

The Cost-effectiveness, Health Benefits, and Financial Costs of New Antiviral Treatments for Hepatitis C Virus



A Viral Hepatitis Free Future
Viral Hepatitis Policy Board
Presented at The London School of Hygiene and
Tropical Medicine
London, UK
June 5, 2015

NORC
at the UNIVERSITY of CHICAGO

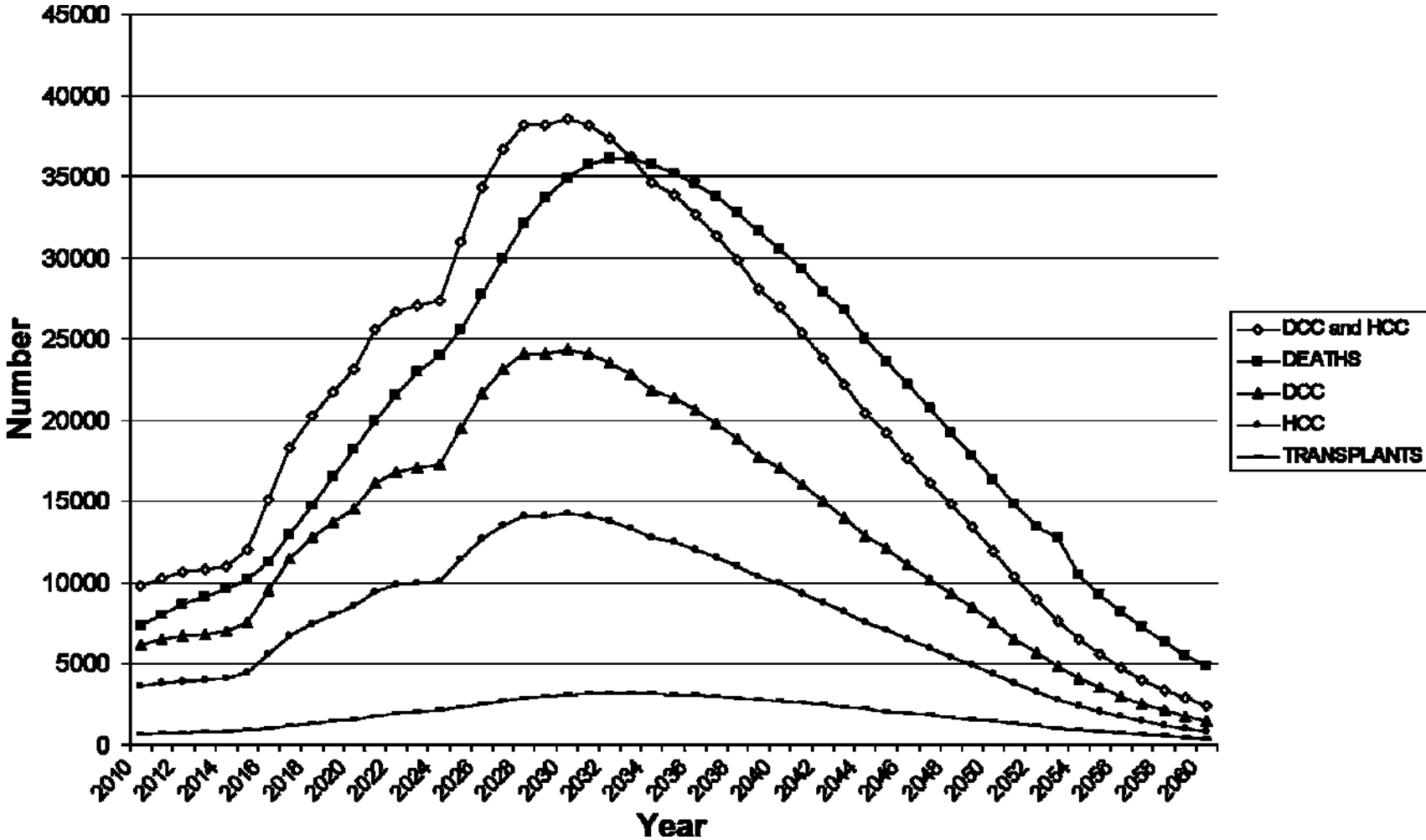
Disclosures

- Past and current contract and grant funding related to HCV from
 - CDC, WHO
 - CDC Foundation, and
 - Commercial Pharmaceutical Industry (contracts ending)

