The Cost of HCV Care

Hepatitis C Virus: The Changing Paradigm

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Suppose a Treatment "Purchases" Added Years at a Price of $250,000 per Added Life-year

- **Option A:** American society should purchase that added life-year for all afflicted patients . . . This would mean that taxpayers should be compelled to pay extra taxes
- **Option B:** Taxpayers should not be asked to purchase such expensive, added life-years for their low income fellow citizens, but Americans with the means to purchase them with their own resources, or who have private health insurance, should be afforded the opportunity to purchase those added life years for themselves or their families.

Reinhardt U. Pricing Human Life(-Years). *The New York Times*. 2009. http://economix.blogs.nytimes.com/2009/03/20/pricing-human-life-years/

Health Budget Limitations

- 2010 U.S. health care expenditures estimated to be $2.6 trillion or >17% of GDP
  - 40% more on health care: ~$650 billion in 2008
- "Every country spends 100% of its gross domestic product on something"
- What is important is the value obtained by the spending: opportunity costs
- Family earning $60,000 "gross wage base" would spend 41% of wages on health care in 2017

Reinhardt U http://economix.blogs.nytimes.com 2008; Fuchs VR Ann Intern Med 2005;143(1):76-8; http://www.census.gov/compendia/statab/cats/health_nutrition/health_expenditures.html

Objectives

- Identify cost components for the care and treatment of chronic HCV infection
- Discuss the economic implications and impact of the new direct acting agents for HCV
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Cost Components

- Hepatitis C disease costs = Units x Price
  - Hospitalizations, office, ER visits, diagnostic and monitoring tests, medications
- Top down
  - Follow cohort and collect actual longitudinal frequency and unit cost data (clinical trial)
- Bottom up
  - Estimate frequency of resource utilization
  - Identify costs for each item (e.g., hospital accounting system or Medicare)

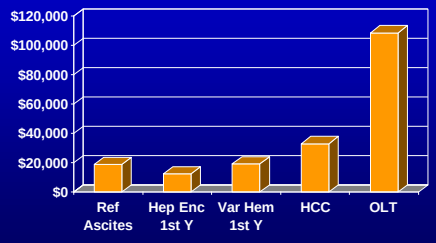
Gold MR et al *Cost-effectiveness in Health and Medicine* 1996

Bottom Up Cost Estimate

- Hepatocellular carcinoma
  - Inpatient admission every 4 months at $5479 each
  - Outpatient visit every month at $82 each
  - Medications (assuming that 80% of patients have cirrhosis and require furosemide, spironolactone, norfloxacin and lactulose)
- Total = $19,589

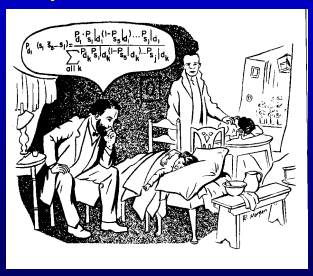
Wong JB et al *Ann Intern Med* 1995;122:664

Annual HCV Costs in 1999



Wong JB et al *Am J Public Health* 2000;90:1562-9

What is the Economic Burden of Hepatitis C for the US?



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Predictions for 2010-2019

- 210,000 HCV deaths (120,000-260,000)
  - 1 million years of advanced liver disease
  - Loss of 3 million years of life
- Direct medical care costs
  - $11 billion ($7-$14)
- Indirect medical care costs <age 65
  - $54 billion from premature mortality
  - $21 billion from disability

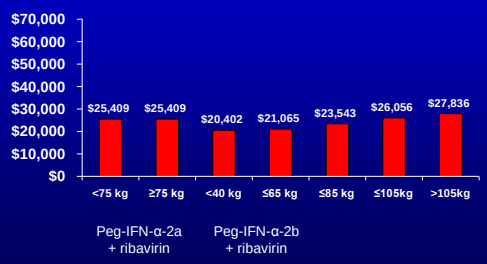
Wong JB et al *Am J Public Health* 2000;90:1562-9

Direct Health Care Costs in Hepatitis C

- Antiviral medication costs
- Induced costs
  - Pretreatment evaluation (office visit, tests, liver biopsy)
  - Antiviral medication
  - Contraception
  - Monitoring (office visit, tests (liver, thyroid, pregnancy)
  - Adverse effects (anemia, neutropenia, depression, quality of life)
- Societal
  - Patient time, caregiving, transportation, sick leave, disability

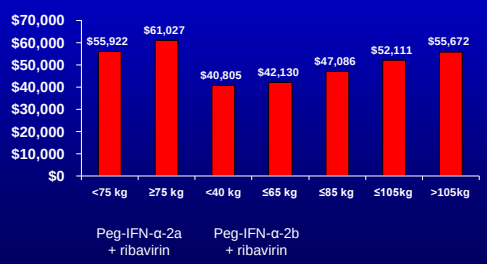
Gold MR et al *Cost-effectiveness in Health and Medicine* 1996; Wong JB et al *Am J Gastroenterol* 2003;98:2354-62

