ▣ Lower rates of liver cancer
 - ▣ Lower rates of cirrhosis
 - ▣ Lower rates of liver transplants
 - ▣ Lower rates of all cause mortality
- People with HIV/HCV who have an SVR are less likely to die from AIDS-related, liver-related and other causes
- Improves quality of life

Impact of SVR on Healthcare Costs

	SVR	Non-SVR
Cost per person year*		
All cause costs	\$6,301	\$10,149
Hospital	\$2,641	\$5,167
Outpatient	\$3,661	\$4,983
Pharmacy	\$708	\$1,037

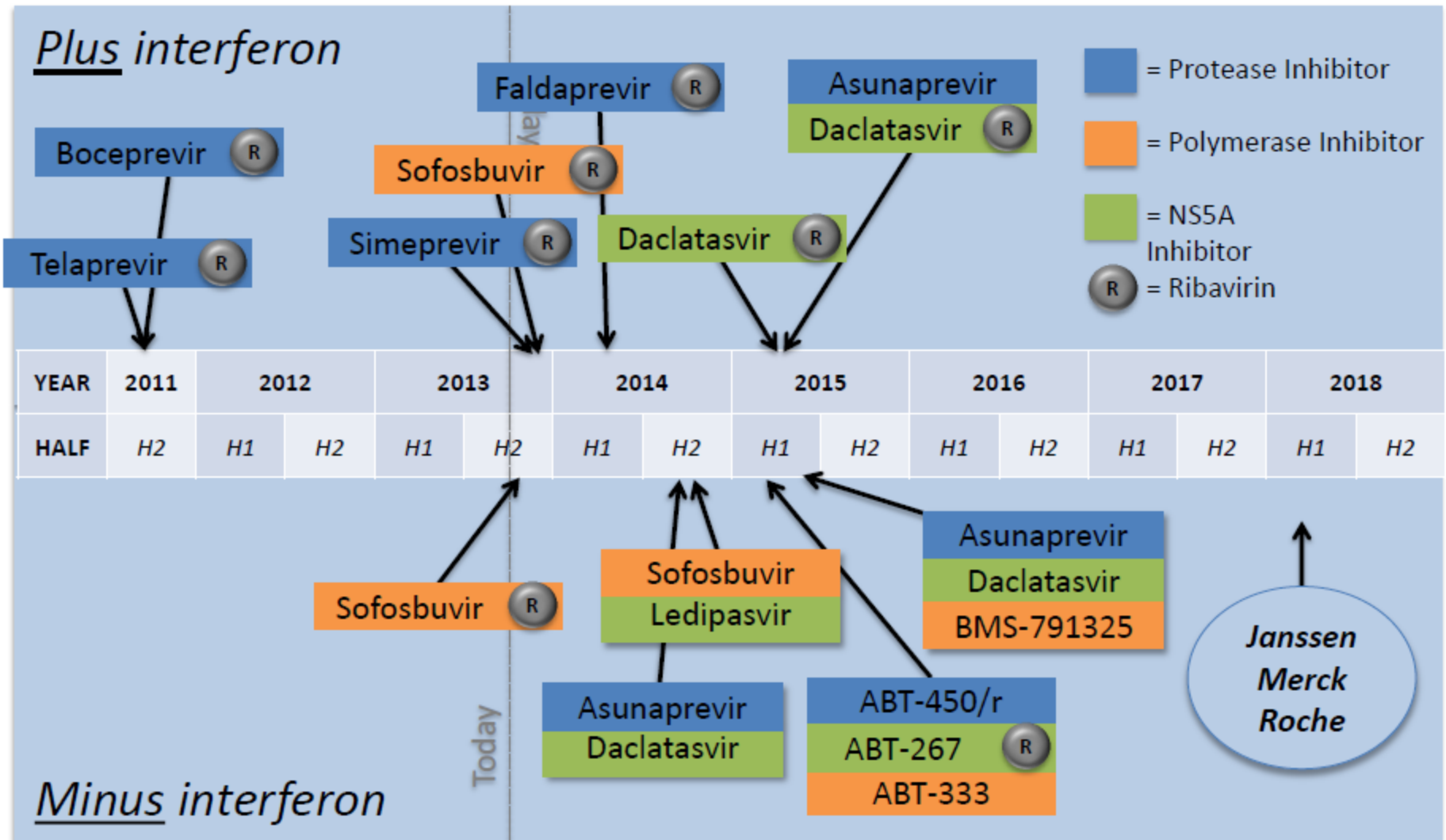
- Total adjusted costs significantly higher in non-SVR
 - ▣ Hospital and outpt pharmacy
- Non-SVR had higher resource use
 - ▣ Hospitalizations
 - ▣ Liver specific lab tests
 - ▣ Internal med visits

*Per person-year costs adjusted to 2007 dollars using consumer price index

Future of HCV Therapy

- Regimens will likely be effective against infection with most or all HCV genotypes
- SVR/cure rates approaching 100% are expected
- Drugs will be effective even in difficult-to-treat patients
- Drugs will be well tolerated and have excellent safety profiles
- Therapy will likely be only 12 weeks, and be relatively simple; no interferon
- Attention will need to be paid to potential drug-drug interactions

HCV treatment time



Sovaldi + Olysio

Monoinfection

- First all oral for genotype 1
- With or without RBV
- No FDA indication for this combination
- Recommended in new AASLD National Guidelines (monoinfected and HIV/HCV coinfecting)
 - ▣ <http://www.hcvguidelines.org/full-report-view>
- COSMOS Phase II data only, no Phase III planned
- High SVR rates
 - ▣ 79-96%; previously failed treatment, minimal liver disease
 - ▣ 96-100% previously failed or never treated with advanced liver disease
 - ▣ No clinical trial data for coinfection

Sovaldi + Olysio

HIV/HCV Coinfection

- Never studied in clinical trial for coinfection
- Combination may be considered:
 - ▣ GT 1 and
 - ▣ Interferon ineligible and
 - ▣ Receiving antiretroviral therapy that may be coadministered with simeprevir (ie, raltegravir, rilpivirine, maraviroc, enfuvirtide, tenofovir, emtricitabine, lamivudine, and abacavir).

HCV therapy in the next 24 months

- **End of 2013:** Initial appearance of more effective, simpler and safer treatments for genotype-1 disease
- **2013:** Beginning of the end of interferon
- **End of 2014:** All-oral regimens that are effective against multiple genotypes of HCV
- **End of 2014:** SVR approaches 100% in most patient groups
- **2015:** Continued addition of new drugs and refinement of treatment. e.g. OLT, HIV
- **And beyond:** Pharmaceutical winners and losers; discussion of cost, access

Conclusion

.....Thus, although DAA therapy may be \$1000 a pill, SVR is arguably priceless.

Contact

- Colleen Flanigan, RN, MS
 - ▣ Director, Viral Hepatitis Section
 - ▣ Division of HIV and Hepatitis Healthcare
 - ▣ New York State Department of Health, AIDS Institute
 - ▣ 518-486-6806
 - ▣ caf03@health.state.ny.us
- Ira Feldman
 - ▣ Deputy Director AIDS Institute
 - ▣ New York State Department of Health, AIDS Institute
 - ▣ 518.486.1383
 - ▣ isf01@health.state.ny.us