Modifiable Medical Burden

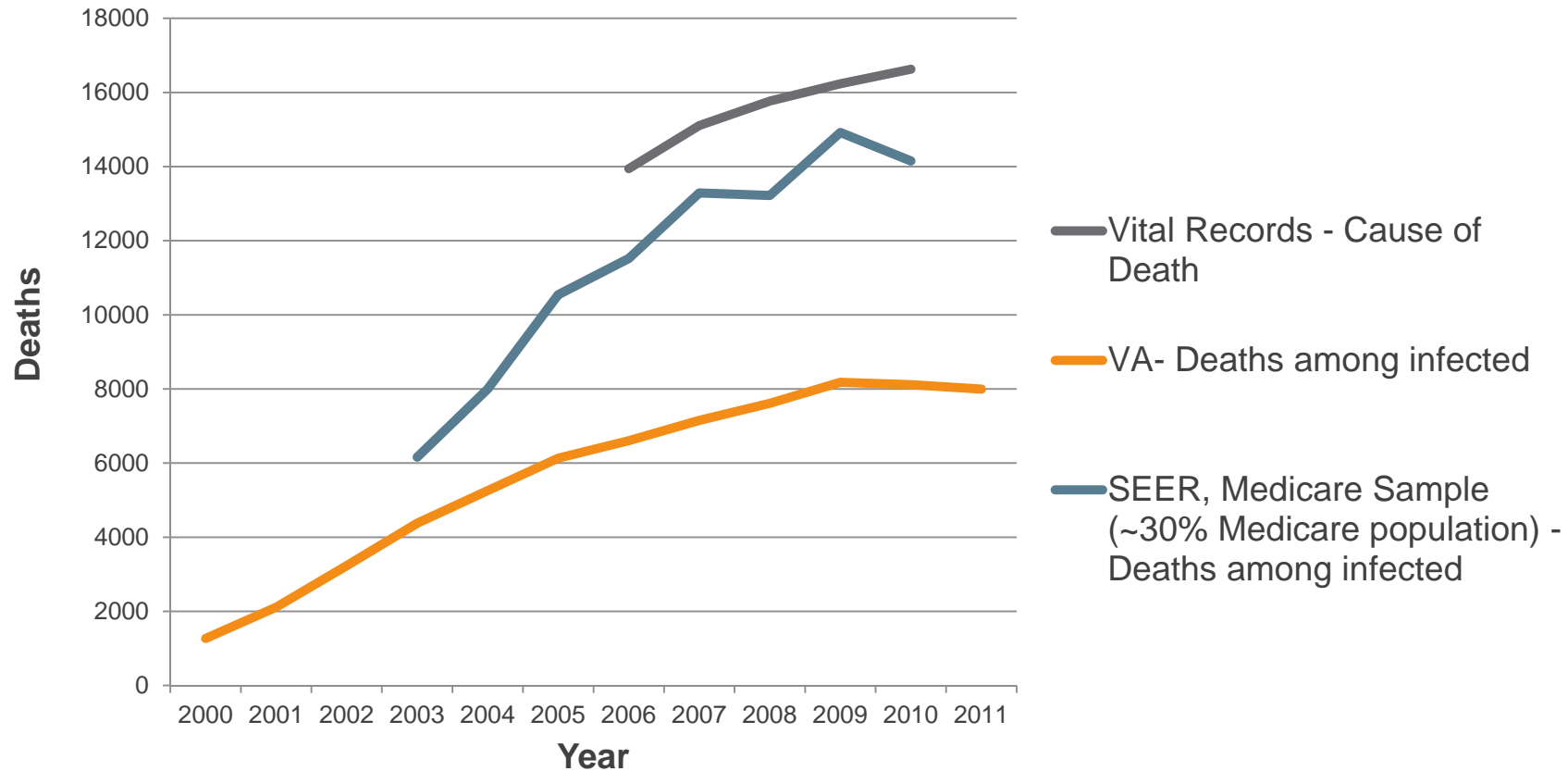


Modifiable Medical Burden of HCV: Forecasts



Rein, Wittenborn, Weinbaum, et al (2010) Forecasting the morbidity and mortality associated with prevalent cases of pre-cirrhotic chronic hepatitis C in the United States. *Digestive Liver Disease*, (43)1:66-72.