24-Week Average Wholesale Drug Costs HCV GT2-3



Drug Red Book 2010

48-Week Average Wholesale Drug Costs HCV GT1-4



Drug Red Book 2010

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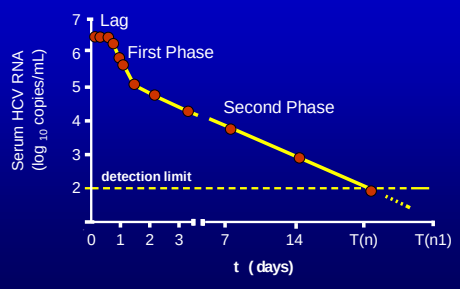
Most Likely Non-responders

- Genotype 1
- Blacks
- Older
- Cirrhosis
- High viral load
- Poor viral kinetic response

Poordad F et al *N Engl J Med* 2011;364:1195-206; Hezode C et al *N Engl J Med* 2009;360:1839-50; Wong JB, Koff RS *Ann Intern Med* 2000;133:665-75

HCV Viral Kinetics with Interferon α



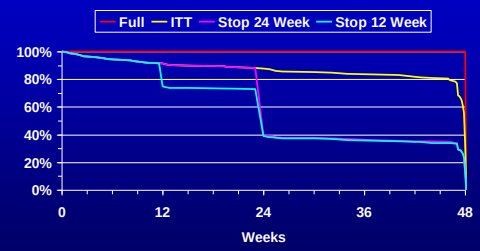
Zeuzem S *J Hepatology* 2002;37:151-3

Viral Kinetics

- RVR (rapid virological response)
  - 4 week viral negative
  - SVR 91% in GT 1 if 24 week viral negative
- Complete EVR (early virological response)
  - 12 week viral negative
  - 75% SVR in GT 1 if 24 week viral negative
- EVR
  - 12 week 2-log reduction
  - 45% SVR in GT 1 if 24 week viral negative

Ghany M et al *Hepatology* 2009;39:1435-74; Ferenci P et al *J Hepatology* 2005;43:425-33

Management Algorithms



Management algorithms decrease drug costs by ~43%

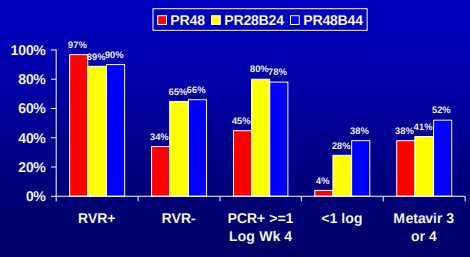
Wong JB et al *Am J Gastroenterol* 2003;98:2354-62

Analysis and Interpretation of Subgroups

- The dilemma articulated by Bernard in 1865 still haunts the clinician: the response of the "average" patient to therapy is not necessarily the response of the patient being treated.
- No analysis of data can predict with certainty the response of a newly presenting patient" so "often analyze . . . by subgroups
- Unfortunately, interpreting the effects of treatment in subgroups . . . is fraught with inferential problems.

Yusuf S et al *JAMA* 1991;266:93-8

SPRINT-2: Boceprevir GT1 Treatment-Naïve



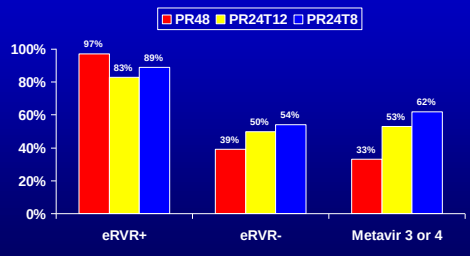
Poordad F et al *N Engl J Med* 2011;364:1195-206

ADVANCE: Telaprevir GT1 Treatment-Naïve

- Shorten duration of treatment to 24 weeks if eRVR+
- eRVR+ = undetectable at week 4 and 12
- Stop if week 4 RNA>1000 or if week 12 RNA < 2 log decline

Jacobson IM et al AASLD #211 *Hepatology* 2010;52(suppl)427A

ADVANCE: Telaprevir GT1 Treatment-Naïve



Jacobson IM et al AASLD #211 *Hepatology* 2010;52(suppl)427A

Directly Acting Agent Considerations

- Pegylated interferon + ribavirin: may ↓ PR 24 weeks if GT 1 low viral load
- Boceprevir: avoid protease inhibitor if RVR+ with PR; ↓ duration to 28 weeks but more erythropoietin & dysgeusia
- Telaprevir: ↓ duration to 24 weeks if eRVR+ but 48 weeks of PR if eRVR- and skin rash

Ghany M et al *Hepatology* 2009;39:1435-74; Poordad F et al N Engl J Med 2011;364:1195-206; Jacobson IM et al AASLD #211 *Hepatology* 2010;52(suppl)427A

Economic Considerations

- "All of marketing comes to focus in the pricing decision" -Robert Corey
- "Medicine is a science of uncertainty and an art of probability." - Sir William Osler
- Considerations: clinical judgment (likelihood of response), patient preferences for duration and possible adverse events, adherence, and costs

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Is treating hepatitis C cost-effective ?