Modifiable Medical Burden of HCV: Data

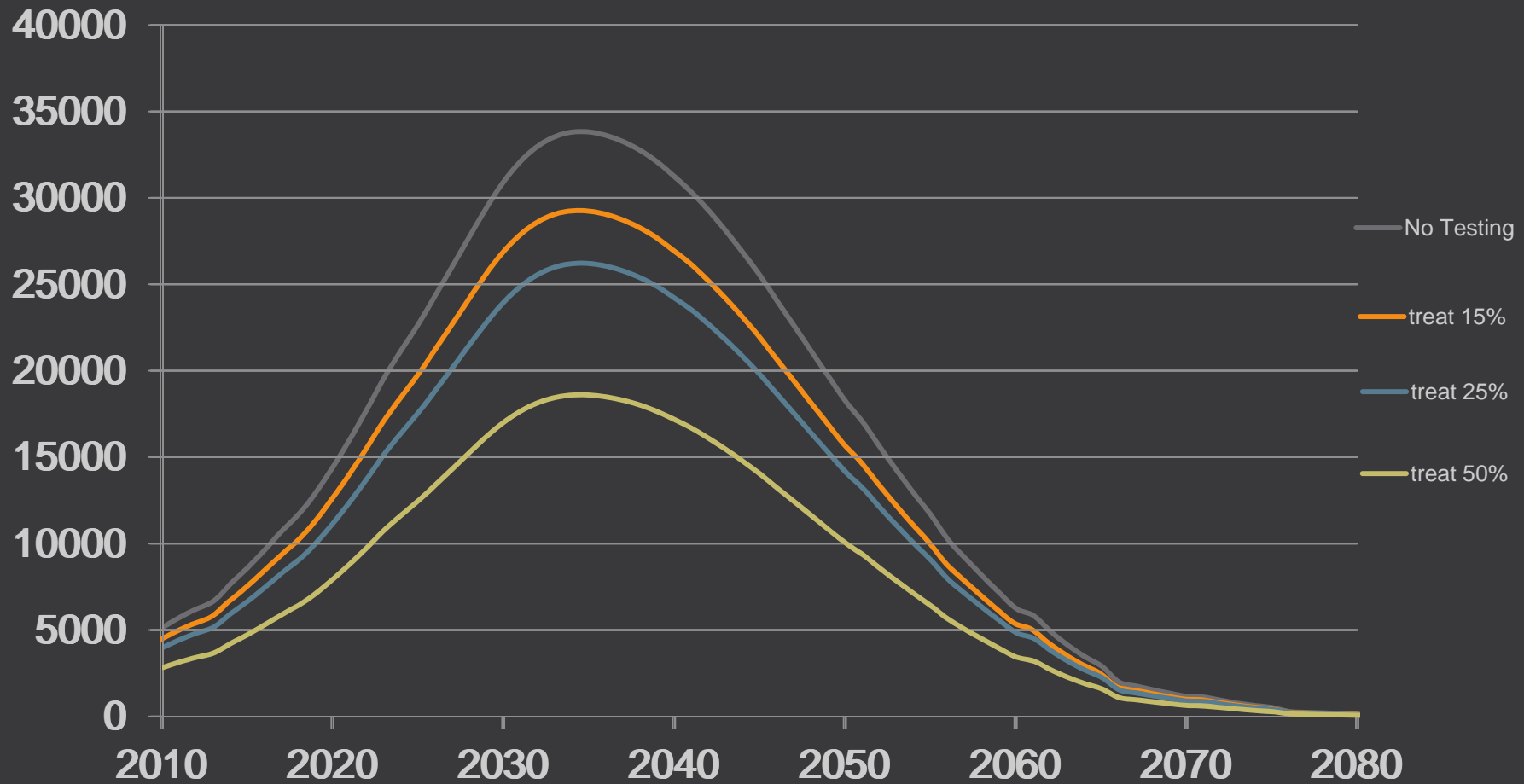


Vital Records - Cause of Death: <http://www.cdc.gov/hepatitis/Statistics/2011Surveillance/Table4.5.htm>

VA- Deaths among chronically Infected: Kanwal, Hoang, Kramer, et al (2011) Increasing Prevalence of HCC and Cirrhosis in Patients With Chronic Hepatitis C Virus Infection. *Gastroenterology*, 140(4):1182-1188.

SEER - Deaths among infected: Weighted result from primary data obtained from the Surveillance, Epidemiology, and End Results (SEER) program data obtained from the National Cancer Institute (<http://seer.cancer.gov/registries/>)

Potential Modifiable Burden

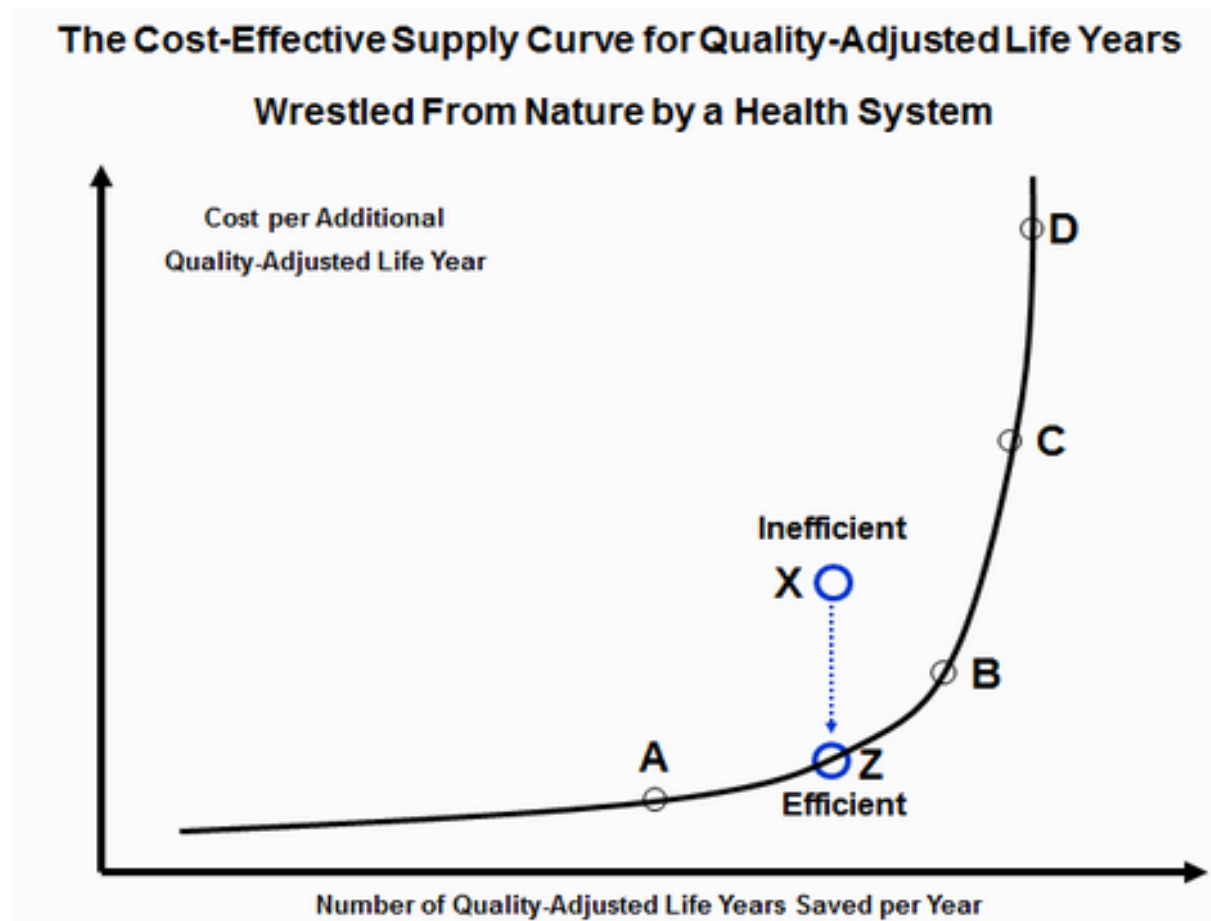


Cost-effectiveness



Diminishing Marginal Returns of Advanced Medical Treatments?

- Uwe Reinhardt, referencing HCV treatments



Is this Hypothesis Supported?