- For prisoners or injection drug users?
- No longer sufficient to know about clinical indications, dosage, safety and monitoring
- Besides *Efficacy* and *Effectiveness*, must now understand *Economics* or *Efficiency* or *Cost-effectiveness*

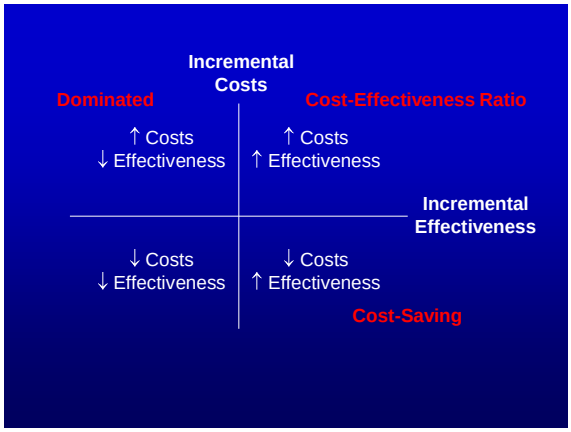
"Our advice: Beware of geeks bearing formulas."

-Warren Buffett

Marginal or Incremental Cost-Effectiveness Analysis

Additional cost divided by additional benefit

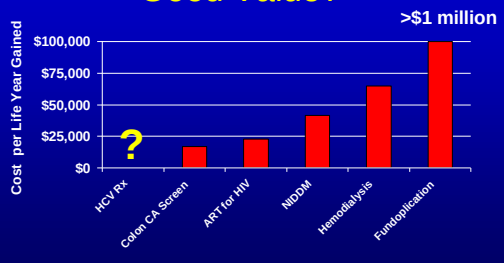
$$\frac{\text{Cost with New Drug} - \text{Cost with Standard Care}}{\text{Effectiveness with New Drug} - \text{Effectiveness with Std Care}}$$



Cost-effectiveness Analysis

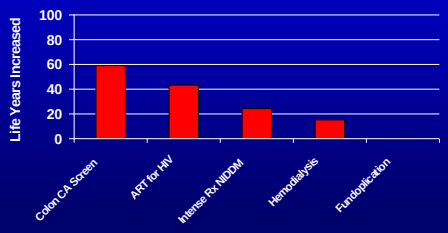
- Considers costs of drugs plus drug monitoring and side effects, and tests and costs of the disease
- Savings from prevention or alleviation of disease complications
- Accounts for death, disability, discomfort, drug toxicity and dollars

Does HCV Treatment Provide Good Value?



Pignone M *Ann Intern Med* 2002;137:96; Freedberg KA *N Engl J Med* 2001;344:824; CDC Diabetes Cost Effectiveness Group *JAMA* 2002;287:2542 Winkelmayer WC *Med Decis Making* 2002;22:417; Heudebert GR *Gastroenterology* 1997;112:1078

Buying Health for $1 Million



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Testing and Treating Hepatitis C in Prison Populations

- If no pretreatment liver biopsy: cost-saving
- If pretreatment liver biopsy=no fibrosis
  - 40-49 y/o men GT1 treatment dominated
  - 50-59 y/o men GT 1 $34,440/QALY
- All other liver biopsies and ages: cost-saving
- Screening and treating HCV in UK prisons: £20,000 and £54,852/QALY but extensive uncertainty

Tan JA et al *Hepatology* 2008;48:1387-95; Castelnuovo, E et al Health Tech Assess 2006;10(32):1-93; Sutton AJ et al J Viral Hep 2008;15:797-808

Testing and Treating Hepatitis C in Injection Drug Users

- US: $5600/QALY for interferon plus ribavirin versus no antiviral therapy in selected current and former IDUs
- UK: Screening for HCV in IDU: £16,514/QALY
- Italy: Screening for HCV in IDUs reduces costs and premature deaths

Wong J et al in *Hepatitis C and Injecting Drug Use: Impact, Costs and Policy Options* 2004:219-41; Castelnuovo, E et al Health Tech Assess 2006;10(32):1-93; Tramarin A et al *Curr Pharmaceutical Design* 2008;14:1655-60

Underinsured

- >50% insured by government managed care system and does not cover HCV treatment
- Dedicated clinic with PCP supervised by the specialists reduces costs
- PR Health Department allocated funds to reduce HCV spread in the community and the future medical and socioeconomic burden of end-stage liver disease

Costas P et al *Puerto Rico Health Sci J* 2004;23(2 Suppl):41-7

Conclusions

- With or without antiviral treatment, costs for chronic HCV infection are likely to be substantial
- Full economic implications and impact of the new direct acting agents for HCV will depend on pricing decisions and clinical judgment
- Testing for and treating HCV in populations such as prisoners and underinsured persons likely to be cost-effective