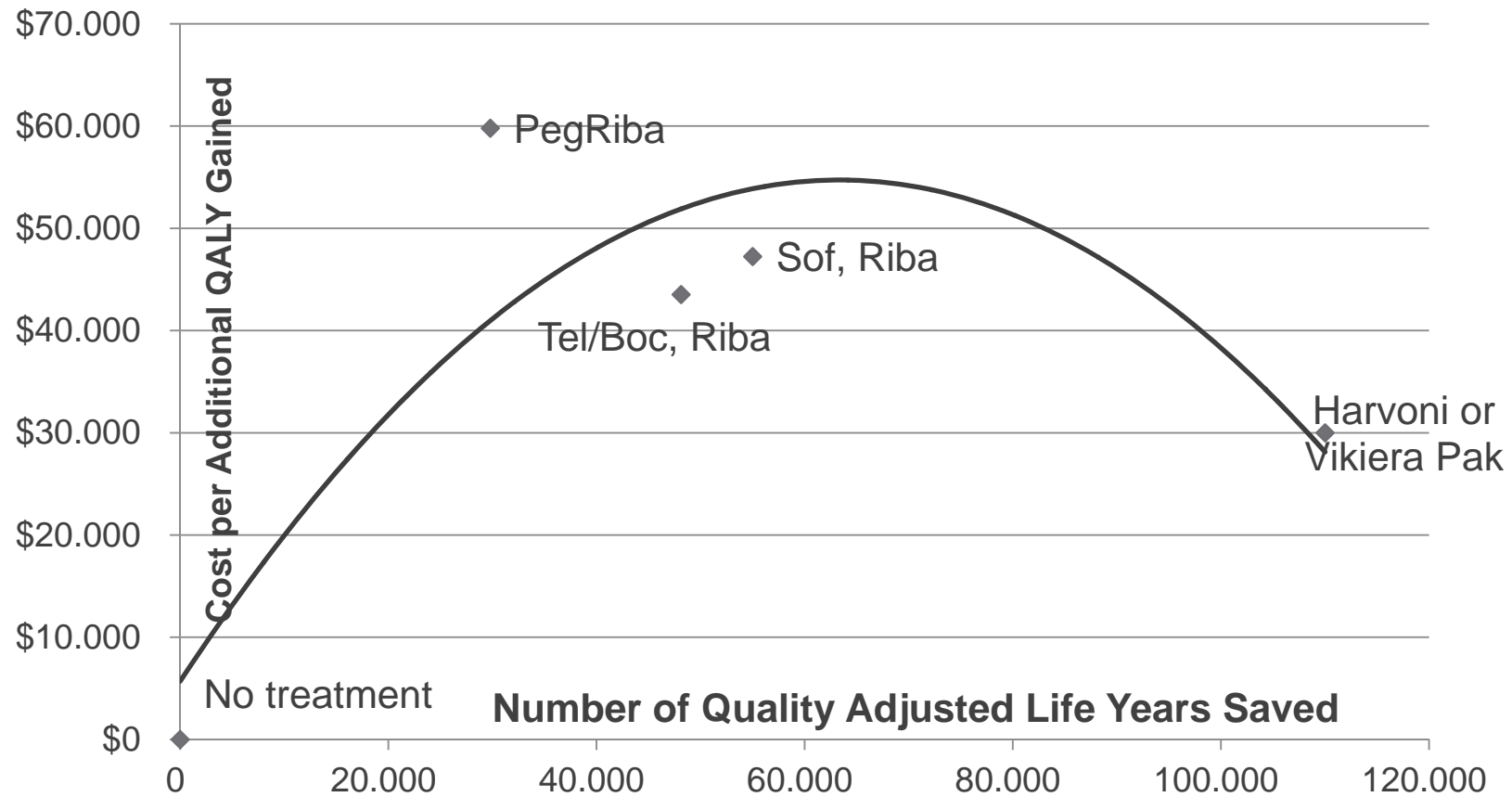
- Study 1 – Rein, Wittenborn, Smith, Liffmann, & Ward (2015)
 - Evaluated the incremental cost-effectiveness of 5 treatment types (genotype 1 treatments listed) at package costs as of 2014 and clinical trial efficacy
 - No treatment
 - Pegylated Interferon with Ribavirin
 - Telaprevir/boceprevir with Peg Riba
 - Sofosbuvir with Peg Riba
 - Sofosbuvir and Simeprevir

ICER of Testing and Treatment by Treatment Type

Treatment	Total Averted Deaths	Incremental Deaths	Cost Per Person 18+	Incremental Cost Per Person 18+	Incremental QALYs per Person 18+	ICER
None	0	-	\$437	-	-	-
PegIFN, Riba	49,916	49,916	\$517	\$80	0.0013	\$59,792
PegIFN, TVP	125,340	75,424	\$528	\$91	0.0021	\$43,530
PegIFN, Riba, Sof	206,202	80,862	\$642	\$114	0.0024	\$47,237
Sim, Sof	370,742	164,540	\$992	\$350	0.0048	\$72,169
Harvoni or Vikeira Pak*	370,742	164,540	\$688	\$243	0.0048	\$30,000

- ***Sensitivity Analyses: ICER of treatment with Sim, Sof Effectiveness but at Harvoni/Vikeira Pak AWP**
- *** Incremental results as compared to PegIFN, Riba, Sof**

Increasing Marginal Returns of HCV Medical Treatment



Other CE Results

Author	Year	Genotype	Treatment	Comparator	ICER	Nation
Rein, et al	2015	Mixed (1, 2, & 3), Assumed Naïve	sofosbuvir-ledipasvir or Vikeira Pak for G1, sofosbuvir-ribavirin for g2,3	sofosbuvir=pegIFN-Ribavirin	\$30,000	USA
Najafzadeh,et al	2015	1, Naïve	sofosbuvir-ledipasvir	boceprevir-ribavirin-pegylated interferon	\$12,825	USA
Najafzadeh,et al	2015	2, Naïve	sofosbuvir-ribavirin	PegIFN-Ribavirin	\$110,000	USA
Najafzadeh,et al	2015	3, Naïve	sofosbuvir-ledipasvir-ribavirin	PegIFN-Ribavirin	\$73,000	USA
Pfeil, et al	2015	Mixed (1 through 4)	sofosbuvir containing treatments	boceprevir-ribavirin-pegylated interferon	10k to 90k CHF	CH
Westerhout, et al	2015	Unclear	simeprevir-PegIFN-Riba	PegIFN-Ribavirin	£9,725	UK
Cure, et al, a	2015	Mixed (1 through 4)	sofosbuvir containing treatments	PegIFN-Ribavirin	< €40,000	Italy
Cure, et al, b	2015	Mixed (1 through 4)	sofosbuvir containing treatments	Telaprevir-PegIFN-Ribavirin	£18 761	UK
Linas, et al	2015	G2,3 Naïve non-cirrhotic	Sofosbuvir-based therapies	pegylated interferon-ribavirin	> \$200,000	USA
Linas, et al	2015	G2,3 Naïve & exp cirrhotic, Exp NonCirrhotic	Sofosbuvir-based therapies	pegylated interferon-ribavirin	<\$100,000	USA
Chhatwal, et al	2015	G1, Naïve and Experienced	Sofosbuvir-based therapies	interferon-based therapies	\$55 400	USA
Kuwabara, et al	2015	G1, Naïve	Simeprevir-PegIFN-Riba	Telaprevir-PegIFN-Ribavirin	¥263,037	Japan
Leidner, et al	2015	G1, 55 year old	Sofosbuvir-based therapies at F2	Delaying Sofosbuvir-based therapies until F3	\$37,300	USA

Implications

Implications

- Case identification and treatment of HCV is cost-effective and should be expanded in the United States to reduce morbidity and mortality from disease.
- Largest problems in the United States involve
 - Identifying asymptomatic cases
 - Linking newly tested positive patients to care
 - Overcoming barriers and restrictions to treatment
- Overall financing impact of HCV Treatment likely to be smaller than feared and spread over time

HCV Tx is Increasingly Efficient and Cost-effective

- New treatments deliver larger cumulative health benefits than older treatments at a lower cost per unit of benefit
- Multiple studies demonstrate that new HCV Tx's are CE for most patients at the published average wholesale price
 - G1, Tx-Naïve, METAVIR of F2 or higher
 - G1, Tx-Experienced (all)
 - G2, G3, Tx-Naïve, METAVIR F4 or higher
 - G2, G3, Tx-Experienced (all)

Restriction Based on CE – Practical Consideration

- New tx's are less cost-effective in subgroups
- G1 patients with no or minimal progression
 - Non-biopsy fibrosis ascertainment technology to differentiate patients does not exist
 - Unmeasured costs of monitoring & loss to follow-up
 - 62% in CHeCKS meet F2+ criteria based on biopsy or FIB4 (many who did not would if FIB4 was more sens)
- G2, G3 less CE
 - Really an issue for G3 patients without cirrhosis (important, but <10% of total patients)
- Unusual and out of step in the United States

Prices are Falling

- Many patients can achieve SVR with shorter tx duration, lowering costs
- Payer/Pharma agreements - average ~46% discount
- Medicaid - mandated 23% discount
- VA Discount ~ 30%
- Merck and other products on the horizon will increase price competition

Financing Crises not Materializing

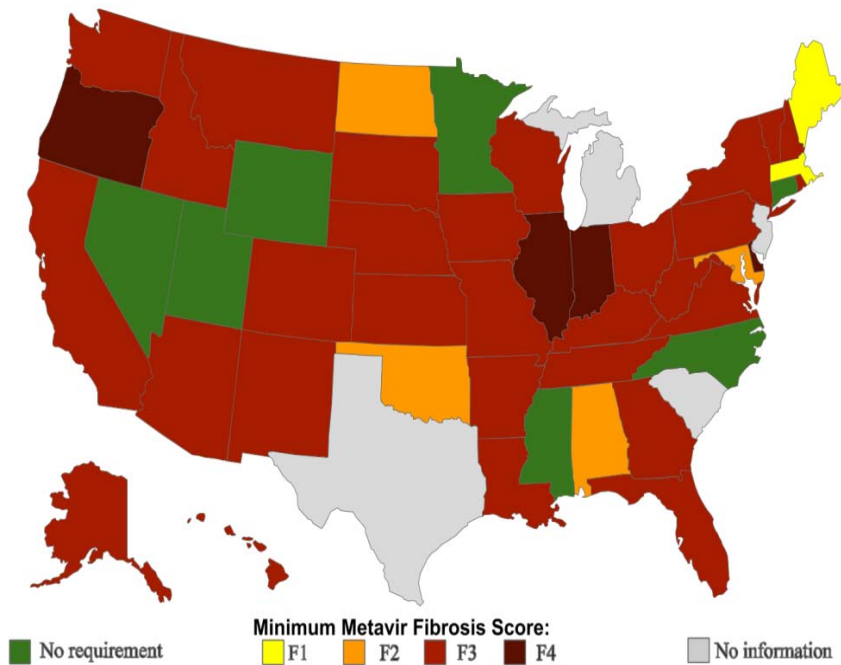
- No observed surge in treatment demand
 - Nrx for 2014 between 150,000-175,000 in line with historical averages
 - A bit of early spike from warehoused patients. Subsequent treatment more or less in line with historical trends.
- No examples of private health insurance companies going out of business due to reimbursement of HCV claims
- No examples of State Medicaid financing crises due to surge in demand for HCV tx

Barriers to Access

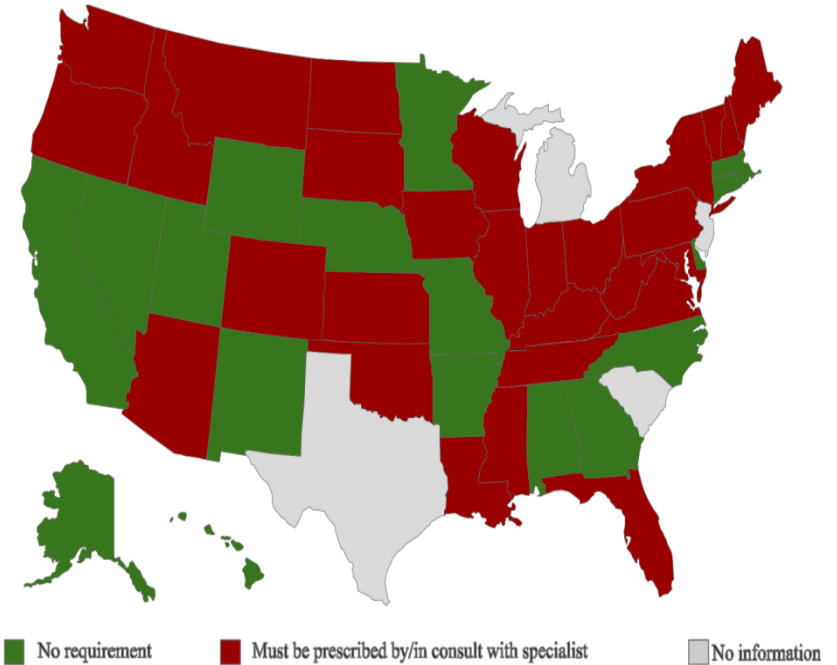


Medicaid Barriers to Coverage

- **Minimum fibrosis score**



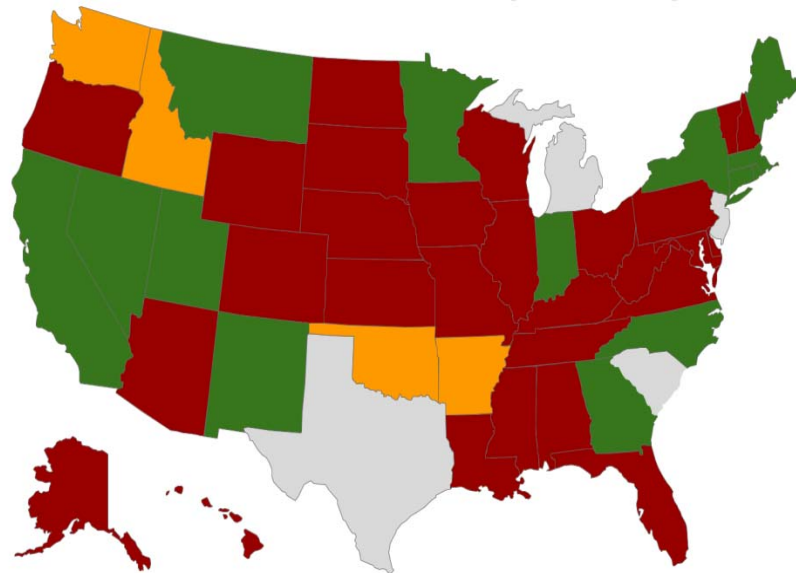
- **Prescription by specialist**



Some states have few specialists; some states require biopsies for fibrosis scoring

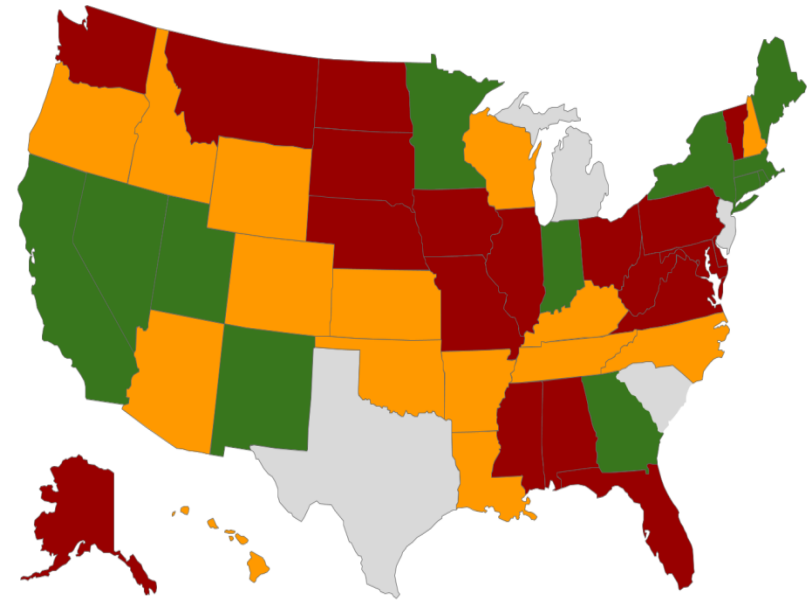
Medicaid Barriers to Coverage

- **Illicit drug abstinence before treatment**



■ No requirement ■ Must abstain from IDU ■ Must abstain from any illicit drug use ■ No information

- **Alcohol abstinence**



■ No requirement ■ Must abstain from alcohol abuse ■ Must abstain from any alcohol use ■ No information

Some states require blood/urine tests; some states deny payment for patients who test positive for methadone, and marijuana.

Why Do these Restrictions Exist?

- New, unbudgeted expense
- Uncertainty about demand, risk aversion
- Public backlash and distaste for private profits
- Lack of powerful constituencies
- Race and class have to be considered

Possible Solutions to Reduce Barriers and Increase Access

- Price competition
- Negotiated contracts
- Government intervention (Medicaid/Medicare coordination)
- Public education
- Other?

David Rein, rein-david@norc.org

Thank You!



NORC
at the UNIVERSITY of CHICAGO

 insight for informed decisions™